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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AQ95

Update and Clarify Regulatory Bars to Benefits Based on Character of Discharge

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: In a document published in the **Federal Register** on July 10, 2020, the Department of Veterans Affairs (VA) proposed to amend its regulation regarding character of discharge (COD) determinations. After considering public comments, VA has decided to finalize its proposal with some modifications to expand VA benefits eligibility, bring more consistency to adjudications of benefits eligibility, and ensure COD determinations consider all pertinent factors.

DATES:

Effective date: This final rule is effective June 25, 2024.

Applicability date: The provisions of this final rule shall apply to all applications for benefits that are received by VA on or after June 25, 2024, or that are pending before VA, the United States Court of Appeals for Veterans Claims, or the United States Court of Appeals for the Federal Circuit (Federal Circuit) on June 25, 2024.

FOR FURTHER INFORMATION CONTACT: Robert Parks, Chief, Part 3 Regulations Staff (211C), Compensation Service, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–9700. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION:

I. COD Regulatory History

Eligibility for most VA benefits requires that a former service member (SM) be a ''veteran.'' ''Veteran'' status is bestowed to former SMs ''who served in the active military, naval, air, or space service, and who [were] discharged or released therefrom under conditions other than dishonorable.'' 38 U.S.C. 101(2). The term ''conditions other than dishonorable'' is not a term of art in the military and was chosen by Congress in 1944 to provide VA some discretion with respect to setting the standard for Veteran status and benefits eligibility of former SMs. *Garvey* v. *Wilkie,* 972 F.3d 1333, 1337, 1339 (Fed. Cir. 2020). In October 1946, VA codified 38 CFR 2.1064, which reiterated that, for a former SM to obtain benefits, the SM must have been terminated under conditions ''other than dishonorable.'' VA provided that ''dishonorable'' discharges included those due to (1) mutiny; (2) spying; or (3) an offense involving moral turpitude or willful and persistent misconduct (terms that originated in Public Law 68–242, section 23, 43 Stat. 613 (1924)). 38 CFR 2.1064(a). VA also considered dishonorable an undesirable discharge to escape trial by general court-martial (GCM) and a discharge due to homosexual acts. 38 CFR 2.1064(c), (d). VA further codified the ''statutory bars'' found in the Servicemen's Readjustment Act of 1944, Public Law 78–346, section 300, 58 Stat. 284, which precluded benefits for a person who was (1) discharged or dismissed by GCM; (2) discharged for being a conscientious objector who refused to perform military duties, wear the uniform or comply with lawful orders of competent military authorities; (3) a deserter; or (4) as an officer who resigned for the good of the service. 38 CFR 2.1064(b).

Since 1946, 38 CFR 2.1064 and its successors (most notably, current 38 CFR 3.12) have provided the criteria used by VA adjudicators for determining Veteran status and evaluating benefit eligibility for former SMs. Currently, there are six ''statutory bars'' to benefits for former SMs listed in 38 U.S.C. 5303(a) and reiterated in paragraph (c) of 38 CFR 3.12. In addition, currently, there are five ''regulatory bars'' to benefits listed in paragraph (d) of 38 CFR 3.12, which states that discharges based on the five listed offenses are ''considered to have been issued under dishonorable conditions.'' The last update to § 3.12(d) occurred in 1980, more than 40 years ago. The 1980 update provided examples of aggravated homosexual acts. 45 FR 2318 (Jan. 11, 1980).

On July 10, 2020, VA published at 85 FR 41471 its proposal to amend its regulation governing COD determinations. Specifically, VA proposed to modify the regulatory standards for discharges considered ''dishonorable'' for VA benefit eligibility purposes, such as discharges due to ''willful and persistent misconduct,'' and ''homosexual acts involving aggravating circumstances or other factors affecting the performance of duty.'' VA also proposed to extend a ''compelling circumstances'' exception to certain regulatory bars to benefits to ensure consideration of all pertinent factors. In response to the proposed rule, over 70 comments were received. Given the ''various and differing'' comments received, VA issued a Request for Information (RFI) in September 2021. 86 FR 50513. Specifically, VA asked the public questions about the factors for consideration in a compelling circumstances analysis. Regarding willful and persistent misconduct, the RFI asked whether VA should define ''serious misconduct''; whether VA should require misconduct to actually cause harm to person or property; and how VA should define persistence. VA asked about the proposed rule's definition of moral turpitude. VA asked whether removing the regulatory bars would affect military order and discipline or denigrate others' honorable service; and what specific changes could be made to the proposed rule to fairly adjudicate the benefits eligibility of historically disadvantaged and vulnerable populations.

In response to the RFI, over 45 comments were received. In addition to the proposed rule and the RFI, in October 2021, VA held a two-day listening session to receive oral comments from any member of the public on the RFI questions. Transcripts from the listening session can be found at *https://www.regulations.gov/docket/VA-2020-VBA-0018.*

II. VA's Decision To Finalize the Proposed Rule With Modifications

After extensive consideration of this issue and all the comments received, VA has decided to finalize the proposed rule with some modifications. This will expand VA benefits eligibility, bring

more consistency to adjudications of benefits eligibility, and ensure character of discharge determinations consider all pertinent factors. This decision respects concerns of the Military Departments regarding the impact to their ability to maintain good order and discipline among their troops. Specifically, that the removal of the regulatory bars would undermine their ability to use the consequence of loss of VA benefits as a deterrent to misconduct. In addition, the Military Departments were concerned that removal of the ''in lieu of general court-martial'' bar would deprive the commander, or for covered offenses, Special Trial Counsel, of a tool to dispose of misconduct in an administrative forum while balancing the interests of justice and victim preferences. Finally, the Military Departments expressed concern that the proposed rule's definition of ''an offense involving moral turpitude'' as ''a willful act that gravely violates accepted moral standards and would be expected to cause harm or loss to person or property'' would exclude certain offenses that do not include a willfulness element.

Thus, with this final rule, there will be only four regulatory bars: (1) acceptance of a discharge under other than honorable conditions or its equivalent in lieu of trial by GCM; (2) mutiny or spying; (3) moral turpitude; and (4) willful and persistent misconduct. The definition for willful and persistent misconduct has been refined for more objective application, and an expanded compelling circumstances exception now applies to both the moral turpitude (MT) and willful and persistent misconduct bars. Based upon interagency concerns, VA has decided not to alter the current regulatory bar for MT and does not adopt the language from the proposed rule. This will allow the military to retain a deterrent to misconduct that promotes good order and discipline, while also allowing VA to provide a case-by-case, more holistic analysis of whether a former SM who received a Bad-Conduct Discharge (BCD) or Other Than Honorable (OTH) discharge nevertheless warrants ''veteran'' status and VA benefits eligibility.

As indicated in its RFI, VA rigorously considered the possibility of making more sweeping liberalizing changes than finalized here. But as discussed throughout this notice, there is concern that more sweeping changes would reduce deterrents to misconduct in the military and undermine good order and discipline, as well as concerns that removal of the ''in lieu of general court-martial'' bar would deprive the commander, or for covered offenses, Special Trial Counsel, of a tool to dispose of misconduct in an administrative forum while balancing the interests of justice and victim preferences.

Given those factors, with this rule, VA seeks to strike a balance between bestowing benefits to those who have earned them, even those whose service was not without blemish, and limiting benefits for those whose service involved serious misconduct. As the Federal Circuit in *Garvey* noted, there are SMs whose significant misconduct rendered their discharge dishonorable, even if the military did not explicitly characterize their discharges as Dishonorable for reasons unrelated to the seriousness of the misconduct itself. 972 F.3d at 1338–40. Military justice is designed to be flexible, allow exercise of discretion, and balance a number of concerns with regard to how SMs are prosecuted and discharged. Military officials may choose not to prosecute an offense for a variety of reasons, including: (1) to spare crime victims, including children, or their families from the trauma of testifying; (2) to avoid evidentiary issues involving classified documents or military operations; or (3) because the SM has already been convicted of the crime in another court. In these situations, the SM may be administratively separated to avoid the burden, expense, or resources involved in GCM litigation. That decision to avoid trial, however, does not necessarily mean that the SM did not commit an offense.

On the other hand, there are some SMs whose service, while not without blemish, was generally of benefit to this Nation and therefore have earned the status of ''veteran'' and the benefits to which veterans are entitled. There are also SMs who service to our nation placed them in high-risk situations which could lead to injuries or other circumstances that increase risk for behaviors or conduct that Military Commanders deem inappropriate. For example, as consequence of repeated traumatic exposures during combat, SMs are at risk of posttraumatic stress disorder,[1] traumatic brain injury,[2] moral injury or other combat related emotional and cognitive consequences.[3] Symptoms of these medical conditions include changes to decision making and behaviors. It is therefore important to institute a robust compelling circumstances exception that considers the individual facts and evidence in a particular case. The compelling circumstances language in this final rule includes consideration of the length and character of service exclusive of a period of misconduct and potential mitigating reasons for the misconduct such as mental impairment, physical health, hardship, sexual abuse/assault, duress, obligations to others, and age, education, cultural background and judgmental maturity. The compelling circumstances exception—along with more specific criteria instituted herein for the willful and persistent misconduct regulatory bar—will help enable SMs whose conduct was not dishonorable to receive the VA benefits they have earned.

It is important to clarify here that the regulatory bars shall only be applied when they are clearly supported by the military record. The benefit of the doubt will be resolved in favor of the former SM. *See* 38 U.S.C. 5107(b), 38 CFR 3.102. In other words, when there is insufficient evidence of the alleged misconduct, racial bias in the allegation, or an approximate balance of positive and negative evidence about the alleged misconduct, the bar shall not be applied.

Further, as discussed below, VA agrees with the commenters who recommended limiting the conduct being considered for a COD determination to only that which formed the basis of the discharge from service. In short, if the military decided that a SM's misconduct did not preclude the SM from continuing to serve, then it also should not preclude benefits eligibility. This limitation will prevent conduct unrelated to the basis of the discharge from contributing to a bar from benefits.

Overall, under this final rule, more SMs will be eligible for benefits than under the prior 38 CFR 3.12(d). That said, a favorable COD determination under this rule does not result in blanket eligibility for all VA benefits or a change in the Department of Defense's (DoD) discharge characterization. Rather, certain VA benefits have specific eligibility requirements as it pertains to COD. For example, education assistance under the Montgomery GI Bill program or Post-9/11 GI Bill program is available only for periods of service resulting in an ''honorable'' discharge. *See* 38 U.S.C. 3011(a)(3)(B) and 3311(c)(1). Therefore, former SMs who do not receive an

[1] How Common is PTSD in Veterans?—PTSD: National Center for PTSD (*va.gov*), *https://www.ptsd.va.gov/understand/common/common_veterans.asp.*

[2] Traumatic Brain Injury and PTSD—PTSD: National Center for PTSD (*va.gov*), *https://www.ptsd.va.gov/understand/related/tbi_ptsd.asp.*

[3] War and Combat—PTSD: National Center for PTSD (*va.gov*), *https://www.ptsd.va.gov/understand/types/types_war_combat.asp.*

Honorable discharge from DoD are ineligible for the VA Education benefit.

Moreover, while relaxing the bars to eligibility, this final rule does not extend VA benefits eligibility to all former SMs. Former SMs who do not meet the criteria for benefits eligibility may remain entitled to certain critical benefits to address the harms caused by their military service such as mental health and substance use care, emergent suicide care, and medical care in emergency situations, as discussed below.

III. Discussion of the Comments Received by Topic (From the Proposed Rule, Request for Information and the Listening Session)

VA received 148 comments total in response to the proposed rule, RFI, and Listening Session. In this section, VA discusses in detail the public comments addressing issues raised in the proposed rule, RFI, and listening session.

Congressional Intent

Multiple commenters stated that Congress authorized the exclusion from VA benefits of only those SMs who received or should have received a dishonorable discharge or those who were discharged for conduct falling within a statutory bar. They stated Congress never intended to give VA authority to create new standards to determine veteran status nor was it Congress's intent to have those standards be more exclusionary than the statutory bars. Other commenters stated that VA is subverting congressional intent by withholding healthcare through these regulatory bars. VA thanks the commenters for these comments but believes that this final rule accords with congressional intent.

Congress has authorized VA to consider discharges based on certain conduct as dishonorable. 38 U.S.C. 101(2); *see Garvey,* 972 F.3d at 340; *Camarena* v. *Brown,* 6 Vet. App. 565, 568 (1994), *aff'd* 60 F.3d 843 (Fed. Cir. 1995) (per curiam); *see also* 90 Cong. Rec. at 3077 (Mar. 24, 1944) (Sen. Clark) (for certain conduct, ''the Veterans' Administration will have some discretion with respect to regarding the discharge from the service as dishonorable''). The bars in question have been in regulation since 1946 and the Federal Circuit has concluded that VA has the authority to institute such bars. *Garvey,* 972 F.3d at 1339–40. To the extent the current regulatory bars are viewed by some as overly restrictive, the modifications finalized in this rule should ensure that only SMs who committed serious, dishonorable misconduct in service are precluded from benefits. This approach generally accords with congressional intent. *Id.* at 1339.

Furthermore, VA disagrees with the comment that VA's regulatory bars subvert congressional intent by withholding healthcare. Under 38 CFR 3.360, VA determines a service member's eligibility for healthcare even if the SM is not eligible for other benefits. Thus, VA makes no changes in response to these comments.

Automatic Eligibility

Some commenters urged VA to establish automatic eligibility for VA benefits for all SMs who received an OTH discharge based on their service to the Nation. One commenter urged VA to update its definition of ''veteran'' to include OTH discharges and to otherwise be more SM-friendly. VA thanks these commenters for their comments, but VA cannot establish automatic eligibility, because some SMs who received an OTH discharge are statutorily barred from benefits by 38 U.S.C. 5303(a). Nevertheless, this final rule is more SM-friendly, as VA has removed one of the regulatory bars, refined another, and instituted a compelling circumstances exception to two bars, which will lead to an increase in benefits eligibility in the COD process.

Healthcare Eligibility

One commenter stated that ''VA should also provide healthcare for those veterans who are waiting for a decision by VA'' and that ''Veterans should be presumed eligible for VA health care unless proven otherwise.'' Another argued that VA should amend 38 CFR 17.34 and 17.36 to provide tentative eligibility for healthcare and update enrollment procedures. VA thanks the commenters for their comments. Currently, some OTH-discharged SMs have access to certain VA health care services, such as health care for service-incurred disabilities, mental health and substance use care, emergent suicide care, and medical care in emergency situations (if it is determined that benefits eligibility will probably be established). 38 U.S.C. 1720I, 1720J; 38 CFR 3.360, 17.34. Moreover, VA has initiated efforts to amend 38 CFR 17.34, but those amendments were not proposed in this rulemaking.

Removal of Homosexual Acts Bar

Some commenters supported the proposed rule's replacement of the word ''homosexual'' with ''sexual.'' However, many commenters still felt that lesbian, gay, bisexual, transgender and queer (LGBTQ+) SMs were subject to discrimination that would manifest even with this amendment. VA agrees that any bar that explicitly relates to sex may still disproportionally affect LGBTQ+ SMs. Additionally, the commenters felt that most of the offenses listed in this section could also be barred under moral turpitude (MT) offenses (*e.g.,* child molestation, sexual assault, etc.) or willful and persistent misconduct, further rendering this bar to benefits unnecessary. VA agrees that the homosexual acts bar is outdated and unnecessary and is entirely removing this regulatory bar. VA is also not adopting the sexual acts bar from the proposed rule, as this misconduct will be sufficiently excluded by either the statutory bars or the remaining regulatory bars.

COD Process/Eligibility

Many commenters asserted that VA presumes that former SMs with OTH discharges are ineligible for VA benefits and must be proven otherwise through the COD determination process. They also stated that VA presumes that former SMs with honorable or under honorable conditions discharges are eligible for VA benefits. Based on this, the commenters asked that VA presume former SMs with OTH discharges as eligible for benefits unless proven otherwise. One commenter stated that VA should not review OTH discharges unless they are issued in lieu of court marital (CM). Further, one commenter stated that the proposed rule did not include changes to § 3.12(a), the provision governing ''which former [SMs] . . . are presumptively excluded from VA access until successful completion of [a COD] review.''

VA thanks these commenters for their comments. VA is not persuaded that modification of § 3.12(a) is necessary here, insofar as it merely reiterates the statutory requirement that discharge must be ''under conditions other than dishonorable.'' There is no need to revise that provision to carry out the goals of this rulemaking. Moreover, there is no regulation that presumes the outcome of a COD determination for a SM with an OTH discharge. Rather, each OTH discharge is assessed to determine VA benefits eligibility.

Another commenter asked VA to presume eligibility for all SMs with administrative discharges except discharge in lieu of CM and stated that ''VA annually deems about 80 to 90 percent of veterans who received OTH have served 'dishonorably'.'' VA thanks the commenter for the comment, but that statistic is inaccurate. Between October 1, 2019, and September 30, 2022, VA deemed SMs with OTH

discharges eligible for healthcare or benefits or both more than 75% of the time. VA is providing the documentation for this data in the rulemaking record.[4] VA makes no changes based on these comments.

Still another commenter stated that VA should presume eligibility for SMs with OTH discharges and terminate benefits ''in exactly the same process as is currently used for statutory bars. This would save VA the expense of processing countless, costly denials of benefits appeals, while providing veterans benefits, they have rightfully earned in service to this country, as Congress intended.'' VA thanks the commenter for their comment. VA believes that, through the modifications of this final rule, including the compelling circumstances exception, it will be able to expand VA benefits eligibility for former SMs with OTH discharges. The reasons that VA has determined more extensive liberalization is not being advanced are discussed in greater detail below.

Another commenter stated ''[t]he majority of veterans do not undergo COD determinations for numerous reasons and those that do are overwhelmingly unsuccessful in establishing eligibility.'' VA thanks the commenter for their comment, but, again, the data above reflects otherwise. In any event, VA anticipates that the amendments in this final rule—including refining the willful and persistent misconduct bar and implementing the compelling circumstances exception for moral turpitude and willful and persistent misconduct—will increase the number of former SMs eligible for benefits.

One commenter stated that ''VA must assert independence from other federal entities'' and that ''VA has a vastly different mission statement from DoD.'' The commenter further noted that VA was proposing to use the Uniform Code of Military Justice (UCMJ) from DoD, but the basis for why DoD wants to remove a SM, such as drug use or minor infractions, does not mean that VA should deny that SM health care, mental health treatment and benefits for service-related injuries. VA recognizes that there is a relationship between dishonorable service and VA benefits eligibility, as reflected in Congress's enactment of 38 U.S.C. 101(2). This final rule precludes benefits eligibility for only those SMs who committed misconduct that renders their service effectively dishonorable.

[4] See *https://www.regulations.gov/docket/VA-2020-VBA-0018.*

Another commenter asserted that ''[c]onduct reviewed for COD determinations must be clearly defined. The review must be limited to the misconduct that led to the discharge.'' The comment includes the story of someone discharged due to absent without leave (AWOL) and disrespecting a superior officer, but the COD determination included a discussion of some AWOL that occurred in a separate enlistment. Other commenters expressed similar sentiments. VA thanks the commenters for their comments and recognizes the concern that COD determinations might consider unrelated conduct. But the introductory language of § 3.12(d) states that the regulatory bars apply to the conditions under which ''the former service member was discharged or released'' and VA affirms that this language means that only misconduct that led to the discharge may be considered in the COD determination. This is implicit in the regulations. Meaning in its COD review, VA will only consider misconduct or AWOL that according to military department records explicitly indicate led to the discharge. VA notes, however, that there remains a statutory bar of a period of AWOL of more than 180 days that only Congress can amend.

Another commenter stated that many VA employees are without the necessary information or training to fully serve SMs and that has led to employees wrongfully turning away eligible SMs. Other commenters also mentioned that many SMs who did not receive an honorable discharge attempt to apply to VA for health care and are simply turned away. VA is aware of these concerns and will continue to provide training to its employees and messaging to the public that VA encourages all SMs to apply for healthcare and benefits regardless of their COD. VA expects that the changes made by this final rule will lead to some increased benefits eligibility for former SMs without Honorable discharges.

Compelling Circumstances

A. Generally Apply Compelling Circumstances Exception

Multiple commenters requested that the compelling circumstances exception should be applied generally and used to counterbalance the negative aspects of the SM's service. Three commenters requested that VA lower the standard necessary to apply the ''benefit to the Nation'' exception found in proposed § 3.12(e)(1). Specifically, commenters stated that requiring the character of service, exclusive of the period of AWOL or misconduct, ''be of such quality and length that it can be characterized as honest, faithful and meritorious and of benefit to the Nation'' is nebulous. One commenter stated that the term ''meritorious'' has a special meaning in military law. This commenter noted ''meritorious sets a higher standard than some former SMs would be able to achieve, as many were willing to, but were never, deployed; never received an award; and otherwise fulfilled their duties, but for the conduct leading to the OTH discharge. Accordingly, VA should create a standard that honors the sacrifice of all SMs, particularly considering how few Americans serve in the military.'' Another commenter recommended that VA only require the service to be ''substantially favorable. A determination of favorable service will consider (a) the overall duration and quality of service; (b) combat, overseas, or hardship service; (c) medals, awards, decorations, and other achievements or acts of merit; and (d) other facts or circumstances relevant to the inquiry.'' That commenter also stated that all service should be considered to the Nation's benefit unless proven otherwise (based on the commenter's belief that DoD is better at documenting bad behavior than good behavior). Similarly, one commenter felt that compelling circumstances should be assessed on a holistic basis considering the totality of the circumstances.

Additionally, some commenters stated that some military branches use OTH at higher rates than others, resulting in disparate discharges for similar misconduct. Some commenters noted that military discharges may vary based on the era of war in which the SM served. One commenter noted the difference between discharges for commissioned officers and enlisted personnel and a ''lack of insight'' into how the regulatory change affected officers. VA thanks these commenters for their comments. VA's intent with the compelling circumstances exception to the moral turpitude and willful and persistent misconduct bars is to provide claims processors a holistic means to evaluate the misconduct underlying a SM's discharge and to determine if that misconduct is outweighed by otherwise honorable service or can be excused due to circumstances influencing the former SM's decision-making around the time of the offense or otherwise providing context for the offense. Consistent with that intent, assessment of the length and quality of service exclusive of the misconduct necessarily must be a case-by-case determination. If VA revised the

standard to suggest that the service of all former SMs who make the sacrifice inherent in all military service is sufficient to establish compelling circumstances, however, this exception would become the rule, not the exception. Regarding the comment that all service is to the Nation's benefit unless proven otherwise, it is important to note that the only cases at issue in a compelling circumstances analysis are those which involved a discharge due to some level of misconduct. The goal of the compelling circumstances analysis is to determine whether the misconduct is mitigated by the circumstances, is outweighed by otherwise honorable service, or actually renders the service dishonorable, not to ignore the fact that misconduct may have taken place.

Moreover, the compelling circumstances exception is designed to counter the possibility that certain military branches may have favored particular types of discharges during particular periods of time, including different periods of war. It allows VA to determine whether the misconduct leading to an OTH discharge actually rendered the service dishonorable, or alternatively was outweighed by otherwise honorable service or mitigated by the circumstances. Each COD determination will be made based on each SM's facts and circumstances.

B. Apply Compelling Circumstances To Discharge in Lieu of General Court-Martial

Several commenters urged VA to apply the compelling circumstances exception to the regulatory bar of discharge in lieu of GCM, because VA proposed to apply compelling circumstances to MT offenses, which (they asserted) are arguably more serious. Other commenters stated that the GCM process is filled with misinformation and procedural gaps. One commenter stated SMs were forced into OTH discharges without being informed of their rights or because they faced retaliation. Another commenter stated innocent civilians routinely accept plea bargains to avoid trial, and some innocent SMs accept discharge in lieu of GCM. Another stated some commanding officers use the SM's acceptance of a discharge in lieu of trial by GCM as a means to force certain SMs out of the military. VA thanks the commenters for their comments. Due to interagency concerns associated with good order and discipline, VA has decided not to extend the compelling circumstances exception beyond the scope laid out in the proposed rule.

One commenter recommended that VA remove ''or its equivalent'' from the text as the commenter was unaware of any equivalent to an OTH discharge. VA thanks the commenter for this comment; however, VA included ''or its equivalent'' to account for historic discharges, such as undesirable discharges. Additionally, DoD may establish new discharge characterizations. Using this terminology allows VA's regulations to remain applicable to both past and future character of discharge determinations.

C. List of Mental and Cognitive Impairments

Several commenters expressed concern that claims adjudicators would fail to recognize the list of mental impairments in proposed § 3.12(e)(2)(i) was non-exhaustive and that claims adjudicators would consider only the listed mental impairments. One commenter stated that the mental impairments contained diagnoses (*e.g.,* bipolar disorder and posttraumatic stress disorder), symptoms (*e.g.,* depression and impulsive behavior), and a neurodevelopmental condition (attention deficit hyperactivity disorder (ADHD)) but stated that the latter is not subject to service connection under 38 CFR 3.303(c), 4.9, and 4.127. That commenter was further concerned that the rule referenced redundant co-morbid conditions when mental impairment alone is enough to trigger consideration. One commenter urged VA to have SMs who suffer from posttraumatic stress disorder, traumatic brain injury, military sexual trauma (MST), or other mental illness examined by specialists prior to being denied benefits.

VA confirms the list of mental and cognitive impairments is non-exhaustive and the included list was intended only as a guide. Additionally, VA confirms the mental or cognitive impairment need not be service connected or subject to service connection to be considered as a compelling circumstance to excuse the prolonged AWOL or misconduct. Hence, neurodevelopmental conditions, such as ADHD or personality disorders, may excuse prolonged AWOL or misconduct even if no VA benefits can be awarded for the same condition. Further, VA agrees that including co-morbid conditions is redundant because a single mental impairment is enough to trigger consideration for compelling circumstances and, if the comorbidity was both mental and physical impairments, § 3.12(e)(2)(ii) will now allow consideration of physical health in any event.

D. Abuses of a Sexual Nature, Discrimination, Disparity Between Branches, and Military Sexual Trauma

Several commenters requested that VA include additional factors to consider when evaluating the reason(s) for prolonged AWOL or misconduct found in proposed § 3.12(e)(2), including sexual harassment and intimate partner violence (IPV); bereavement; discrimination due to protected class; disparate discharge outcomes based on military branch; and ''mistreatment, misdiagnosis, or other intentional or unintentional injustice.'' One commenter stated VA should include whether the SM experienced discrimination in service or the discharge was due to a discriminatory pretextual reason instead of the stated reason(s). Other commenters requested VA add the terms MST and sexual harassment as a compelling circumstance. One was concerned application of a regulatory bar would retraumatize a SM by causing isolation from the military community.

Multiple commenters commented on the proposed rule's impact on SMs, who are homeless women and victims of sexual assault and MST. Other commenters noted disparate racial treatment in the military, including infractions for certain hairstyles or facial hair. VA thanks these commenters for their comments.

VA is committed to protecting SMs who are homeless, MST victims, and victims of harassment, all forms of discrimination and IPV. VA believes that a compelling circumstances exception—that includes factors such as mental and cognitive impairment; physical trauma; sexual abuse/assault; duress, coercion, or desperation; hardships; abuses of a sexual nature; and the former SM's age, education, cultural background, and judgmental maturity—when combined with refined criteria for defining ''willful and persistent misconduct'' will sufficiently allow victims of MST, discrimination, and misdiagnosis to receive fairer COD evaluations. VA will consider any records or attestations from SMs about experiencing these circumstances to be relevant in their consideration of COD.

Although VA acknowledges that many forms of discrimination exist and may contribute to or result in former SMs receiving OTH discharges, VA evaluates each particular SM's COD based on the record before it. When VA conducts a COD determination, VA reviews the SM's service personnel and medical treatment records and any other pertinent records. VA reviews that SM's military units' duty locations and

combat engagements. Should any given record establish discrimination as the basis for the OTH discharge, including but not limited to discrimination based on race or sex, the compelling circumstances exception would allow VA to adjudicate a favorable COD determination. And, even if no such record exists, the reforms of this final rule will ensure a fair COD adjudication, considering all pertinent factors on a case-by-case basis, for all SMs, including those who are homeless or victims of MST, IPV or potential discrimination.

E. Compelling Circumstance Unknown to Service Members

One commenter noted that the compelling circumstances factors are complicated for SMs to understand on their own. This commenter notes the standard is not helpful to many SMs who apply without assistance. VA thanks this commenter for these comments. VA encourages all former SMs and claimants to seek the assistance of qualified Veterans Service Organizations (VSOs) or other accredited representatives to assist with the claims process, including COD determinations. Further, assistance with the claims process, COD determinations, and governing regulations is available at *www.va.gov* and at Regional Offices. VA makes every effort to provide training to its employees to assist former SMs in the non-adversarial COD process. VA has a duty to assist and will work with former SMs to ensure appropriate records, including self-attestations, are well documented in the record being reviewed in the COD process. Whenever possible, VA aims to review records sympathetically and give the benefit of the doubt, particularly when records are missing or incomplete.

F. Include Due Process Errors to Legal Defense Exception

Finally, one commenter requested VA add to its compelling circumstances exception an additional legal defense for cases when the prosecution committed due process errors or violations. VA thanks the commenter for this comment. However, VA believes that due process errors would be included as a valid legal defense under § 3.12(e)(3). Therefore, no changes are necessary in response to this comment.

Acceptance of an Undesirable Discharge To Escape General Court-Martial

One commenter opined that the regulatory bar associated with discharge in lieu of GCM should be clarified. The commenter went on to state that even though ''undesirable'' is not used anymore as a discharge characterization, there are still some living veterans with ''undesirable'' discharges that should not be excluded. The commenter also noted that the proposed rule's phrase ''or its equivalent'' is vague and that some claims processors may think a ''general'' discharge is equivalent. The same commenter stated that VA should explicitly state that this bar does not apply to special CM discharges. Another commenter stated that the bar for discharge in lieu of GCM should be limited to cases where charges were referred to a GCM. Another commenter similarly stated that the regulations should clearly identify the need for documentation of a GCM charge before applying regulatory bar. Another commenter stated, ''there should be evidence of a [GCM] convening.''

VA thanks the commenters for their comments. Per the plain language of revised § 3.12(d)(1)(i), this regulatory bar requires accepting an OTH discharge in lieu of trial by *GCM;* the former SM will receive the benefit of the doubt in the determination of whether the OTH discharge was accepted *in lieu of* trial, and whether that trial would have been *by GCM.* Accordingly, VA sees no need to further amend the regulatory language.

One commenter agreed with the decision to eliminate stigma from a SM's actions by removing the language of ''undesirable'' and ''escape'' from the regulation. However, the commenter stressed the need for an in-depth and personalized evaluation of a SM's file, to determine whether a discharge was received because of coercive pressure from a commanding officer to ''get rid'' of the SM. A different commenter stated that VA should require a more thorough analysis of the conditions and circumstances surrounding a former SM's acceptance of discharge in lieu of CM, because former SMs may accept this result without committing an offense, much like civilian plea deals. Another commenter suggested that excluding former SMs discharged in lieu of trial misunderstands the nature of the administrative separation and that systematic misinformation and gaps in those procedures are well documented. The commenter also stated some SMs are unable to respond rationally when they are still engaging in misconduct (substance abuse, AWOL) that is leading to discharge. The commenter continued that it is difficult for claims processors to determine whether the discharge was in lieu of GCM or another CM. VA thanks the commenters for the comments but is not modifying this regulatory bar (beyond what was proposed) due to concerns raised by the Military Departments that further changes to this bar would undermine their ability to maintain good order and discipline within their ranks. That said, again, if there is a question about whether the discharge was in lieu of GCM or special CM, VA will consider all appropriate records and the former SM will receive the benefit of the doubt.

Moral Turpitude

One commenter stated the proposed definition of MT is too broad and does not adequately put former SMs on notice as to what constitutes an offense involving MT. The commenter also stated that it is contrary to fundamental fairness to bar a former SM from their benefits for life based on commission of an MT crime without a guilty finding in a formal proceeding with adequate procedural and due process protections. The commenter noted that the definition also does not contain any reference to deception, fraud, or depravity by the SM; therefore, a simple assault or loss of property that does not involve fraud or deceit could meet this definition.

In addition, many commenters opined that MT is unclearly defined and vague. One commenter stated that VA should simplify such a standard. Another commenter asserted that the MT standard is imprecise and legalistic, lacking definition in civilian and military jurisprudence. VA thanks the commenters for their comments.

Based on interagency concerns regarding the proposed definition of MT, VA has decided not to implement the language from the proposed rule and will maintain the current regulatory language. VAOPGC 6–87 (July 27, 1987), a VA General Counsel Opinion, states ''an offense will, for veterans' benefit purposes, be considered to involve moral turpitude if it is willful, gravely violates accepted moral standards, is committed without justification or legal excuse, and, by reasonable calculation, would be expected to cause harm or loss to person or property.'' [5] This precedential opinion continues to govern VA's application of this bar in COD determinations.

Given that the definition of moral turpitude under VAOPGC 6–87 requires a willful act that gravely violates accepted moral standards, it is difficult to imagine that minor misconduct—misconduct for which the maximum punishment is not longer than one year confinement—could ever meet that definition. This accords with common Federal appellate court decisions interpreting the term in other contexts.

[5] *https://www.va.gov/OGC/docs/1987/06-87.pdf.*

Garcia-Martinez v. *Barr,* 921 F.3d 674, 676 (7th Cir. 2019) (MT ''shocks the public conscience as being inherently base, vile, or depraved, and contrary to the accepted rules of morality and the duties owed between persons or to society in general''); *Escobar* v. *Lynch,* 846 F.3d 1019, 1023 (9th Cir. 2017) (MT ''is generally a crime that (1) is vile, base, or depraved and (2) violates accepted moral standards'').

Moreover, VA declines to require a felony conviction for MT, because the military's choice not to prosecute could be premised on a desire to protect victims or other reasons, rather than any view that the conduct was not felonious or dishonorable. Moreover, while obtaining a final conviction may be necessary for the military to confine an SM, it is not necessary for VA's purposes of evaluating the character of a SM's discharge. So long as the offense is clearly established by the record (after applying the benefit of the doubt to the advantage of the SM), VA may conclude that offense was committed. This is also supported by VAOPGC 6–87 which states ''while the conviction of a felony creates a rebuttable presumption that an offense involved moral turpitude, the absence of such conviction does not absolve an offense from the taint of moral turpitude.'' In sum, due to concerns about changes to this bar that could impact the Military Departments' ability to maintain good order and discipline, VA makes no changes to the current regulatory text based on these comments.

Willful and Persistent Misconduct

A. VA's Proposed Definition

Some commenters stated that the definition of willful and persistent misconduct should be redefined to be more favorable to former SMs. Others conveyed that minor misconduct should not be a disqualification. Multiple commenters were concerned that the proposed rule continued to punish offenders removed from the military for minor offenses with a maximum sentence of one year. Other commenters commented on those who received an OTH discharge due to drug possession or use, including those who became addicted to painkillers after surgery in the military, and noted such members should not be deprived of VA benefits for the same. Another was concerned that VA's definition would result in ''lengthy, complex investigations for rating officers.'' One commenter stated this regulatory bar allows VA to exclude former SMs for misconduct that would not lead to a dishonorable discharge. Other commenters stated that using the maximum punishment for the offense ignores instances where the offense is adjudicated as minor by the prosecuting authority. One commenter stated that the only conduct considered should be that causing harm to a person or property. VA thanks these commenters for their comments.

VA noted in the preamble to the proposed rule that ''willful misconduct'' is already defined in 38 CFR 3.1(n) as ''an act involving conscious wrongdoing or known prohibited action'' that must involve ''deliberate or intentional wrongdoing with knowledge of or wanton and reckless disregard of its probable consequences.'' Additionally, VA noted that 38 CFR 3.1(n)(2) states that ''[m]ere technical violations of police regulations or ordinances will not per se constitute willful misconduct.'' But the term ''persistent,'' VA explained, was undefined. Thus, VA proposed a framework for determining ''persistence'' derived from the statutes of limitations for punishment in the Manual for Court-Martial United States (MCM)[6] and UCMJ. This makes sense, because—if the military will no longer prosecute an offense after a certain period of time—there is no reason for VA to link that offense to other misconduct in order to find persistence.

Overall, the proposed rule (and this final rule) brings both objectivity and liberalization to the ''willful and persistent misconduct'' standard. The bar only applies if there are (1) instances of minor misconduct (as defined in reference to the MCM) occurring within two years of each other; (2) an instance of minor misconduct occurring within two years of more serious misconduct; or (3) instances of more serious misconduct occurring within five years of each other. Moreover, the compelling circumstances exception applies to this bar, such that even SMs whose misconduct meets the definition of ''willful and persistent'' will receive an individualized review that considers whether the misconduct should be considered mitigated or outweighed by otherwise meritorious service or other factors. To the extent this is still unsatisfactory to certain commenters, VA declines to make further amendments due to interagency concerns regarding the Military Departments' ability to use the loss of VA benefits as a deterrent to misconduct in order to promote good order and discipline.

[6] *See https://jsc.defense.gov/Portals/99/2024%20MCM%20files/MCM%20(2024%20ed)%20-%20TOC%20no%20index.pdf?ver=b7JVpxV5rbIHg0ENlCRVKQ%3D%3D.*

B. Minor Misconduct

Several commenters stated that minor misconduct should not be used as a bar because Congress never intended for former SMs to be barred from VA benefits due to minor misconduct. One commenter asserted that almost every UCMJ punitive article is punishable by either one-year confinement or a dishonorable discharge, rendering almost any SM subject to a bar to benefits. Instead, the commenter stated, VA should only bar people for serious misconduct. Others noted that adjudicators must determine COD on only that which led to discharge, and not prior misconduct. VA thanks these commenters for these comments.

VA clarifies that, even though it uses the term ''minor'' to distinguish one type of misconduct from another, this regulatory bar applies only to former SMs who have not received an Honorable or General (under honorable conditions) discharge. If a SM has an Honorable or General discharge, VA does not conduct a COD determination and this bar is irrelevant. *See* 38 CFR 3.12(a). Therefore, VA does not bar former SMs simply because they have minor offenses in their record. And even for SMs with a BCD or OTH discharge, VA will not bar benefits for sporadic, minor misconduct, given the definition of ''persistent'' in this final rule. Finally, any misconduct that meets the definition of ''persistent'' can also be outweighed by otherwise meritorious service or mitigated by the circumstances in a compelling circumstances analysis. Accordingly, as a practical matter, VA commits that the only former SMs who will be barred under the willful and persistent misconduct standard of this final rule are those that committed willful, frequent misconduct, which according to documentation in their military discharge records led to their discharge, outweighed the merit of their service, and was not mitigated by any relevant factors. To the extent this is still unsatisfactory to certain commenters, VA declines to make further amendments due to interagency interest in maintaining deterrents to misconduct that promote good order and discipline.

C. Definition of Persistent

Several commenters believed VA's use of the term ''persistent'' did not comport with the dictionary definition of ''persistent.'' Specifically, the commenters felt that the dictionary definition of persistent would either require three instances of misconduct or be habitual misconduct. Additionally, some commenters thought that VA

should consider service members' patterns of offenses instead of the offenses in succession. Commenters also suggested VA consider multiple offenses that are committed within a short time period and/or have a similar origin, such as mental distress, as a single instance of misconduct. Others were concerned VA adjudicators would consider actions beyond those considered by the service branch for discharge. VA thanks these commenters for their comments and clarifies here that VA will consider multiple offenses that originate from a single event or circumstance (*e.g.,* attempted robbery leading to fleeing and then leading to resisting arrest) as one ''instance'' of misconduct. Moreover, VA cited a dictionary definition in the preamble to its proposed rule and maintains that it is appropriate to align its definition of ''persistent'' with military statutes of limitations in order to exclude earlier misconduct that would not have been considered in a discharge. To the extent this is unsatisfactory to certain commenters, VA declines to make further amendments due to interagency interest in maintaining deterrents to misconduct that promote good order and discipline within the military.

D. Department of Defense and Congress

One commenter stated the willful and persistent misconduct bar should apply only if the commanding officer discharges or releases a SM for such misconduct. The commenter felt that VA should rely on DoD or the commanding officers to determine the conduct's nature rather than making its own assessment. Another commenter stated the willful and persistent misconduct bar was ''unlawful'' and should be removed as contravening congressional intent. This commenter states any exclusion should be based on only severe misconduct. VA thanks the commenters for their comments.

VA agrees that the willful and persistent misconduct bar should be reserved only for misconduct that is willful and persists and ultimately renders the service dishonorable. To the extent this bar has been susceptible to subjectivity, this final rule provides (1) the time frame in which the misconduct must occur, and (2) a compelling circumstances analysis, which combine to ensure that this regulatory bar will be applied only against SMs who willfully and persistently committed misconduct in service that explicitly led to their discharge, is not mitigated by any circumstances, and was not outweighed by otherwise meritorious service. VA believes this is consistent with congressional intent. Finally, as stated above, VA assures that misconduct that did not lead to discharge will not be considered—because conduct that did not concern DoD or the commanding officer in a dispositive way should similarly not concern VA.

Concerns Over the COD Adjudicatory Process

Multiple commenters expressed concern that the proposed rules will create an onerous and time-consuming adjudicatory process for VA and SMs. Some of these commenters also noted that the process left too much discretion to individual adjudicators. VA thanks these commenters for these comments. However, VA notes no additional burden is placed on VA's adjudicators than currently exists. Indeed, the objective criteria for willful and persistent misconduct should accelerate the COD process. Moreover, VA has robust training procedures and subregulatory guidance to ensure consistency among decisionmakers and accordingly makes no changes based on these comments.

Enforcement of Military Discipline and the Message to Honorable Veterans

Many commenters stated that they supported this rule but urged VA to not further liberalize current COD rules. One commenter noted that additional liberalization of the COD rules would send ''a message to those [SMs] committing misconduct, that there are few if any repercussions for doing so.'' Another commenter asserted VA should not liberalize benefits for OTH SMs unless such discharge is upgraded to at least a general discharge because the basis for OTH discharges is at least the violation of a lawful order. The commenter continued that allowing benefits for such SMs communicated that there were no ''adverse repercussions'' for wrongful actions, and such behavior would ''severely undermine good order and discipline in units. Problem [SMs] get the message that committing misconduct will have little to no adverse [e]ffect on their subsequent civilian lives and therefore are not deterred from continuing misconduct.'' The commenter was concerned about the demoralization of law-abiding SMs, who would be ''in no better steed [sic] than the derelicts, malingerers, rule breakers, malfeasant and criminal amongst them in the ranks.'' This commenter further asked whether VA wished to send the message that one could be ''a crook in the Army and get VA benefits notwithstanding.''

Another commenter, a former master sergeant, stated ''[t]he VA should not denigrate our honorable service by changing the rules to provide care to people who could not, or would not, serve in the same manner. There are, and must remain to be, consequences for people who fail to live up to the ideals expected of military service. Treating those who failed in the same manner as those who succeeded detracts from the status of all of us who served honorably and will be looked at as a slap in the face to most of us.'' Another commenter stated that this rule means ''get discharged with an OTH and get benefits anyway. This is bad for moral [sic] and dangerous, military people need to have a form of trust, without this, it will create more poor serving members.'' That commenter noted that ''[h]onor and honesty saves lives.''

In contrast, however, other commenters (further discussed below) requested VA remove all regulatory bars because they are not necessary to enforce military discipline. As one commenter noted, ''[w]ith such a robust system in place within the military itself, we doubt that any commander in the U.S. Military relies on VA's eligibility rules to maintain good order and discipline within her command.''

VA recognizes the challenging nature of this subject and included it in the RFI for this very reason. VA thanks all the commenters for their comments on the issues of military discipline and denigration of honorable service. After extensive interagency discussion, VA was advised that Commanders within the Military Departments use the prospect of VA benefits bars as one tool to enforce good order and discipline, and that the Military Departments were concerned that any expansion of VA benefits to former SMs who committed serious misconduct would have the effect of removing disincentives to misconduct. Thus, VA is retaining four of the regulatory bars, with modifications. Those modifications will help distinguish those who committed serious misconduct that renders their service dishonorable from those whose misconduct comes with a mitigating circumstance or is outweighed by otherwise meritorious service. This strikes an appropriate balance: it expands VA benefits eligibility, but also avoids sending a message that misconduct has no repercussions. It aligns with the necessary Military Department incentives for military discipline, while also guaranteeing a more holistic and equitable COD review for former SMs.

One commenter requested that VA not extend benefits to those with BCD or OTH discharges. The commenter stated that ''determination of character of service should reside solely with the

service department'' and not VA employees. The commenter continued: ''There is already a legal mechanism in place to allow the individual to appeal the character of discharge with the service department.'' Another commenter stated: ''Getting a BCD, OTH, or dishonorable discharge is extremely difficult, and the process has numerous layers to ensure the integrity of the process. Those individuals who receive these discharges are not worthy of the military and totally undeserving of veteran benefits . . . Providing hard earned benefits to those who could not and did not serve honorable [sic] is a slap in the face to the millions of veterans who did the right things during their service.'' A commenter stated that ''VA should be prohibited from deciding why a character of discharge is issued. Allowing this change disrupts the military process and weakens the authority of the Secretary of each military branch and within due process. VA employees do not follow the same regulatory requirements as those who service on military boards.''

VA thanks the commenters for their comments. It is true that character of service determinations remain DoD's responsibility, and upgrades are available from the Military Departments. But VA has both the authority and responsibility to determine eligibility for veterans' benefits. It has been performing this function for decades via 38 CFR 3.12 and its predecessors. Even if DoD has a different approach to or framework for characterizing the service of its former members, VA maintains its authority to determine COD for purposes of VA benefits eligibility.

One commenter stated ''I do not believe that anyone who receives a bad conduct or dishonorable discharge deserves to be treated by VA. Veterans wait forever for appointments and it's not right to add another million people to the rolls. We, honorable veterans, will never be seen. The VA needs to improve its track record before starting to reclassify people. The VA needs a lot more doctors and a lot more hospitals already.'' Another added that ''the added patient workload will also adversely impact the availability and timeliness of care received by all veterans at VA health care facilities.'' VA thanks the commenters for their comments and assures the commenters that those who received a Dishonorable discharge from the military are excluded from benefits eligibility. That said, VA has determined (after several rounds of public input) that the current regulatory approach to SMs with BCD and OTH discharges needs a restructuring to strike the appropriate balance between bestowing benefits to those who have earned them, while also limiting benefits for those whose service involved serious misconduct. This final rule's revision of § 3.12(d) attempts to strike that balance.

Similarly, a few commenters stated that former SMs with ''Bad Paper,'' OTH or dishonorable discharges should not be eligible for VA benefits, do not deserve any VA assistance and that their eligibility may delay the receipt of care for former SMs with honorable service. VA thanks these commenters for their comments. As noted above, VA aims to strike an appropriate balance between bestowing benefits to those who have earned them and limiting benefits for those whose service involved serious misconduct. VA believes this final rule does so by eliminating one of the regulatory bars, refining another, and applying a compelling circumstances exception to two of the regulatory bars, which provides a more holistic assessment of all appropriate factors in determining whether a former SM, despite a BCD or OTH discharge, has nevertheless earned ''veteran'' status.

Another commenter opined that ''[u]nless a discharge is upgraded, every OTH, BC[D], and D[ishonorable] D[ischarge] should be barred from getting any VA benefit. Doing otherwise would teach servicemembers that misconduct does not have repercussions which undermines good order and discipline.'' The commenter stated that ''I have experience processing CODs for VA and every case, the misconduct was severe, not simple things like eating too much or being late. If we allow these people to receive benefits, the message to the public will be deleterious. If there has been a miscarriage of justice in the discharge by the military, the military has upgrade boards to fix that.'' Still another commenter cautioned against changes that give people license to behave badly knowing they can still get benefits. ''The military relies on trust, and this undermines that. Personal experience of having two soldiers, under his/her command, get court-martialed out due to drugs and team remained understaffed. OTH are given to non-conforming or repeat offenders, or just criminals.''

VA thanks the commenter for this comment. VA has refined the willful and persistent misconduct bar, as well as implemented a compelling circumstances exception, to distinguish between serious misconduct worthy of a ''dishonorable'' determination and misconduct that is mitigated by the circumstances or outweighed by otherwise meritorious service. The aim is to provide benefits in the latter situation, but not the former.

One commenter stated that ''[c]hanges to VA shouldn't be bureaucratic, they should be legislative. In addition, Veterans should serve honorably throughout their contract otherwise they shouldn't be entitled to VA benefits.'' VA thanks the commenter for their comment. As discussed above, Congress delegated to VA the ability to set criteria for what constitutes ''other than dishonorable'' service for purposes of VA benefits eligibility. This rulemaking is necessary to refine those criteria. VA makes no changes to the regulatory text based on this comment.

Support Expanding Benefits Eligibility

Some commenters requested that all regulatory bars be removed. They stated that removing the regulatory bars would not affect military order and discipline. One commenter stated that, ''having served as a lower enlisted soldier, I can tell you I had no idea what the regulatory or statutory bars to VA benefits were. What was most important to me was . . . the people to my right and my left . . ., and the idea that [the bars] would have any impact on my behavior [i]s frankly absurd to me.'' Another commenter, former military defense counsel, stated ''I've done hundreds of cases. I can tell you very confidently that when people [commit repeated but minor misconduct], the last thing on their minds is VA benefits.'' Another commenter, a former SM, stated that most SMs ''have little or no knowledge of VA regulations or practice.'' Another commenter noted that misconduct during service can result in a criminal conviction and concluded that ''it is difficult to believe that the loss of disability compensation is not dwarfed by the incentive to avoid a criminal conviction.'' Another commenter asserted that ''[a]ny concerns regarding military order and discipline should be reflected in [DoD's] policies and regulations,'' and that removal of the regulatory bars would have ''minimal if any affect [sic] on military order and discipline as there are other remedies readily available to the chain of command.''

Relatedly, some commenters stated that expanding benefits eligibility would not denigrate other veterans' honorable service. One commenter in particular, a former SM, stated that ''any argument that providing a disabled former [SM] with life-saving healthcare, an ability to eat or an ability to be sheltered somehow denigrates honorable service is [ ] patently [ ] inhumane.'' Another commenter, a former SM, stated: ''What would *truly*

denigrate my honorable service would be to leave those comrades behind, to suffer from poverty, homelessness, and the lack of access to healthcare while I enjoy the benefits of my discharge'' (emphasis added). Similarly, another commenter, a former SM, stated: ''I'm not honored by seeing other [SMs] left homeless, by seeing them without medical care . . . That does not honor me or my service.'' Another commenter stated that the provision of VA benefits is not about bestowing or withholding ''honor''; it is about delivering lifesaving and life-changing benefits to those who served this country. Another commenter similarly stated that VA should ''leave to the DoD the matter of conferring or withholding honor'' and focus on its ''top clinical priority [of] preventing suicide among all Veterans,'' regardless of discharge status.

VA thanks the commenters for these comments. As noted above, VA recognizes the challenging nature of this subject and included it in the RFI for this very reason. Ultimately, after considering the comments for and against further limitation or removal of the regulatory bars to benefits, VA has determined that the provisions of this final rule strike a balance that will better ensure consistency in VA character of discharge determinations while also respecting the Military Departments' interest in disincentivizing significant misconduct prejudicial to good order and discipline. VA recognizes that the Military Departments use the prospect of VA benefits bars as one tool to enforce good order and discipline, and, for that reason, VA has decided not to remove all the regulatory bars, but to remove one and modify one. In that way, the changes in this final rule expand VA benefits to more SMs than ever before, but still align with the necessary incentives for military discipline.

One commenter stated VA should look into the circumstances underlying a ''bad paper discharge.'' The commenter continued that ''VA should clear up the definition of willful and persistent misconduct.'' VA thanks the commenter for their comment. In this final rule, VA has crafted objective criteria to limit willful and persistent misconduct to specific parameters, and implemented a compelling circumstances exception that examines potential reasons why the misconduct underlying an OTH discharge may be mitigated or outweighed by otherwise meritorious service.

One commenter asked VA to ''[p]lease revise the rules to allow all who have served our country to receive VA Benefits and Healthcare but have been denied based on their character of discharge. Cold War Veterans, and particularly those who served during Vietnam and post-Vietnam were hit hard with many poor leaders. Many [v]eterans suffered significantly from mental health issues during a time in which mental health programs were not readily available, and to those who took advantage where they were available, were given bad paper.'' VA thanks the commenter for their comment. Instances of injustice or inequity in the military about discharges should be addressed to the Boards for Correction of Military Records and/or the Discharge Review Board. That said, the compelling circumstances exception is designed to consider factors like mental impairment and overseas-related hardship, and to consider whether (notwithstanding misconduct) the service was honest, faithful, and meritorious.

Other Comments (General)

One commenter noted concerns over the effect of OTH discharges on homeless former SMs. VA thanks this commenter for this comment, and notes that VA currently provides certain healthcare and homeless support benefits to former SMs with OTH, and in some cases, BCD, discharges. As the commenter offered no regulatory change, VA makes no changes based on this comment.

One commenter suggested that VA should not use the term ''insanity'' in 38 CFR 3.12(b). VA thanks the commenter for their comment; however, VA proposed no changes to the definition of insanity, and solicited no comments on that definition, in the proposed rule. Further, the regulatory language originates in statute, so VA has a legal basis for using it. 38 U.S.C. 5303(b). Thus, VA is not changing the definition in this final rule.

Numerous commenters stated their general opposition to VA-related matters outside of the scope of COD determinations, such as opposition to the privatization of VA services and the Choice Act. VA thanks the commenters for their comments, though they are outside the scope of this rulemaking and will not be addressed here.

Some commenters requested assistance with VA benefits unrelated to the rulemaking package. VA thanks these commenters for their comments. However, as they are not related to the rulemaking, and offer no change to the regulatory text, VA makes no changes in response to these comments. These commenters are encouraged to seek out VSOs, other accredited representatives, or employees at VA Regional Offices to assist with VA benefits questions.

One commenter noted that the new rule would help that commenter's case personally. VA thanks the commenter for the comment, but as the commenter offered no regulatory change, VA makes no changes based on this comment.

IV. Uncharacterized Discharges and Coast Guard Discharges

VA wishes to clarify the applicability of this rule to uncharacterized discharges and Coast Guard discharges. Per 38 CFR 3.12(k) (redesignated in this rule to § 3.12(l)), there are three types of uncharacterized separations: (1) entry level separation; (2) void enlistment or induction; and (3) dropped from the rolls. An entry level separation is considered under conditions other than dishonorable; accordingly, this rulemaking does not apply to this type of uncharacterized separation. *See* 38 CFR 3.12(a). Void enlistments are reviewed under the factors listed in 38 CFR 3.14, and thus are also not impacted by this rulemaking.

However, when a former SM was dropped from the rolls, the facts and circumstances surrounding the separation must be reviewed to determine whether the separation was under conditions other than dishonorable. These determinations are conducted in the same manner as if such former SM received an OTH discharge. Accordingly, these former SMs will be favorably impacted by this rulemaking for the reasons discussed above.

The Coast Guard serves a unique place in the armed Forces. The term ''armed forces'' means the Army, Navy, Air Force, Marine Corps, Space Force, and Coast Guard. 10 U.S.C. 101(a)(4). The military departments are the Departments of the Army, Navy, and Air Force. 10 U.S.C. 101(a)(8). The Secretary of the Air Force has authority over the Air Force and the Space Force, and the Secretary of the Navy has authority over the Navy and Marine Corps. 10 U.S.C. 101(a)(9)(B), (C). The Coast Guard serves under the Department of Homeland Security, except upon Presidential direction to transfer it to the Department of the Navy or a declaration of war including a direction for its transfer to the Department of the Navy. 14 U.S.C. 101; 14 U.S.C. 103(a), (b); 10 U.S.C. 101(a)(9)(B). The Coast Guard issues the following discharges for officers: honorable, general/under honorable conditions, OTH, dismissal pursuant to GCM or administrative separation. For an enlisted SM, the discharges are the same as any other SM—honorable, general/under honorable conditions, OTH, bad conduct or dishonorable. SMs may also receive uncharacterized

discharges. As these discharges are identical to any other SM, this rulemaking will have the same effect on the SMs or officers who receive a BCD or OTH discharge and apply for VA benefits or health care or seek a COD determination.

V. Past Denials and Effective Date

In view of the complexity of the law VA administers, a brief discussion of the effect of prior COD adjudications and how to re-adjudicate the same is likely to reduce confusion, both by claimants and by VA adjudicators, and may facilitate timely access to benefits.

When this rule becomes effective, any claimant with a prior unfavorable COD determination, to include the no longer used undesirable discharge, may request a new COD determination under new § 3.12. *Cf. Routen* v. *West,* 142 F.3d 1434, 1441 (Fed. Cir. 1998). For those claimants found eligible for benefits under new § 3.12, the effective date of such benefits would be governed by 38 U.S.C. 5110(g) and 38 CFR 3.114. In short, if the claim is submitted within one year of the effective date of this final rule, the effective date of benefits could be as early as the effective date of this final rule. 38 CFR 3.114(a)(1).

However, VA makes clear this regulatory change is not a ground for clear and unmistakable error (CUE) in prior COD determinations. Although this final rule departs from VA's prior approach to COD, that does not render VA's prior regulation unlawful, *Garvey,* 972 F.3d at 1339, and, even if it were, a change in law cannot support a claim of CUE, *George* v. *McDonough,* 142 S. Ct. 1953, 1957 (2022). Accordingly, prior final decisions would not be subject to revision for CUE based on the new rulemaking. Claims for CUE on bases other than a change in regulation shall be considered on a case-by-case basis.

VI. Severability

The purpose of this section is to clarify VA's intent with respect to the severability of provisions of this rule. Each provision of this rulemaking is capable of operating independently, and VA intends them to operate independently. If any provision of this rule is determined by judicial review or operation of law to be invalid, that partial invalidation will not render the remainder of this rule invalid. For example, amendments to any given regulatory bar are intended to operate independently, and are capable of operating independently, from amendments to other regulatory bars. Likewise, if the application of any portion of this rule to a particular circumstance is determined to be invalid, VA intends that the rule remain applicable to all other circumstances.

VII. Amendment Summary

As noted above, 38 U.S.C. 101(2) defines a ''veteran'' as an individual ''who served in the active military, naval, air, or space service, and who was discharged or released therefrom under conditions other than dishonorable.'' Pursuant to binding judicial precedent, VA has the discretion to determine who satisfies the ''under conditions other than dishonorable'' requirement. Moreover, 38 U.S.C. 501(a) provides that ''[t]he Secretary has authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by [VA] and are consistent with those laws, including—(1) regulations with respect to the nature and extent of proof and evidence and the method of taking and furnishing them in order to establish the right to benefits under such laws.'' These authorities permitted VA to establish a COD regulation, 38 CFR 3.12, and to amend that regulation herein.

In this final rule, VA amends the section heading to read ''Benefit eligibility based on character of discharge'' to reflect the fact that VA does not have the authority to alter character of service determinations made by the Armed Forces. Rather, VA utilizes the characterization to determine basic VA benefit eligibility.

Consistent with the proposed rule, VA amends paragraphs (a) and (b) by adding descriptive headers and implementing non-substantive changes for clarity.

VA adds a descriptive header to paragraph (c) and amends paragraph (c)(1) to make ''lawful order'' plural so that it accurately reflects the text of 38 U.S.C. 5303(a). VA also amends paragraph (c)(6) by dividing the language of current paragraph (c)(6) into two subordinate paragraphs and making edits to that language, as well as moving current paragraphs (c)(6)(i) through (iii) to new paragraphs (e)(1) through (3) and making edits to that language.

VA amends paragraph (d) to add a descriptive header ''Regulatory bars to benefits''; to revise the regulatory bars as discussed above, and to remove the homosexual acts bar.

New paragraph (e) addresses the ''compelling circumstances'' exception. As noted above, new paragraphs (e)(1) through (3) expand upon current paragraphs (c)(6)(i) through (iii), with minor wording changes to reflect the fact that this language will now be applied to not just prolonged AWOL but also certain misconduct.

Current paragraphs (e) through (k) are redesignated as paragraphs (f) through (l). Several of these paragraphs are provided descriptive headers and updated cross-references after the addition of new paragraph (e). Moreover, the authority citation for redesignated paragraph (i) has been embedded into that paragraph's text. Finally, VA is amending the authority citation for the section to clarify the statutory authorities through which 38 CFR 3.12 is promulgated.

Executive Orders 12866, 13563 and 14094

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Executive Order on Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866 of September 30, 1993 (Regulatory Planning and Review), and Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review). The Office of Information and Regulatory Affairs has determined that this rule is a significant regulatory action under Executive Order 12866, section 3(f)(1), as amended by Executive Order 14094. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). The anticipated costs of this regulatory action are directly and only attributed to VA's internal processing and budgetary appropriations. There are no small entities involved or impacted by this regulatory action. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule 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. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act (PRA)

Although this final rule contains a collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), there are no provisions associated with this rulemaking constituting any new collection of information or any revisions to the current collection of information. The collection of information for 38 CFR 3.12 is currently approved by the Office of Management and Budget (OMB) and has valid OMB control numbers of 2900–0747, 2900–0886, 2900–0002 and 2900–0004.

Congressional Review Act

Under the Congressional Review Act, this regulatory action may result in an annual effect on the economy of $100 million or more, 5 U.S.C. 804(2), and so is subject to the 60-day delay in effective date under 5 U.S.C. 801(a)(3). In accordance with 5 U.S.C. 801(a)(1), VA will submit to the Comptroller General and to Congress a copy of this regulation and the Regulatory Impact Analysis (RIA) associated with the regulation.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on April 23, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 3 as set forth below:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

■ 1. The authority citation for part 3, subpart A, continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

■ 2. Amend § 3.12 as follows:
■ a. Revise the section heading and paragraphs (a), (b), (c) introductory text, (c)(1) and (6), and (d).
■ b. Redesignate paragraphs (e) through (k) as paragraphs (f) through (l).
■ c. Add new paragraph (e).
■ d. Add a heading at the beginning of newly redesignated paragraph (f).
■ e. Revise newly redesignated paragraphs (g), (h) introductory text, and (i) introductory text.
■ f. Remove the authority citation after newly redesignated paragraph (i).
■ g. Revise newly redesignated paragraph (j).
■ h. Add a heading at the beginning of newly redesignated paragraph (k).
■ i. Revise the authority citation at the end of the section.

The revisions and additions read as follows:

§ 3.12 Benefit eligibility based on character of discharge.

(a) *General rule.* If the former service member did not die in service, then pension, compensation, or dependency and indemnity compensation is payable for claims based on a period of service that was terminated by discharge or release under conditions other than dishonorable. (38 U.S.C. 101(2)) A discharge under honorable conditions is binding on the Department of Veterans Affairs as to character of discharge.

(b) *Insanity exception.* No bar to benefits under this section shall be applied if VA determines that the former service member was insane at the time he or she committed the offense(s) leading to the discharge or release under dishonorable conditions. (38 U.S.C. 5303(b)) Insanity is defined in § 3.354.

(c) *Statutory bars to benefits.* Benefits are not payable where the former service member was discharged or released under one of the following conditions:

(1) As a conscientious objector who refused to perform military duty, wear the uniform, or comply with lawful orders of competent military authorities.

* * * * *

(6) By reason of a discharge under other than honorable conditions issued as a result of an absence without official leave (AWOL) for a continuous period of at least 180 days (38 U.S.C. 5303(a)).

(i) *Compelling circumstances exception.* This paragraph (c)(6) does not apply if compelling circumstances mitigate the prolonged unauthorized absence, as discussed in paragraph (e) of this section.

(ii) *Applicability prior to October 8, 1977.* This paragraph (c)(6) applies to any person awarded an honorable or general discharge prior to October 8, 1977, under one of the programs listed in paragraph (i) of this section, and to any person who prior to October 8, 1977, had not otherwise established basic eligibility to receive Department of Veterans Affairs benefits. *Basic eligibility* for purposes of this paragraph (c)(6)(ii) means either a Department of Veterans Affairs determination that an other than honorable discharge was issued under conditions other than dishonorable, or an upgraded honorable or general discharge issued prior to October 8, 1977, under criteria other than those prescribed by one of the programs listed in paragraph (i) of this section. However, if a person was discharged or released by reason of the sentence of a general court-martial, only a finding of insanity (paragraph (b) of this section) or a decision of a board of correction of records established under 10 U.S.C. 1552 can establish basic eligibility to receive Department of Veterans Affairs benefits.

(d) *Regulatory bars to benefits.* Benefits are not payable where the former service member was discharged or released under one of the conditions listed in paragraph (d)(1) or (2) of this section.

(1) Compelling circumstances exception is not applicable for:

(i) *Discharge in lieu of trial.* Acceptance of a discharge under other than honorable conditions or its equivalent in lieu of trial by general court-martial.

(ii) *Mutiny or espionage.* Mutiny or spying.

(2) Compelling circumstances exception is applicable for:

(i) *An offense involving moral turpitude.* This paragraph (d)(2)(i) includes, generally, conviction of a felony.

(ii) *Willful and persistent misconduct.* For purposes of this section, instances of minor misconduct occurring within two years of each other are persistent; an instance of minor misconduct occurring within two years of more serious misconduct is persistent; and instances of more serious misconduct occurring within five years of each other are persistent. For purposes of this section, minor misconduct is misconduct for which the maximum sentence imposable pursuant to the

Manual for Courts-Martial United States would not include a dishonorable discharge or confinement for longer than one year if tried by general court-martial.

(e) *Compelling circumstances exception.* The bar to benefits for prolonged AWOL under paragraph (c)(6) of this section and the two types of misconduct described in paragraph (d)(2) of this section will not be applied if compelling circumstances mitigate the AWOL or misconduct at issue. The following factors will be considered in a determination on this matter:

(1) *Length and character of service exclusive of the period of prolonged AWOL or misconduct.* Service exclusive of the period of prolonged AWOL or misconduct should generally be of such quality and length that it can be characterized as honest, faithful, and meritorious and of benefit to the Nation.

(2) *Reasons for prolonged AWOL or misconduct.* Factors considered are as follows:

(i) Mental or cognitive impairment at the time of the prolonged AWOL or misconduct, to include but not limited to a clinical diagnosis of (or evidence that could later be medically determined to demonstrate existence of) posttraumatic stress disorder (PTSD), depression, bipolar disorder, schizophrenia, substance use disorder, attention deficit hyperactivity disorder (ADHD), impulsive behavior, or cognitive disabilities.

(ii) Physical health, to include physical trauma and any side effects of medication.

(iii) Combat-related or overseas-related hardship.

(iv) Sexual abuse/assault.

(v) Duress, coercion, or desperation.

(vi) Family obligations or comparable obligations to third parties.

(vii) Age, education, cultural background, and judgmental maturity.

(3) Whether a valid legal defense would have precluded a conviction for AWOL or misconduct under the Uniform Code of Military Justice. For purposes of this paragraph (e)(3), the defense must go directly to the substantive issue of absence or misconduct rather than to procedures, technicalities, or formalities.

(f) *Board of corrections upgrade.* * * *

(g) *Discharge review board upgrades prior to October 8, 1977.* An honorable or general discharge issued prior to October 8, 1977, under authority other than that listed in paragraphs (i)(1) through (3) of this section by a discharge review board established under 10 U.S.C. 1553, sets aside any bar to benefits imposed under paragraph (c) or (d) of this section except the bar contained in paragraph (c)(2) of this section.

(h) *Discharge review board upgrades on or after October 8, 1977.* An honorable or general discharge issued on or after October 8, 1977, by a discharge review board established under 10 U.S.C. 1553, sets aside a bar to benefits imposed under paragraph (d) of this section, but not under paragraph (c) of this section, provided that:

* * * * *

(i) *Special review board upgrades.* Under 38 U.S.C. 5303(e), unless a discharge review board established under 10 U.S.C. 1553 determines on an individual case basis that the discharge would be upgraded under uniform standards meeting the requirements set forth in paragraph (h) of this section, an honorable or general discharge awarded under one of the following programs does not remove any bar to benefits imposed under this section:

* * * * *

(j) *Overpayments after October 8, 1977, due to discharge review board upgrades.* No overpayments shall be created as a result of payments made after October 8, 1977, based on an upgraded honorable or general discharge issued under one of the programs listed in paragraph (i) of this section which would not be awarded under the standards set forth in paragraph (h) of this section. Accounts in payment status on or after October 8, 1977, shall be terminated the end of the month in which it is determined that the original other than honorable discharge was not issued under conditions other than dishonorable following notice from the appropriate discharge review board that the discharge would not have been upgraded under the standards set forth in paragraph (h) of this section, or April 7, 1978, whichever is the earliest. Accounts in suspense (either before or after October 8, 1977) shall be terminated on the date of last payment or April 7, 1978, whichever is the earliest.

(k) *Overpayments after October 8, 1977, based on application of AWOL statutory bar.* * * *

(Authority: 38 U.S.C. 101, 501, and 5303)

* * * * *

[FR Doc. 2024–09012 Filed 4–25–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 4

[PS Docket Nos. 21–346, 15–80; ET Docket No. 04–35; FCC 24–5; FR ID 214797]

Resilient Networks; Disruptions to Communications; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Communications Commission published a document in the **Federal Register** on April 11, 2024, containing the effective and compliance dates for a new rule. While the **DATES** section at the beginning of the document was correct, Section E of the document, ''Timelines for Compliance,'' requires a correction.

DATES: Effective April 26, 2024.

FOR FURTHER INFORMATION CONTACT: Scott Cinnamon, Attorney Advisor, 202–418–2319.

SUPPLEMENTARY INFORMATION:

Federal Register Correction

In rule document 2024–07402 at 89 FR 25535 in the issue of April 11, 2024, on page 25541, in the second column, the first sentence of Section E, ''Timelines for Compliance,'' is corrected to read as follows:

We set a single date for compliance by all subject providers for implementing these rules as the later of 30 days after the FCC publishes notice in the **Federal Register** that the OMB has completed its review of Paperwork Reduction Act requirements, or November 30, 2024.

Dated: April 17, 2024.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2024–08646 Filed 4–25–24; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 240419–0114]

RIN 0648–BM83

Fisheries of the Northeastern United States; 2024 and 2025 Summer Flounder and Scup, and 2024 Black Sea Bass Recreational Management Measures

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

ACTION: Final rule.

SUMMARY: NMFS announces Federal management measures for the 2024 and 2025 summer flounder fishery and the 2024 black sea bass recreational fishery. The implementing regulations for these fisheries require NMFS to publish recreational measures for each fishing year and to provide an opportunity for public comment. The intent of this action is to set management measures that allow the recreational fisheries to achieve, but not exceed, the recreational harvest targets and thereby prevent overfishing.

DATES: This rule is effective April 26, 2024.

ADDRESSES: Copies of this final rule and the small entity compliance guide prepared for permit holders are available from: Michael Pentony, Regional Administrator, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930, and accessible via the internet at: *https://www.fisheries.noaa.gov/action/proposed-rule-implement-2024-and-2025-summer-flounder-and-scup-and-2024-black-sea-bass.*

FOR FURTHER INFORMATION CONTACT: Emily Keiley, Fishery Policy Analyst, (978) 281–9116, or *Emily.Keiley@noaa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council (Council) and the Atlantic States Marine Fisheries Commission (Commission) cooperatively manage summer flounder, scup, and black sea bass. The Council and the Commission's Management Boards meet jointly each year to recommend recreational management measures. For summer flounder and black sea bass, NMFS must implement coastwide measures or approve conservation-equivalent measures, per 50 CFR 648.102(d) and 648.142(d), as soon as possible once the Council and Commission's makes their recommendation. This action approves conservation equivalency for summer flounder and black sea bass in 2024 and for summer flounder in 2025.

For scup, no changes to the Federal recreational management measures are being implemented. The 2024 and 2025 Federal recreational scup management measures are a 10-inch (25.4-centimeters (cm)) minimum fish size, a 50-fish per person possession limit, and a year-round open season.

Conservation Equivalency

In this final rule, NMFS is implementing conservation equivalency to manage the 2024 and 2025 summer flounder and 2024 black sea bass recreational fisheries, as proposed in the proposed rule published on February 23, 2024 (89 FR 13674). Under conservation equivalency, Federal recreational measures are waived and all recreational vessels fishing in Federal waters are subject to the recreational fishing measures implemented by the state in which they land. This approach allows for more customized measures to constrain recreational harvest at a state or regional level that are likely to meet the needs of anglers in each area, as opposed to coastwide measures that may be advantageous to anglers in some areas and unnecessarily restrictive in others.

The combination of state or regional measures must be ''equivalent'' in terms of conservation to a set of ''non-preferred coastwide measures,'' which are recommended by the Council and the Summer Flounder, Scup, and Black Sea Bass Board (Board) each year. States, through the Commission, are collectively implementing measures designed to constrain landings to the recreational harvest targets. Additional information on the development of these measures is provided in the proposed rule (see 89 FR 13674, February 23, 2024) and not repeated here.

Summer Flounder Recreational Management Measures

On April 4, 2024, the Commission notified NMFS that it had certified that the 2024 and 2025 recreational fishing measures required to be implemented in state waters for summer flounder are, collectively, the conservation equivalent of the season, fish size, and possession limit prescribed in §§ 648.104(b), 648.105, and 648.106(a). Pursuant to § 648.102(d)(2), if conservation equivalency is adopted, vessels subject to the recreational fishing measures are not subject to Federal measures and instead are subject to the recreational fishing measures implemented by the state in which they land. Section 648.107(a) is amended through this final rule to recognize state-implemented measures as the conservation equivalent of the Federal coastwide recreational management measures for 2024 and 2025.

In addition, this action revises the default ''non-preferred'' summer flounder coastwide measures at §§ 648.104(b), 648.105, and 648.106(a). For 2024 and 2025, the non-preferred coastwide measures are: (1) an 18.5-inch (46.99-cm) minimum fish size; (2) a three-fish per person possession limit; and (3) an open season from May 8 to September 30. The coastwide measures become the default management measures the year after conservation equivalency expires (in this case 2026) until the joint process establishes either coastwide or conservation-equivalency measures for the next year.

Black Sea Bass Recreational Management Measures

On April 4, 2024, the Commission notified NMFS that it had certified that the 2024 recreational fishing measures required to be implemented in state waters for black sea bass are, collectively, the conservation equivalent of the season, fish size, and possession limit prescribed in §§ 648.145(a), 648.146, and 648.147(b). According to § 648.142(d)(2), if conservation equivalency is adopted, vessels subject to the recreational fishing measures are not subject to Federal measures and instead are subject to the recreational fishing measures implemented by the state in which they land. Section 648.151 is amended through this final rule to recognize state-implemented measures as the conservation equivalent of the Federal coastwide recreational management measures for 2024.

Regulatory Text Correction

The definition of a recreational fishing vessel found at § 648.2 previously only referenced the recreational scup fishery. However, the definition applies to all recreational fisheries. This action corrects this definition, removing the reference to the scup fishery.

Changes From the Proposed Rule

There are no changes from the proposed rule.

Comments and Responses

NMFS received 18 comments on the proposed rule. Comments were received from 15 individuals, the Natural Resources Defense Council (NRDC), the Virginia Beach Charter Captains, and one comment was submitted anonymously. Ten comments focused, in whole or in part, on state measures or commercial management, which were not part of the proposed action and, therefore, are not addressed in the following responses.

NMFS received a comment from the NRDC. Attached to NRDC's comment letter was a copy of the complaint they filed in ongoing litigation on Framework 17 (*NRDC* v. *Raimondo,* No. 23–cv–982 (D.D.C. Aug. 29, 2023)). That legal challenge is fully briefed, and the parties await the court's decision. Given that this litigation is ongoing, NMFS will not address the complaint here. NRDC also incorporated, by reference, its comments on the 2023 summer flounder, scup, and black sea bass recreational measures. Our responses to those comments are provided in the final rule (88 FR 55411, August 15, 2023), and are not repeated here.

Comment 1: A comment from NRDC stated that the proposed rule and Framework 17, on which this proposed rule is based, are inconsistent with the Magnuson-Stevens Fishery Conservation Management Act's (Magnuson-Stevens Act) annual catch limits (ACL) provisions because they allow the Council to manage recreational fishing to new recreational harvest target levels that are not consistent with the ACLs derived from the Science and Statistical Committee's (SSC) recommendations.

Response: The Percent Change Approach has been established by the rulemaking implementing Framework 17 and, as such, must be followed in setting the recreational management measures in this action. Deviating from this approach would require new rulemaking to modify Framework 17, which is beyond the scope of this action. However, as explained in detail in the final rule implementing Framework 17, the new Percent Change Approach is a harvest control rule designed by the Council and Commission for use in managing mid-Atlantic recreational fisheries and uses two factors to determine if management measures could remain status quo, could be liberalized, or must be restricted. These two factors are: (1) a comparison of the confidence interval (CI) around an estimate of expected harvest under status quo measures with the average Recreational Harvest Limit (RHL) for the upcoming 2 years; and (2) biomass compared to the target level, as defined by the most recent stock assessment. These two factors also determine the appropriate degree of change (*i.e.,* a percentage change in expected harvest).

The Percent Change Approach does not change the process for setting measurable and objective status determination criteria (*e.g.,* overfishing limit (OFL), acceptable biological catch (ABC), ACL) as required by National Standard 1. The status determination criteria continue to be based on the best available scientific information as determined by the Council's SSC. The Percent Change Approach does not eliminate the recreational ACL or RHL and continues to use both in the process of setting measures and triggering accountability measures (AM). Together, these measures meet the requirements of National Standard 1. The Percent Change Approach is a method for determining the need for, and extent of, recreational fishing measures to prevent overfishing while allowing catch to target optimal yield. This approach attempts to constrain harvest to prevent overfishing while also acknowledging that recreational catch estimates are uncertain and often highly variable (more so than commercial catch estimates). The Percent Change Approach makes incremental adjustments, thus reducing the tendency of management measures to chase after the highs and lows by either liberalizing or restricting measures too much in any given year in reaction to potentially large swings in recreational catch estimates.

The approach also builds in more precaution for stocks at lower biomass levels. Biomass levels and the target are taken directly from the approved and peer-reviewed stock assessments that occur every other year. Consider that when biomass is in decline, the stock often becomes less available to the recreational fishery, and, therefore, catch estimates may decline relative to the RHL. Formerly, management measures would be liberalized, sometimes significantly, while catch fell due to a declining biomass, increasing fishing pressure on a declining stock. Conversely, as healthy stocks increase, sometimes far above the target biomass level, such as the current situations with black sea bass and scup, the fish become more available to the fishery even under restrictive measures, resulting in catch estimates that exceed the RHL. However, what appear to be overages have, in these circumstances, been found to have no negative biological impact on abundant stocks, as NMFS continues to see increases in biomass in a subsequent stock assessment. Therefore, not all overages result in overfishing. For example, black sea bass has not been subject to overfishing in over 10 years despite sustained high recreational catch levels that sometimes exceeded the RHL and the recreational ACL.

Prior to implementing the Percent Change Approach, the method used to determine recreational measures used the same criteria (*i.e.,* RHL and estimated catch) but did not consider or incorporate stock biomass in determining the extent of changes (whether more liberal or more conservative). The prior method prescribed the same degree of changes to management measures whether a stock biomass was considered overfished (*i.e.,* less than 50 percent of its maximum sustainable yield target) or over 200 percent of its target level. The Percent Change Approach also considers the estimated harvest compared to the RHL, but, in contrast to the previous approach, also incorporates information about stock status to determine whether, and how much, to either liberalize or restrict management measures. This ensures more conservative responses than the previous method for stocks in lower biomass conditions, while allowing potentially more liberal responses only for stocks at very high biomass levels.

Comment 2: NRDC commented that the recreational harvest target for scup (13.76 million pounds (lb); 6,241 metric tons (mt)) overshoots the 2024 and 2025 RHLs prescribed by the specifications. The NRDC comment also concludes that the total expected scup harvest will exceed the OFL in 2025.

Response: Application of the Percent Change Approach and the Recreational Demand Model (RDM) resulted in a recommendation of a 10-percent reduction in scup harvest in 2024 and 2025. This is because scup has a very high biomass, but harvest under status quo measures is expected to be above the RHL.

Scup is a healthy stock far above the target biomass level, because of the high abundance and availability to the fishery, even under restrictive measures, the catch is likely to exceed the RHL. However, observed recent overages of the scup RHL, ACL, ABC, and even OFL have had no negative biological impact on the stock. The conservation risk of a harvest reduction that is less than what would have previously been applied is negligible for a stock, like scup, that has a very high biomass (over 150 percent of its biomass target). The Magnuson-Stevens Act defines overfishing as a

''rate or level of fishing mortality that jeopardizes the capacity of a fishery to produce the maximum sustainable yield *on a continuing basis*'' (emphasis added) (16 U.S.C. 1802(34)). This scenario, in which a stock continues to maintain biomass significantly above the target, does not constitute overfishing.

Moreover, it is highly unlikely that there will be overfishing of scup when such a determination takes into account both recreational and commercial harvest, and the commercial scup fishery has not come close to harvesting its allocation of the scup ACL in recent years. From 2018 to 2021, the commercial sector only landed between 55 percent and 63 percent of its allocated scup quota, an annual average of 13.42 million lb (6,087 mt) landed. The commercial scup quotas for 2024 and 2025 are 21.15 million lb (9,593 mt) and 18.80 million lb (8,527 mt), respectively, higher than recent commercial landings. In this context, even if there is a recreational harvest above the RHL it is unlikely to result in negative biological consequences for the scup stock, where the overall total of commercial and recreational harvests remains below overfishing levels.

In 2022, the total scup catch did exceed the 2022 OFL. The scup total catch was 35.98 million lb (16,322 mt), compared to the OFL of 32.56 million lb (14,770 mt), corresponding to an 11 percent overage. Although the catch exceeded the OFL and the ABC, the status determination criteria for scup makes use of the annual fishing mortality rate relative to a maximum fishing mortality rate to determine if overfishing has occurred. The 2023 Management Track Assessment estimated fishing mortality rate was 0.171, which is below the fishing mortality rate at maximum sustainable yield (F_{MSY}) of 0.19, which means that despite an exceedance of the OFL, there was no overfishing of scup.

Additionally, the estimated biomass (159,050 mt) was estimated to be well above the biomass at maximum sustainable yield (78,593 mt). Despite the overage of the OFL in 2022, the best available science supports the determination that overfishing was not occurring. As seen in 2022 with scup, overages of the OFL do not always correspond to overfishing. The OFL and corresponding catch limits are based on projections from a stock assessment and can prove to be inaccurate when considered retrospectively with the insight of a subsequent stock assessment.

It is also important to again note the uncertainty in estimated recreational harvests. This uncertainty is one of the main drivers for the adoption of the Percent Change Approach in Framework 17. Here, the median coastwide projected 2024–2025 harvest under 2023 measures is 15.29 million lb (6,935 mt), with an 80 percent CI of 14.07–16.29 million lb (6,382–7,389 mt), meaning that, statistically, the estimate can fall anywhere in that range with equal likelihood. With the 10 percent reduction adopted here, the recreational harvest of scup could be anywhere from 12.66 million lb (5,744 mt) to 14.66 million lb (6,650 mt). The average 2024–2025 scup RHL is 12.51 million lb (5,674 mt), which is only about 1 percent below the likely range of scup harvest after the 10 percent reduction is applied. Given the significant uncertainty of both recreational harvest and the specifications themselves, coupled with low risk of overfishing, a 10 percent scup reduction is a reasonable approach. To the extent that biomass remains high but additional reductions are needed the next time that recreational measures are developed, another 10-percent reduction would occur. However, due to the inherent variability and uncertainty in recreational catch data in the context of a very high biomass of scup, more drastic changes to measures could prove to be unwarranted and could lead to the undesirable result of increased recreational discards of dead fish. Scup provides an example of how the gradual approach of adjustments to recreational targets that the Harvest Control Rule provides for abundant stocks can work effectively with little risk of negative consequences to the stock.

Comment 3: One comment expressed concern about the lack of new information on the biomass of black sea bass, three comments noted that the black sea bass stock is very abundant and expanding, and one of these comments noted concerns about the impact of the high abundance of black sea bass on other species.

Response: In December 2023, a research track assessment was completed for black sea bass. Research track assessments are not used to inform management or make official determinations of stock status. In spring 2024, a management track assessment will be conducted for black sea bass, incorporating data through 2023. The results of this assessment will be used to inform specifications and recreational management measures for 2025. Although the research track assessment is not used for official status determinations, the results did indicate that the black sea bass stock is at a very high biomass level and that biomass has been increasing in recent years.

Comment 4: One comment on the summer flounder recreational management measures noted concerns about the minimum size requirement (18.5 inches (46.99 cm)). This commenter suggested that the minimum size should be lower (16.5 inches (41.91 cm)). The lower minimum size was suggested due to concerns about the post-release survival of small summer flounder. The comment noted that most of the fish they encounter are less than the minimum size.

Response: The 18.5-inch (46.99-cm) minimum size is part of the non-preferred coastwide measures. These measures are being waived for 2024 and 2025, as NMFS has approved conservation equivalency. Anglers must adhere to the measures in the state where they land. The minimum size specified for a state or region may differ from the 18.5-inch (46.99-cm) minimum size proposed as part of the non-preferred measures. One benefit of the conservation equivalency approach is that states and regions can tailor recreational management measures to meet the needs of anglers in their state or region, compared to coastwide measures that may be advantageous to anglers in some areas and unnecessarily restrictive in others.

Comment 5: Four comments expressed concern about recreational data. Two comments specifically suggested that new data collection techniques be implemented, such as the development of a reporting application or the use of for-hire vessel trip reports (VTR). One commenter was concerned about the underreporting of recreational catch.

Response: The data used to inform the summer flounder, scup, and black sea bass recreational management measures are the best available data on recreational catch. In addition to Marine Recreational Information Program (MRIP) data, a bioeconomic model, the RDM, was used to estimate harvest. The RDM uses trip attributes such as expected harvest and costs, as well as the availability of different sizes of fish, to estimate the likelihood that an angler will go fishing under a given set of regulations. The RDM is informed by a 2022 survey of anglers from Maine through Virginia as well as recent size distribution information from the stock assessment.

Expanded use of recreational for-hire VTRs may be considered in the future. The Council has initiated an action to consider additional changes to recreational fisheries management, including the consideration of options

related to recreational catch accounting, such as private angler reporting and enhanced VTR requirements.

Comment 6: One comment cited concerns about the recreational data, specifically MRIP data and that the recent pilot study that indicates that the current configuration of MRIP may be resulting in effort being overestimated. The comment expressed concern that information from the pilot study was not currently being accepted or used.

Response: This comment correctly points out that NMFS has conducted a pilot study on the recreational Fishing Effort Survey. The preliminary results suggest that the order of the questions in the Fishing Effort Survey may lead to overestimation of fishing effort. However, these are preliminary results and a more robust study to analyze this issue is currently underway. Additional analyses are necessary to confirm findings. Once sufficient information has been collected and the implications of the MRIP estimates are fully understood, that information will be incorporated into the relevant science and management processes.

Comment 7: Two comments opposed more restrictive black sea bass recreational regulations and one comment opposed more restrictive summer flounder recreational regulations. These comments also highlighted the importance of recreational fisheries to the economy.

Response: The 2024 black sea bass measures are the same as those implemented in 2023, no additional restrictions have been implemented.

The 28-percent reduction implemented for summer flounder is based on the results of the Percent Change Approach. Because summer flounder biomass is in the low category and the 2023 management measures were expected to result in an RHL overage, the approach requires a reduction in recreational harvest. It is also important to note that the 2023 management track assessment for summer flounder indicated that overfishing was occurring. Thus, this reduction, in addition to commercial quota reductions, is necessary to ensure that overfishing is ended.

Comment 8: One comment asked if jigging would become illegal for summer flounder, noting that they are a terrible fish to spear.

Response: This action does not ban jigging for summer flounder.

Comment 9: One comment supported the implementation of conservation equivalency.

Response: NMFS agrees, and this action implements conservation equivalency for both summer flounder and black sea bass.

Comment 10: One comment supported the 28-percent harvest reduction for summer flounder, citing their observations of declining recreational catch over the years. An additional comment was supportive of the non-preferred coastwide measures for summer flounder.

Response: NMFS agrees. NMFS has approved conservation equivalency. States and regions have implemented measures consistent with the 28-percent harvest reduction. While the non-preferred coastwide measures have been waived for 2024 and 2025, the measures implemented by the states or regions are equivalent in terms of their conservation benefit.

Classification

Pursuant to section 305(d) of the Magnuson-Stevens Act, the Assistant Administrator for Fisheries, NOAA, has determined that this action is necessary to carry out the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan, and its implementing regulations and that this final rule is consistent with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan, other provisions of the Magnuson-Stevens Act, and other applicable law.

The Assistant Administrator for Fisheries, NOAA, finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay of effectiveness period for this rule, to ensure that the final management measures are in place as soon as possible. This action implements 2024 recreational management measures for summer flounder and black sea bass.

NMFS could not publish this final rule at an earlier date. The recreational management measure setting process begins after the Council and Board set the annual specifications. The Council's Monitoring Committee evaluates the needed changes in recreational harvest and develop recommendations for coastwide management measures for the Council and Board to consider. At the December 12–14, 2023, meeting, the Council and Board voted on recommended recreational management measures. Council staff then prepared and submitted those recommendations to NMFS on January 16, 2024. The proposed rule was published on February 23, 2024, with a public comment period open through March 11, 2024. After the comment period closes NMFS, must review, consider, and respond to all comments on the proposed rule and develop the final rule package, which is then subject to further review upon completion. In addition, during the proposed rule development and comment period, the states are developing management measures and submitting that information to the Commission to ensure that the suite of state measures are the conservation equivalent of coastwide Federal measures. The letter confirming conservation equivalent measures from the Commission was received by NMFS on April 4, 2024. Pursuant to §§ 648.102(d)(2)(ii) and 648.142(d)(2)(ii), NMFS cannot finalize conservation equivalency without this information from the Commission. This final rule was submitted to the Department of Commerce Office of General Council on April 9, 2024. Given the time needed to review the recommendations and prepare the Federal rulemaking, and the need to confirm conservation equivalency through the Commission's process, this is the earliest this rule could be published.

The Federal coastwide regulatory measures for recreational summer flounder and black sea bass fishing that were codified last year (88 FR 55411, August 15, 2023) remain in effect until the decision to waive Federal measures for 2024 is made effective by this final rule. Many states have already implemented their conservationally equivalent 2024 measures and a delay in implementing the measures of this rule will increase confusion on what measures are in place in Federal waters. Inconsistencies between the states' measures and the Federal measures could lead to misunderstanding of the applicable regulations and could increase the likelihood of noncompliant landings.

Additionally, the Federal summer flounder measures currently in place are more liberal than many of the measures in state waters. Further delay of the implementation of the 2024 measures will increase the likelihood that the 2024 RHL and recreational ACL will be exceeded. NMFS is required to implement measures to constrain recreational harvest to prevent overfishing.

Unlike actions that require an adjustment period to comply with new rules, this action does not require recreational and charter/party operators to purchase new equipment or otherwise expend time or money to comply with this action's management measures. Rather, compliance with this final rule simply means adhering to the published state management measures for summer flounder and black sea bass while the recreational and charter/party

operators are engaged in fishing activities.

Additionally, stakeholder and industry groups have been involved with the development of this action and have participated in public meetings throughout the past year. Generally, stakeholders are supportive of the use of conservation equivalency because it allows states, and regions, more flexibility to set measures, instead of one set of coastwide measures that apply to all. A delay in implementation past the start of the recreational fishing season would be contrary to the public interest, as it could create confusion both in the recreational fisheries regarding the management measures, and with state agencies as they prepare and finalize their recreational management measures.

For these reasons, the Assistant Administrator finds good cause to waive the 30-day delay in the date of effectiveness and to implement this rule upon the date of publication in the **Federal Register**.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. NMFS received no comments regarding this certification. Therefore, a final regulatory flexibility analysis was not required and none was prepared.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: April 19, 2024.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 648 as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.2, revise the definition of a recreational fishing vessel to read as follows:

§ 648.2 Definitions.

* * * * *

Recreational fishing vessel, means any vessel from which no fishing other than recreational fishing is conducted. Charter and party boats are considered recreational fishing vessels for purposes of minimum size, season, and possession limit requirements.

* * * * *

■ 3. In § 648.104, revise paragraph (b) to read as follows:

§ 648.104 Summer flounder size requirements.

* * * * *

(b) *Party/charter permitted vessels and recreational fishery participants.* The minimum size for summer flounder is 18.5 inches (46.99 cm) total length for all vessels that do not qualify for a summer flounder moratorium permit under § 648.4(a)(3), and charter boats holding a summer flounder moratorium permit if fishing with more than three crew members, or party boats holding a summer flounder moratorium permit if fishing with passengers for hire or carrying more than five crew members, unless otherwise specified in the conservation-equivalency regulations at § 648.107. If conservation equivalency is not in effect in any given year, possession of smaller (or larger, if applicable) summer flounder harvested from state waters is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.111 and abide by state regulations.

* * * * *

■ 4. In § 648.105, revise the introductory text to read as follows:

§ 648.105 Summer flounder recreational fishing season.

No person may fish for summer flounder in the EEZ from October 1 to May 7 unless that person is the owner or operator of a fishing vessel issued a commercial summer flounder moratorium permit, or is issued a summer flounder dealer permit, or unless otherwise specified in the conservation-equivalency measures at § 648.107. Persons aboard a commercial vessel that is not eligible for a summer flounder moratorium permit are subject to this recreational fishing season. This time period may be adjusted pursuant to the procedures in § 648.102. Possession of summer flounder harvested from state waters during this time is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.111 and abide by state regulations.

■ 5. In § 648.106, revise paragraph (a) to read as follows:

§ 648.106 Summer flounder possession restrictions.

(a) *Party/charter and recreational possession limits.* No person shall possess more than three summer flounder in, or harvested from, the EEZ, per trip unless that person is the owner or operator of a fishing vessel issued a summer flounder moratorium permit, or is issued a summer flounder dealer permit, or unless otherwise specified in the conservation-equivalency measures at § 648.107. Persons aboard a commercial vessel that is not eligible for a summer flounder moratorium permit are subject to this possession limit. The owner, operator, and crew of a charter or party boat issued a summer flounder moratorium permit are subject to the possession limit when carrying passengers for hire or when carrying more than five crew members for a party boat, or more than three crew members for a charter boat. This possession limit may be adjusted pursuant to the procedures in § 648.102. Possession of summer flounder harvested from state waters above this possession limit is allowed for state-only permitted vessels when transiting Federal waters within the Block Island Sound Transit Area provided they follow the provisions at § 648.111 and abide by state regulations.

* * * * *

■ 6. In § 648.107, revise paragraph (a) introductory text to read as follows:

§ 648.107 Conservation equivalent measures for the summer flounder fishery.

(a) The Regional Administrator has determined that the recreational fishing measures proposed to be implemented by the states of Maine through North Carolina for 2024 and 2025 are the conservation equivalent of the season, size limits, and possession limit prescribed in §§ 648.104(b), 648.105, and 648.106. This determination is based on a recommendation from the Summer Flounder Board of the Atlantic States Marine Fisheries Commission.

* * * * *

■ 7. In § 648.151, revise paragraph (a) introductory text to read as follows:

§ 648.151 Black sea bass conservation equivalency.

(a) The Regional Administrator has determined that the recreational fishing measures proposed to be implemented by the states of Maine through North Carolina for 2024 are the conservation

equivalent of the season, size limits, and possession limit prescribed in §§ 648.146, 648.147(b), and 648.145(a).

This determination is based on a recommendation from the Black Sea Bass Board of the Atlantic States Marine Fisheries Commission.

* * * * *

[FR Doc. 2024–08795 Filed 4–25–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 82
Friday, April 26, 2024

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1003; Project Identifier MCAI–2023–00712–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2023–11–01, which applies to certain Bombardier, Inc., Model BD–100–1A10 airplanes. AD 2023–11–01 requires a records check and replacement of affected left-hand (LH) direct current power center (DCPC) units. AD 2023–11–01 also provides optional terminating action for the records check and replacement. However, it has been determined that certain LH DCPC units require additional modification. This proposed AD would require checking maintenance records of certain airplanes, replacing certain DCPC units, and modifying certain DCPC units. This proposed AD would also expand the applicability of AD 2023–11–01. This proposed AD would also prohibit the installation of affected parts. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by June 10, 2024.

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–2024–1003; 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 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 NPRM, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, 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 relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2024–1003; Project Identifier MCAI–2023–00712–T'' 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 the 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 Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, 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

The FAA issued AD 2023–11–01, Amendment 39–22446 (88 FR 44042, July 11, 2023) (AD 2023–11–01), for certain Bombardier, Inc., Model BD–100–1A10 airplanes. AD 2023–11–01 was prompted by an MCAI originated by Transport Canada, which is the aviation authority for Canada. Transport Canada issued AD CF–2022–28, dated May 26, 2022 (Transport Canada AD CF–2022–28), to correct an unsafe condition.

AD 2023–11–01 requires a records check and replacement of affected LH DCPC units, and provides optional terminating action for those actions. The FAA issued AD 2023–11–01 to address erratic indications, which could cause the flightcrew to turn off fully operational electrical power sources, leading to partial or complete loss of electrical power. The unsafe condition, if not addressed, could result in loss of flight displays and reduced controllability of the airplane.

Actions Since AD 2023–11–01 Was Issued

The preamble to AD 2023–11–01 explains that the FAA considers the requirements ''interim action'' and was considering further rulemaking. The FAA has now determined that further rulemaking is indeed necessary, and this NPRM follows from that determination.

Transport Canada superseded AD CF–2022–28, dated May 26, 2022 (Transport Canada AD CF–2022–28), and issued Transport Canada AD CF–2023–35, dated May 26, 2023 (Transport Canada AD CF–2023–35) (referred to after this as the MCAI), to correct an unsafe condition on all Bombardier, Inc., Model BD–100–1A10 airplanes. The MCAI states that airplanes could experience misleading electrical system status indications (push button annunciators (PBA) and engine indicating and crew alerting system (EICAS)) as a result of contamination of electrical contacts in the LH DCPC internal communication data bus. These erratic indications could cause the flightcrew to turn off fully operational electrical power sources, leading to partial or complete loss of electrical power. Loss of electrical power could result in the loss of flight displays and reduced controllability of the airplane. The MCAI retains the requirement to verify the airplane records, requires removal of certain LH DCPC units for cleaning, and requires modification of certain LH DCPC units by adding a protective layer of tape to prevent the ingress of contaminants into the printed circuit board cage. The MCAI also prohibits installation of affected parts. The FAA is proposing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–1003.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Bombardier Service Bulletins 100–24–29 and 350–24–004, both Revision 01, both dated July 27, 2023. This service information specifies procedures for a records check to determine the total flight hours and replacement of affected LH DCPC units (part numbers 975GC02Y04, 975GC0Y05, 975GC02Y06, and 975GC02Y07). These documents are distinct since they apply to different airplane configurations.

The following documents specify procedures for removing LH DCPC units.

- Task 24–61–01–000–801, Removal of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation, Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, Revision 82, dated November 9, 2023. (For obtaining the task for the Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, use Document Identification No. CH 300 AMM.)
- Task 24–61–01–000–801, Removal of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation, Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, Revision 38, dated November 9, 2023. (For obtaining the task for the Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, use Document Identification No. CH 350 AMM.)

The following documents specify procedures for installing LH DCPC units.

- Task 24–61–01–400–801, Installation of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation, Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, Revision 82, dated November 9, 2023. (For obtaining the task for the Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, use Document Identification No. CH 300 AMM.)
- Task 24–61–01–400–801, Installation of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation, Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, Revision 38, dated November 9, 2023. (For obtaining the task for the Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, use Document Identification No. CH 350 AMM.)

The following documents specify procedures for testing LH DCPC units.

- Task 24–61–01–720–801, Functional Test of the DC Power Center (DCPC), Subject 24, 61–01, DC Power Center (DCPC), Adjustment/Test, Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, Revision 82, dated November 9, 2023. (For obtaining the task for the Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, use Document Identification No. CH 300 AMM.)
- Task 24–61–01–720–801, Functional Test of the DC Power Center (DCPC), Subject 24, 61–01, DC Power Center (DCPC), Adjustment/Test, Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, Revision 38, dated November 9, 2023. (For obtaining the task for the Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, use Document Identification No. CH 350 AMM.)

This proposed AD would also require the following service information, which the Director of the Federal Register approved for incorporation by reference as of August 15, 2023 (88 FR 44042, July 11, 2023).

- Bombardier Service Bulletin 100–24–29, dated April 9, 2021.
- Bombardier Service Bulletin 100–24–30, dated November 29, 2022.
- Bombardier Service Bulletin 350–24–004, dated April 9, 2021.
- Bombardier Service Bulletin 350–24–005, dated November 29, 2022.

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

FAA's Determination

This product has been approved by the aviation authority of another country, and is 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 referenced above. The FAA is issuing this NPRM after determining that 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 expand the applicability of AD 2023–11–01 and require the actions specified in the service information described previously, except as discussed under ''Differences Between this Proposed AD and the MCAI.''

Differences Between This Proposed AD and the MCAI

Although the MCAI only requires LH DCPC P/N 975GC02Y07 that have been cleaned or replaced to be modified to P/N 975GC02Y08, this proposed AD would also require that LH DCPC P/N 975GC02Y04, 975GC02Y05, and 975GC02Y06 that have been cleaned or replaced, as required by Transport

Canada AD CF–2022–28 (which corresponds to AD 2023–11–01), to be replaced with LH DCPC P/N 975GC02Y08.

Additionally, although the MCAI only requires the test of the DCPC logic and protections after modification of P/N 975GC02Y07 that have been cleaned or replaced, as required by Transport Canada AD CF–2022–28, to P/N 975GC02Y08, this proposed AD also requires the functional test of the LH DCPC unit.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 356 airplanes of U.S. registry.

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

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Records check	1 work-hours × $85 per hour = $85	$0	$85	$30,260
New proposed actions (modification)	2 work-hours × $85 per hour = $170	0	170	60,520

The FAA estimates the following costs to do any necessary on-condition actions that would be required based on the results of any required actions. The FAA has no way of determining the number of aircraft that might need this on-condition action:

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
7 work-hours × $85 per hour = $595	Up to $35,000	Up to $35,595.

According to the manufacturer, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage for affected individuals. As a result, the FAA has included all known costs in the cost estimate.

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 has 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) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

The 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:

■ a. Removing Airworthiness Directive (AD) 2023–11–01, Amendment 39–22446 (88 FR 44042, July 11, 2023); and

■ b. Adding the following new AD:

Bombardier, Inc.: Docket No. FAA–2024–1003; Project Identifier MCAI–2023–00712–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by June 10, 2024.

(b) Affected ADs

This AD replaces AD 2023–11–01, Amendment 39–22446 (88 FR 44042, July 11, 2023) (AD 2023–11–01).

(c) Applicability

This AD applies to all Bombardier, Inc., Model BD–100–1A10 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical Power.

(e) Unsafe Condition

This AD was prompted by multiple reports of erratic electrical system status on the push button annunciators (PBAs) and the engine instrument and crew alerting system (EICAS) while on-ground and during flight, and by the determination that certain direct current power center (DCPC) units require additional modification or replacement. The FAA is issuing this AD to address erratic indications, which could cause the flightcrew to turn off fully operational electrical power sources, leading to partial or complete loss of electrical power. The unsafe condition, if not addressed, could result in loss of flight displays and reduced controllability of the airplane.

(f) Compliance

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

(g) Records Check

For any left-hand (LH) DCPC unit having part number (P/N) 975GC02Y04, 975GC02Y05, 975GC02Y06, or 975GC02Y07 that was not cleaned before the effective date of this AD as specified in Safran Service Bulletin 975GC02Y–24–018 or replaced before the effective date of this AD as specified in Bombardier Service Bulletin 100–24–29 or Bombardier Service Bulletin 350–24–004: Within 60 days after the effective date of this AD, verify the total flight hours of the LH DCPC unit since the date of manufacture by doing a records check in accordance with paragraph 2.B.(1) of the Accomplishment Instructions of the applicable service bulletin identified in paragraphs (g)(1) and (2) of this AD.

(1) For airplanes having serial numbers 20001 through 20500 inclusive, use Bombardier Service Bulletin 100–24–29, dated April 9, 2021, or Revision 01, dated July 27, 2023. As of the effective date of this AD, use only Bombardier Service Bulletin 100–24–29, Revision 01, dated July 27, 2023.

(2) For airplanes having serial numbers 20501 through 20999 inclusive, use Bombardier Service Bulletin 350–24–004, dated April 9, 2021, or Revision 01, dated July 27, 2023. As of the effective date of this AD, use only Bombardier Service Bulletin 350–24–004, Revision 01, dated July 27, 2023.

(h) Replacement of the LH DCPC

If, during the records check required by paragraph (g) of this AD, the total flight hours since date of manufacture of the LH DCPC unit is equal to or more than 3,500 total flight hours as of the effective date of this AD, and the LH DCPC was not previously cleaned as specified in Safran Service Bulletin 957GC02Y–24–018, or replaced as specified in Bombardier Service Bulletin 100–24–29 or Bombardier Service Bulletin 350–24–004: Within 12 months after the effective date of this AD, remove, replace with LH DCPC P/N 975GC02Y08, test the DCPC logic and protection cards, and do the functional test for the LH DCPC unit, in accordance with the applicable service information specified in paragraphs (h)(1) through (8) of this AD. If any test fails, do corrective actions and repeat the test before further flight until the test passes.

(1) Task 24–61–01–000–801, Removal of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation, Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, Revision 82, dated November 9, 2023.

(2) Task 24–61–01–000–801, Removal of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation, Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, Revision 38, dated November 9, 2023.

(3) Task 24–61–01–400–801, Installation of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation, Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, Revision 82, dated November 9, 2023.

(4) Task 24–61–01–400–801, Installation of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation, Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, Revision 38, dated November 9, 2023.

(5) For airplanes having serial number 20001 through 20500 inclusive, use paragraph 2.D. of the Accomplishment Instructions of Bombardier Service Bulletin 100–24–30, dated November 29, 2022.

(6) For airplanes having serial number 20501 through 20999 inclusive, use paragraph 2.D. of the Accomplishment Instructions of Bombardier Service Bulletin 350–24–005, dated November 29, 2022.

(7) Task 24–61–01–720–801, Functional Test of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Adjustment/Test, Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, Revision 82, dated November 9, 2023.

(8) Task 24–61–01–720–801, Functional Test of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Adjustment/Test, Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, Revision 38, dated November 9, 2023.

(i) Exception to the Service Information

Although the note in paragraph 2.B.(4) of the Accomplishment Instructions of Bombardier Service Bulletin 100–24–29, dated April 9, 2021, and Revision 01, dated July 27, 2023, and Bombardier Service Bulletin 350–24–004, dated April 9, 2021, and Revision 01, dated July 27, 2023, specify that actions will reset ''the unit total flight hours to zero at date of incorporation,'' this AD does not include that requirement.

(j) Modification

For LH DCPC P/N 975GC02Y07 units that were cleaned before the effective date of this AD as specified in Safran Service Bulletin 975GC02Y–24–018, or replaced before the effective date of this AD as specified in Bombardier Service Bulletin 100–24–29 or Bombardier Service Bulletin 350–24–004: Within 12 months after the effective date of this AD, modify each LH DCPC P/N 975GC02Y07 into LH DCPC P/N 975GC02Y08, in accordance with paragraph 2.C. of the Accomplishment Instructions of the applicable service bulletin identified in paragraph (j)(1) or (2) of this AD. Before further flight after the modification, test the DCPC logic and protection cards in accordance with paragraph 2.D. of the Accomplishment Instructions of the applicable service bulletin identified in paragraph (j)(1) or (2) of this AD, and do the functional test for the LH DCPC unit, in accordance with the applicable service information specified in paragraphs (j)(3) or (4) of this AD. If any test fails, do corrective actions and repeat the test before further flight until the test passes.

(1) For airplanes having serial number 20001 through 20500 inclusive, use Bombardier Service Bulletin 100–24–30, dated November 29, 2022.

(2) For airplanes having serial number 20501 through 20999 inclusive, use Bombardier Service Bulletin 350–24–005, dated November 29, 2022.

(3) Task 24–61–01–720–801, Functional Test of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Adjustment/Test, Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two—Publication No. CH 300 AMM, Revision 82, dated November 9, 2023.

(4) Task 24–61–01–720–801, Functional Test of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Adjustment/Test, Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, Revision 38, dated November 9, 2023.

(k) Replacement of Certain LH DCPC P/N 975GC02Y04, 975GC02Y05, and 975GC02Y06

For LH DCPC P/N 975GC02Y04, 975GC02Y05, and 975GC02Y06 that were cleaned before the effective date of this AD as specified in Safran Service Bulletin 975GC02Y–24–018, or replaced before the effective date of this AD as specified in Bombardier Service Bulletin 100–24–29 or Bombardier Service Bulletin 350–24–004: Within 12 months after the effective date of this AD, remove, replace with LH DCPC P/N 975GC02Y08, test the DCPC logic and protection cards, and do the functional test for the LH DCPC unit, in accordance with the applicable service information specified in paragraphs (h)(1) through (8) of this AD. If any test fails, do corrective actions and repeat the test before further flight until the test passes.

(l) Parts Installation Prohibition

As of 60 days from the effective date of this AD, it is prohibited to install a LH DCPC with P/N 975GC02Y04, 975GC02Y05, 975GC02Y06, or 975GC02Y07, on any airplane.

(m) Additional AD Provisions

(1) *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 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (n)(2) of this AD. Information may be emailed to: *9-AVS-NYACO-COS@faa.gov.*

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or Bombardier, Inc.'s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(n) Additional Information

(1) Refer to Transport Canada AD CF–2023–35, dated May 26, 2023, for related information. This Transport Canada AD may be found in the AD docket at regulations.gov under Docket No. FAA–2024–1003.

(2) For more information about this AD, contact Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) 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 this AD specifies otherwise.

(3) The following service information was approved for IBR on [DATE 35 DAYS AFTER PUBLICATION OF THE FINAL RULE].

(i) Bombardier Service Bulletin 100–24–29, Revision 01, dated July 27, 2023.

(ii) Bombardier Service Bulletin 350–24–004, Revision 01, dated July 27, 2023.

(iii) Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two, Publication No. CH 300 AMM, Revision 82, dated November 9, 2023.

(A) Task 24–61–01–000–801, Removal of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation.

Note 1 to paragraph (o)(3)(iii)(A): For obtaining the tasks specified in paragraphs (o)(3)(iii)(A) through (C) of this AD for the Bombardier Challenger 300 Aircraft Maintenance Manual, Part Two, Publication No. CH 300 AMM, use Document Identification No. CH 300 AMM.

(B) Task 24–61–01–400–801, Installation of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation.

(C) Task 24–61–01–720–801, Functional Test of the DC Power Center (DCPC), Subject 24, 61–01, DC Power Center (DCPC), Adjustment/Test.

(iv) Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two, Publication No. CH 350 AMM, Revision 38, dated November 9, 2023.

(A) Task 24–61–01–000–801, Removal of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation.

Note 2 to paragraph (o)(3)(iv)(A): For obtaining the tasks specified in paragraphs (o)(3)(iv)(A) through (C) of this AD for the Bombardier Challenger 350 Aircraft Maintenance Manual, Part Two—Publication No. CH 350 AMM, use Document Identification No. CH 350 AMM.

(B) Task 24–61–01–400–801, Installation of the DC Power Center (DCPC), Subject 24–61–01, DC Power Center (DCPC), Removal/Installation.

(C) Task 24–61–01–720–801, Functional Test of the DC Power Center (DCPC), Subject 24, 61–01, DC Power Center (DCPC), Adjustment/Test.

(4) The following service information was approved for IBR on August 15, 2023 (88 FR 44042, July 11, 2023).

(i) Bombardier Service Bulletin 100–24–29, dated April 9, 2021.

(ii) Bombardier Service Bulletin 100–24–30, dated November 29, 2022.

(iii) Bombardier Service Bulletin 350–24–004, dated April 9, 2021.

(iv) Bombardier Service Bulletin 350–24–005, dated November 29, 2022.

(5) For service information identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

(6) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(7) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on April 15, 2024.

Victor Wicklund,

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

[FR Doc. 2024–08347 Filed 4–25–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 80

[Docket No. FDA–2022–N–1635]

RIN 0910–AI69

Color Additive Certification; Increase in Fees for Certification Services; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the proposed rule, ''Color Additive Certification; Increase in Fees for Certification Services,'' which published in the **Federal Register** of November 2, 2022. We are taking this action to add supporting information to the administrative record and to adjust the record to reflect the same cost and benefits figures that were published in the preliminary regulatory impact analysis. We are reopening the comment period for 30 days specifically to invite public comments on the new information being added to the administrative record.

DATES: FDA is reopening the comment period on the proposed rule ''Color Additive Certification; Increase in Fees for Certification Services,'' which published in the **Federal Register** on November 2, 2022 (87 FR 66116). Either electronic or written comments must be submitted by May 28, 2024.

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 May 28, 2024. 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–1635 for ''Color Additive Certification; Increase in Fees for Certification Services; Reopening of the

Comment Period.'' 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.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Bryan Bowes, Office of Cosmetics and Colors (HFS–105), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1122; or Carrol Bascus, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 2, 2022 (87 FR 66116), FDA published a proposed rule to amend the color additive regulations to increase the fee for certification services. The change in fees would allow FDA to continue to maintain an adequate color certification program as required by the Federal Food, Drug, and Cosmetic Act. The fees are intended to recover the full costs of operation of FDA's color certification program. We originally gave interested persons until January 3, 2023, to provide comments on the proposed rule. On January 24, 2023, in response to a stakeholder request, we reopened the comment period for an additional 45 days to allow interested parties more time to collect, analyze, and incorporate data and submit comments to the proposed rule.

Subsequently, we determined that additional supporting information should be included in the administrative record. Therefore, we are adding a Color Certification Fee Study (March 2024) to the administrative record that further explains the basis for the proposed rule. The fee study documents the need for increased fees and outlines the basis on which we developed the fee schedule in the proposed rule. We are adding the fee study to the administrative record and reopening the comment period for 30 days to provide the public an opportunity to comment on the document. Comments are invited, and will be considered, only to the extent they are focused on the information being newly added to the record.

Additionally, for transparency, we are adjusting the Preliminary Economic Analysis of Impacts, in Section V. B. Summary of Costs and Benefits (87 FR 66116 at 66118). The proposed rule did not include the same estimates that were published in the Preliminary Regulatory Impact Analysis (PRIA) listed in the reference section (87 FR 66116 at 66119). The PRIA, entitled ''Color Additive Certification; Increase in Fees for Certification Services'' Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, and available at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria* describes the estimates of the costs and benefits of the proposed rule.

Consistent with the published PRIA, Section V.B. Summary of Costs and Benefits should read as follows:

This proposed rule, if finalized, would amend existing color additive regulations by increasing fees for certification services. The fee schedule for color additive certification, as provided for in this proposed regulation, is designed to cover all the costs of operation of FDA's color certification program. This includes both the cost of specific tests required by the regulations and the general costs associated with the certification program, such as the costs of accounting, reviewing data, issuing certificates, conducting research, inspecting establishments, and purchasing and maintaining equipment. The fee for certification services of straight colors including lakes would increase from $0.35 per pound to $0.45 per pound, with the minimum fee increasing from $224 to $288. The fees for repacks of certified color additives and color additive mixtures would increase from $35 for 100 pounds or less to $45 for 100 pounds or less. The fee for repacks of certified color additives and color additive mixtures over 100 pounds, but not over 1,000 pounds would increase from $35 plus $0.06 for each pound over 100 pounds to $45 plus $0.08 for each pound over 100 pounds. The fee for repacks of certified color additives and color additive mixtures over 1,000 pounds would increase from $89 plus $0.02 for each pound over 1,000 pounds to $114 plus $0.03 for each pound over 1,000 pounds.

The economic burdens of this proposed rule, if finalized, would accrue to color additive manufacturers. We estimate a one-time cost to read and understand the rule for all color additive manufacturers. The present value of this cost is approximately $2,307 at a 3 percent rate of discount, and $2,221 at a 7 percent rate of discount. The annualized value of these costs estimates is approximately $270 at a 3 percent discount rate and $316 at a 7 percent discount rate. Because the value of these impacts is small relative to manufacturer revenues, we assume that the supply of color additives would not be affected by this proposed rule. Consequently, we estimate no other impacts associated with this proposed rule.

As noted in the preamble, the fees are intended to recover the full costs of operation of FDA's color certification program. Since 2005, the costs of the certification program significantly increased as a result of escalating staff payroll, rent and facility charges, as well as general operational expenses including purchasing and maintaining equipment. As the increase in fees is not associated with any change in the FDA certification program, no economic benefits are expected to result from the proposed rule. Similarly, the impact of

the increase in certification fees on color additive manufacturers is considered a transfer, rather than an economic cost. Accordingly, we do not estimate economic benefits associated with this proposed rule, and the impact of the increase in color certification fees is estimated as an ongoing transfer from manufacturers of color additives to the federal government. Our estimates are summarized in Table 1, below.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

[Millions of 2020 dollars over 10-year time horizon]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized					7		
Monetized $/year					3		
Annualized					7		
Quantified					3		
Qualitative							
Costs:							
Annualized	$0.00032			2020	7	10	
Monetized $/year	$0.00027			2020	3	10	
Annualized					7		
Quantified					3		
Qualitative							
Transfers:							
Federal	$2.46			2020	7	10	
Annualized	$2.46			2020	3	10	
Monetized $/year							
From/To	From: Manufacturers of color additives			To: Federal Government			
Other Annualized					7		
Monetized $/year					3		
From/To	From:			To:			

Effects:

State, Local or Tribal Government: No effect.

Small Business: The proposed rule, if finalized, would generate costs to small businesses, as well as transfers from small businesses to FDA that we treat as costs from the perspective of the small business. On average, these costs amount to approximately 0.2733% of annual average revenues of the small firms in the affected industry.

Wages: No effect.

Growth: No effect.

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08950 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. FDA–2024–F–1912]

Filing of Food Additive Petition From Environmental Defense Fund, Breast Cancer Prevention Partners, Center for Food Safety, Environmental Working Group, Tom Neltner, and Maricel Maffini; Request To Amend the Food Additive Regulations To Remove Authorization of Fluorinated Polyethylene

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a food additive petition, submitted by Environmental Defense Fund, et al., proposing that the food additive regulations be amended to remove fluorinated polyethylene.

DATES: The food additive petition was filed on April 17, 2024. Either electronic or written comments must be submitted by June 25, 2024.

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 June 25, 2024. 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–2024–F–1912 for ''Filing of Food Additive Petition from Environmental Defense Fund, et al.; Request to Amend the Food Additive Regulations to Remove Fluorinated Polyethylene.'' 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 comment only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Lillian Mawby, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301–796–4041.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 3B4837), submitted by Environmental Defense Fund, Breast Cancer Prevention Partners, Center for Food Safety, Environmental Working Group, Tom Neltner, and Maricel Maffini, c/o Maricel Maffini, Frederick, MD 21701. The petition proposes that we revoke § 177.1615 (21 CFR 177.1615, ''Polyethylene, fluorinated'').

II. Request To Repeal 21 CFR Part 177.1615

In accordance with the procedures for amending or repealing a food additive regulation in § 171.130 (21 CFR 171.130), the petition asks us to repeal § 177.1615. Specifically, the petitioners state that the fluorinated polyethylene manufactured consistent with § 177.1615 can produce polymeric per- and poly-fluorinated alkyl substances that can migrate to food and, therefore, are not safe pursuant to section 409(c)(5) of the FD&C Act (21 U.S.C. 348(c)(5)).

The petition is available in the docket. We invite comments, additional scientific data, and other information related to the issues raised by this petition. If we determine that the available data justifies repealing § 177.1615, we will publish our decision in the **Federal Register** in accordance with § 171.130.

The petitioners have claimed that this action is categorically excluded under 21 CFR 25.32(m), which applies to an action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics. In addition, the petitioners have stated that, to their knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09027 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R04–OAR–2021–0258; FRL–9562–01–R4]

South Carolina; Approval of State Plan for Control of Emissions From Commercial and Industrial Solid Waste Incineration Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the Clean Air Act (CAA or Act) section 111(d)/129 State plan submitted by the State of South Carolina, through the South Carolina Department of Health and Environmental Control (SCDHEC), on December 19, 2014, and supplemented on September 17, 2018, and June 19, 2019, and November 5, 2019, for implementing and enforcing the Emissions Guidelines (EG) applicable to existing Commercial and Industrial Solid Waste Incineration (CISWI) units. The State plan provides for implementation and enforcement of the EG, as finalized by the EPA on June 23, 2016, applicable to existing CISWI units for which construction commenced on or before June 4, 2010, or for which modification or reconstruction commenced after June 4, 2010, but no later than August 7, 2013; the State plan also incorporates the CISWI technical amendments finalized by the EPA on April 16, 2019. The State plan establishes emission limits, monitoring, operating, recordkeeping, and reporting requirements for affected CISWI units.

DATES: Comments must be received on or before May 28, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2021–0258 at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Mark Bloeth, Communities and Air Toxics Section, Air Analysis and Support Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303. Mr. Bloeth can be reached via telephone at (404) 562–9013 and via email at *bloeth.mark@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 129 of the Clean Air Act (CAA or the Act) directs the Administrator to establish performance standards and emission guidelines pursuant to section 111(d) of the Act limiting emissions of nine air pollutants (particulate matter, sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins/furans) from four categories of solid waste incineration units: municipal solid waste; hospital, medical, and infectious solid waste; commercial and industrial solid waste; and other solid waste.

Section 129(b)(2) of the CAA requires States to submit to the EPA for approval State plans and revisions that implement and enforce the EG—in this case, 40 CFR part 60, subpart DDDD. State plans and revisions must be at least as protective as the EG, and they become federally enforceable upon approval by the EPA. The procedures for adoption and submittal of State plans and revisions are codified in 40 CFR part 60, subpart B.

On December 1, 2000, the EPA promulgated new source performance standards (NSPS) and EG to reduce air pollution from CISWI units, which are codified at 40 CFR part 60, subparts CCCC and DDDD, respectively. *See* 65 FR 75338. The EPA revised the NSPS and EG for CISWI units on March 21, 2011. *See* 76 FR 15704. Following promulgation of the 2011 CISWI rule, the EPA received petitions for reconsideration requesting that the EPA reconsider numerous provisions in the rule. The EPA granted reconsideration on certain issues and promulgated a CISWI reconsideration rule on February 7, 2013. *See* 78 FR 9112 (February 7, 2013). Subsequently, EPA received petitions to further reconsider certain provisions of the 2013 NSPS and EG for CISWI units. On January 21, 2015, the EPA granted reconsideration on four specific issues, and it finalized reconsideration of the CISWI NSPS and EG on June 23, 2016. *See* 81 FR 40956. On April 16, 2019, the EPA finalized amendments to the NSPS and EG for CISWI units, which discussed clarifications and/or corrections regarding: (1) an alternative equivalent emission limit for mercury (Hg) for waste-burning kilns, (2) timing of initial test and initial performance evaluation, (3) extension of electronic data reporting requirement, (4) non-delegated authorities, (5) demonstrating initial and continuous compliance when using a continuous emissions monitoring system (CEMS), (6) continuous opacity monitoring requirements, (7) other CEMS requirements, (8) reduced testing requirements, (9) deviation reporting requirements for continuous monitoring data, and (10) clarification of air curtain incinerator requirements (ACI), as well as corrections to typographical errors. *See* 84 FR 15846.

II. Review of South Carolina's CISWI State Plan Submittal

South Carolina submitted a State plan to implement and enforce the EG for existing CISWI units in the State [1] on December 19, 2014, with a subsequent supplemental revision on September 17, 2018, an addendum on June 19, 2019, and a final updated State plan on November 5, 2019. The EPA has reviewed the State plan submittals for existing CISWI units in the context of the requirements of 40 CFR part 60, subparts B and DDDD. State plans must include the following nine essential elements: identification of legal authority; identification of mechanism for implementation; inventory of affected facilities; emissions inventory; emission limits; compliance schedules; testing, monitoring, recordkeeping, and reporting; public hearing records; and annual State progress reports on plan enforcement. For the reasons explained below, the EPA is proposing to approve South Carolina's CISWI State plan as consistent with those requirements.

In addition to the foregoing statutory and regulatory provisions, South Carolina's regulations also include, through incorporation by reference, 40 CFR part 60, subpart DDDD (as amended most recently at 84 FR 15846 (April 16, 2019), which includes the following Federal requirements: (1) Increments of Progress, (2) Waste Management Plan, (3) Operator Training and Qualification, (4) Emission Limitations and Operating Limits, (5) Performance Testing, (6) Initial Compliance Requirements, (7) Continuous Compliance Requirements, (8) Monitoring, (9) Recordkeeping and Reporting, (10) Title V Operating Permits, (11) Air Curtain Incinerators, (12) Definitions, (13) a modified Table 1 to include the final compliance date of February 7, 2018, and (14) Tables 2 through 9 of 40 CFR part 60, subpart DDDD.

A. Identification of Legal Authority

Under 40 CFR 60.26 and 60.2515(a)(9), an approvable State plan must demonstrate that the State has legal authority to adopt and implement the EG's emission standards and compliance schedule. In its submittals, South Carolina cites the following State law provisions for its authority to implement and enforce the State plan via its air quality program: South Carolina Code Section 48–1, Chapter 1 of the Pollution Control Act, South Carolina Department of Health and Environmental Control, Chapter 61, Statutory Authority: 1976 Code Section 48–1–10 through Section 48–1–350.; SCDHEC Regulation 61–62.60, Subpart DDDD, State effective on August 23, 2019. The EPA has reviewed the cited authorities and proposes to find that the State has adequately demonstrated legal authority to implement and enforce the CISWI State plan in South Carolina.

B. Identification of Enforceable State Mechanisms for Implementing the Plan

Under 40 CFR 60.24(a), a State plan must include emission standards, defined at 40 CFR 60.21(f) as ''a legally enforceable regulation setting forth an allowable rate of emissions into the atmosphere, or prescribing equipment specifications for control of air pollution emissions.'' *See also* 40 CFR 60.2515(a)(8). South Carolina has adopted enforceable emission standards for affected CISWI units by incorporating by reference 40 CFR part 60, subpart DDDD (as amended most recently at 84 FR 15846), at SCDHEC's Regulation 61–62.60, Subpart DDDD—Performance Standards and Compliance

[1] The submitted State plan does not apply in Indian country located in the State.

Times for Existing Commercial and Industrial Solid Waste Incineration Units, as described in South Carolina State Register Vol. 43, Issue 8 (August 23, 2019). The EPA proposes to find that South Carolina's Regulation 61–62.60, Subpart DDDD, meets the emission standards requirement under 40 CFR 60.24(a).

C. Inventory of Affected Units

Under 40 CFR 60.25(a) and 60.2515(a)(1), a State plan must include a complete source inventory of all CISWI units. South Carolina has identified affected units at six facilities: Argos (kiln), DAK Americas (fluidized bed incinerator), Ulmer Brothers, Inc. (air curtain incinerator), Coastal Debris (air curtain incinerator), Advanced Machining & Fabrication, Inc. (air curtain incinerator), and Tri-County Pallet (air curtain incinerator). Omission from this inventory of CISWI units does not exempt an affected facility from the applicable section 111(d)/129 requirements. The EPA proposes to find that South Carolina has met the affected unit inventory requirements under 40 CFR 60.25(a) and 60.2515(a)(1).

D. Inventory of Emissions From Affected CISWI Units

Under 40 CFR 60.25(a) and 60.2515(a)(2), a State plan must include an emissions inventory of the pollutants regulated by the EG. Emissions from CISWI units may contain cadmium, carbon monoxide, dioxins/furans, hydrogen chloride, lead, mercury, nitrogen oxides, particulate matter, and sulfur dioxide. South Carolina submitted an emissions inventory for CISWI units as part of its State plan. This emissions inventory contains CISWI unit emissions rates for each regulated pollutant. Therefore, the EPA proposes to find that South Carolina has met the emissions inventory requirements of 40 CFR 60.25(a) and 60.2515(a)(2).

E. Emission Limitations, Operator Training and Qualification, Waste Management Plan, and Operating Limits for CISWI Units

Under 40 CFR 60.24(c) and 60.2515(a)(4), the State plan must include emission standards that are no less stringent than the EG. 40 CFR 60.2515(a)(4) also requires operator training and qualification requirements, a waste management plan, and operating limits. At its Regulation 61–62.60 Subpart DDDD, South Carolina has incorporated by reference the EG's emission standards, operator training and qualification requirements, waste management plan, and operating limits for CISWI units. Therefore, the EPA proposes to find that South Carolina's State plan satisfies the requirements of 40 CFR 60.24(c) and 60.2515(a)(4).

F. Compliance Schedules

Under 40 CFR 60.24(a), (c), and (e) and 40 CFR 60.2515(a)(3), each State plan must include a compliance schedule, which requires affected CISWI units to expeditiously comply with the State plan requirements. In the State plan at Regulation 61–62.60 Subpart DDDD, South Carolina requires that affected sources comply with the EG initial compliance requirements for CISWI units, which the EPA has codified at 40 CFR 60.2700 through 40 CFR 60.2706. Therefore, EPA proposes to find that South Carolina's State plan satisfies the requirements of 40 CFR 60.24(a), (c), and (e) and 40 CFR 60.2515(a)(3).

G. Testing, Monitoring, Recordkeeping, and Reporting Requirements

Under 40 CFR 60.24(b)(2), 60.25(b), and 60.2515(a)(5), an approvable State plan must require that sources conduct testing, monitoring, recordkeeping, and reporting. South Carolina's State plan incorporates by reference the model rule provisions of the EG at Regulation 61–62.60 Subpart DDDD, including performance testing provisions at 40 CFR 60.2690 through 60.2695, monitoring provisions at 40 CFR 60.2730 through 60.2735, and recordkeeping and reporting provisions at 40 CFR 60.2740 through 60.2800. Additionally, all reports required under 40 CFR 60.2795(a), (b)(1), and (b)(2) must be submitted to SCDHEC as well as to the EPA. Therefore, the EPA proposes to find that South Carolina's State plan satisfies the requirements of 40 CFR 60.24(b)(2), 60.25(b), and 60.2515(a)(5).

H. A Record of Public Hearing on the State Plan Revision

Requirements at 40 CFR 60.23 sets forth the public participation requirements for each State plan. The State must conduct a public hearing; make all relevant plan materials available to the public prior to the hearing; and provide notice of such hearing to the public, the Administrator of the EPA, each local air pollution control agency, and, in the case of an interstate region, each State within the region. Under 40 CFR 60.2515(a)(6) requires each State plan include certification that the hearing was held, a list of witnesses and their organizational affiliations, if any, appearing at the hearing, and a brief written summary of each presentation or written submission.

In its submittal, South Carolina submitted records, including transcripts, of three public hearings. A public hearing was held on November 24, 2014, for the original December 19, 2014, State plan submittal. South Carolina held a second hearing on May 30, 2018, for the September 17, 2018, supplemental State plan submission which addressed the EPA's June 23, 2016, CISWI amendments and reconsideration. *See* 81 FR 40956 (June 23, 2016). South Carolina held a third public hearing on October 29, 2019, for the November 5, 2019, final supplement to the SCDHEC State plan submittal. South Carolina provided notice and made all relevant plan materials available prior to each hearing. Additionally, South Carolina certifies in each of its State plan submittals that hearings were held, and that the State received no written or oral comments on the plan. Therefore, the EPA proposes to find that South Carolina's CISWI plan satisfies the requirements of 40 CFR 60.23 and 60.2515(a)(6).

I. Annual State Progress Reports to EPA

Under 40 CFR 60.25(e) and (f) and 40 CFR 60.2515(a)(7), the State must provide in its State plan for annual reports to EPA on progress in enforcement of the plan. Accordingly, South Carolina provides in its plan that it will submit reports on progress in plan enforcement to the EPA on an annual (calendar year) basis, commencing with the first full reporting period after plan revision approval. The EPA proposes to find that South Carolina's CISWI plan satisfies the requirements of 40 CFR 60.25(e) and (f) and 40 CFR 60.2515(a)(7).

III. Incorporation by Reference

In this action, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference South Carolina Regulation 61–62.60, Subpart DDDD, State effective August 23, 2019, which includes provisions regarding applicability, emission limits, operating, testing, monitoring, recordkeeping, reporting, compliance schedules, and all other relevant requirements contained in EPA's emission guidelines for existing CISWI units and further described in Section II of this preamble. The EPA has made, and will continue to make these materials generally available through *http://www.regulations.gov,* Docket ID No. EPA–R04–OAR–2021–0258, and at

the EPA Region 4 Office (please contact the person identified in the ''For Further Information Contact'' section of this preamble for more information).

IV. Proposed Action

Pursuant to CAA section 111(d), CAA section 129, and 40 CFR part 60, subparts B and DDDD, the EPA is proposing to approve South Carolina's State plan for regulation of CISWI units as submitted on December 19, 2014, with a subsequent supplemental revision submitted on September 17, 2018, an addendum submitted on June 19, 2019, and a final updated State plan submitted on November 5, 2019. In addition, the EPA is proposing to amend 40 CFR part 62, subpart B to reflect this action.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a 111(d)/129 plan submission that complies with the provisions of the CAA and applicable Federal regulations. In reviewing 111(d)/129 plan submissions, the EPA's role is to approve State choices, provided they meet the criteria and objectives of the CAA and the EPA's implementing regulations. 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 proposed 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 (Public Law 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); and
- 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.

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

The EPA believes that the human health and environmental conditions that exist prior to this action result in, or have the potential to result in, disproportionate and adverse human health or environmental effects on people of color, low-income populations, and/or Indigenous peoples. Certain areas of the State include communities that are pollution-burdened and underserved according to demographic data. EPA performed a screening-level analysis using EPA's EJSCREEN to identify environmental burdens and susceptible populations in communities surrounding CISWI units in the State. The results of the demographic analysis are presented in the *EJ Screening Report for South Carolina CISWI Units,* a copy of which is available in the docket for this action, Docket ID No. EPA–R04–EPA–2021–0258.

The EPA believes that this action is not likely to change existing disproportionate and adverse effects on people of color, low-income populations, and/or Indigenous peoples because the State plan implements national standards in the CISWI EG that would result in reductions in emissions of a wide array of air pollutants released due to the incineration of solid waste at commercial and industrial facilities. Some such pollutants exist in the waste feed material and are released unchanged during combustion, and some are generated as a result of the combustion process itself. These pollutants include particulate matter, sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins/furans . These pollutants are associated with certain negative health effects; for example, SO_2 and NO_X are precursors for the formation of $PM_{2.5}$, which is associated with health effects such as premature mortality for adults and infants, cardiovascular morbidity such as heart attacks, and respiratory morbidity such as asthma attacks, acute bronchitis, and other respiratory symptoms. Reducing these emissions will decrease the amount of such pollutants to which all affected populations are exposed. The EPA has determined that this action increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or income or environmental effects on any population, including any minority, low-income, or Indigenous populations. To the extent that any minority, low-income, or Indigenous subpopulation is disproportionately impacted by emissions of any of the pollutants identified above due to the proximity of their homes to sources of these emissions, that subpopulation also stands to see increased environmental and health benefits from the emission reductions called for by this action.

In addition, this proposed approval of South Carolina's State plan for CISWI units does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the EPA is not proposing to approve the submitted plan to apply in Indian country located in the State, and because the submitted plan will not impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects in 40 CFR Part 62

Administrative practice and procedure, Air pollution control, Aluminum, Environmental protection, Fertilizers, Fluoride, Incorporation by reference, Industrial facilities, Intergovernmental relations, Methane, Ozone, Phosphate, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds, Waste treatment and disposal.

Authority: 42 U.S.C. 7411.

Dated: April 19, 2024.

Jeaneanne M. Gettle,

Acting Regional Administrator Region 4.

[FR Doc. 2024–08930 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 89, No. 82
Friday, April 26, 2024

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

[OMB Control No. 0412–0609]

Information Collection; Improving Customer Experience (OMB Circular A–11, Section 280 Implementation)

AGENCY: U.S. Agency for International Development

ACTION: Notice; request for comment.

SUMMARY: The U.S. Agency for International Development (USAID) as part of its continuing effort to reduce paperwork and respondent burden, is announcing an opportunity for public comment on a new proposed collection of 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, and to allow 30 days for public comment in response to the notice. This notice solicits comments on a renewal collection proposed by the Agency.

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: Submit comments identified by Information Collection 0412–0609, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation), by any of the following methods:

- *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.
- *E-Mail:* ATTN: Allana Welch/IC 0412–0609, A–11 Section 280 Improving Customer Experience, *alwelch@usaid.gov*

Instructions: Please submit comments only and cite Information Collection 0412–0609, Improving Customer Experience (OMB Circular A–11, Section 280 Implementation), in all correspondence related to this collection. To confirm receipt of your comment(s), please check *regulations.gov,* approximately two to three business days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

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.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Allana Welch via email to *alwelch@usaid.gov* or by phone to 202–712–4264.

SUPPLEMENTARY INFORMATION:

A. Purpose

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. ''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 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. USAID published a 60-day notice for this proposed information collection on February 21, 2024 (89 FR 13033). OMB regulations also require Federal Agencies to submit a notice to the **Federal Register** informing the public of its intent to seek OMB approval for an information collection. 5 CFR 1320.10(a). To comply with this requirement, USAIDis publishing notice of the proposed collection of information set forth in this document.

Whether seeking a loan, Social Security benefits, veteran's benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector.

A modern, streamlined and responsive customer experience means: raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. USAID will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on performance.gov to help build transparency and accountability of

Federal programs to the customers they serve.

Method of Collection

USAID will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. USAID may also utilize observational techniques to collect this information.

Data

Form Number(s): None.
Type of Review: Renewal.

B. Annual Reporting Burden

Affected Public: Collections will be targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future. For the purposes of this request, ''customers'' are individuals, businesses, and organizations that interact with a Federal Government agency or program, either directly or via a Federal contractor. This could include individuals or households; businesses or other for-profit organizations; not-for-profit institutions; State, local or tribal governments; Federal government; and Universities.

Estimated Number of Respondents: 1,000,775.

Estimated Time per Response: Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 1.5 hours to participate in an interview.

Estimated Total Annual Burden Hours: 50,563.

Estimated Total Annual Cost to Public: $0.

C. Public Comments

USAID invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 24, 2024.

Allana Welch,

Senior Advisor & Digital Strategy Lead, USAID IPI/ITR/T.

[FR Doc. 2024–09163 Filed 4–25–24; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–TM–24–0001]

Notice of Availability of the Final Programmatic Environmental Assessment and Finding of No Significant Impact for AMS Resilient Food Systems Infrastructure Program

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Agricultural Marketing Service (AMS) announces the availability of the Final Programmatic Environmental Assessment (PEA) and Finding of No Significant Impact (FONSI) for the Resilient Food Systems Infrastructure (RFSI) Program.

FOR FURTHER INFORMATION CONTACT: Lara Shockey, Natural Resource Specialist, Transportation and Marketing Program; Telephone: (304) 373–5875; Email: *lara.s.shockey@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

The final PEA and FONSI analyze and disclose the potential environmental impacts associated with the establishment of the Resilient Food Systems Infrastructure (RFSI) Program. The United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) has proposed to fund cooperative agreements to coordinate initiatives for non-meat and poultry food products in the middle of the supply chain. Funds will support expanded capacity for the aggregation, processing, manufacturing, storing, transporting, wholesaling, and distribution of locally and regionally produced food products, including specialty crops, dairy, grains for human consumption, aquaculture, and other food products, excluding meat and poultry.

States will make subawards to support local and regional food and farm businesses and other entities. States will also provide supply chain and market development services. Through these efforts, the RFSI program aims to enhance market access for small and mid-size producers and food businesses, contributing to a more resilient and sustainable food system.

The RFSI Program is authorized by section 1001 (b)(4) of the American Rescue Plan Act (ARPA) (Pub. L. 117–2), which funds ''loans and grants and other assistance to maintain and improve food and agricultural supply chain resiliency''. Recipients of funding from this proposed program would be allowed 48 months to complete work funded by the awards.

The environmental impacts of funding projects to expand capacity for the aggregation, processing, manufacturing, storing, transporting, wholesaling, and distribution of locally and regionally produced, non-meat and poultry food products and provide supply chain and market development services have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA) of 1969, Public Law 91–190, 42 U.S.C. 4321–4347, as amended.

A final PEA and FONSI have been prepared, and based on this analysis, AMS has determined there will not be a significant impact to the human environment. As a result, an Environmental Impact Statement (EIS) has not been initiated (40 CFR 1501.6). AMS intends for this PEA to create efficiencies by establishing a framework that can be used for ''tiering,'' where appropriate, to project-specific actions that require additional analysis. As decisions on specific applications are made, to the extent additional NEPA analysis is required, environmental review will be conducted to supplement the analysis set forth in this PEA.

The final PEA and FONSI are available for review online at the program website: *https://www.ams.usda.gov/services/grants/rfsi.*

Comments

AMS published a Draft PEA for public comment on February 12, 2024. The public comment period ended on March 13, 2024. No comments were received during the public comment period.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2024–08971 Filed 4–25–24; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2024–0021]

National Wildlife Services Advisory Committee: Intent To Reestablish

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of intent to reestablish the National Wildlife Services Advisory Committee.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. 10) notice is hereby given that the Secretary of Agriculture (Secretary) intends to reestablish the National Wildlife Services Advisory Committee (the ''Committee'') for a 2-year period. The Secretary has determined that the Committee is necessary and in the public interest.

DATES: Once approved by the Secretary, the charter will be valid on the date of filing by the U.S. Department of Agriculture Committee Management Officer and once the filing requirements are met.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Joyce, Designated Federal Officer, Wildlife Services, APHIS, 4700 River Road, Unit 87, Riverdale, MD 20737; (301) 851–3999; *carrie.e.joyce@usda.gov*.

SUPPLEMENTARY INFORMATION: The purpose of the National Wildlife Services Advisory Committee (the Committee) is to advise the Secretary of Agriculture on policies, program issues, and research needed to conduct the Wildlife Services program. The Committee also serves as a public forum enabling those affected by the Wildlife Services program to have a voice in the program's policies. The duration of the NWSAC is for 2 years unless renewed by the Secretary, USDA.

U.S. Department of Agriculture (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.

Persons with disabilities who require alternative means of communication for program information (*e.g.*, Braille, large print, audiotape, American Sign Language, etc.) should contact the responsible Agency or USDA's TARGET Center at (202) 720–2600 (voice and TTY) or contact USDA through the Federal Relay Service at (800) 877–8339. Additionally, program information may be made available in languages other than English. Equal opportunity practices in accordance with USDA's policies will be followed in all appointments to the Committee. To ensure that the recommendations of the Committee have taken in account the needs of the diverse groups served by USDA, membership shall include to the extent possible, individuals with demonstrated ability to represent minorities, women and person with disabilities. USDA is an equal opportunity provider, employer, and lender.

Dated: April 18, 2024.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2024–08919 Filed 4–25–24; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Tongass National Forest; Alaska; Assessment Phase of Revision of the Land Management Plan for the Tongass National Forest

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to initiate the assessment phase of the Land Management Plan revision for the Tongass National Forest.

SUMMARY: The Forest Service, U.S. Department of Agriculture, is initiating the assessment phase of the Land Management Plan revision process for the Tongass National Forest, located in Southeast Alaska. The assessment supports the subsequent planning phase, which will result in a revised land management plan to guide resource management activities on the Tongass National Forest. The assessment will identify and consider relevant and readily accessible material about ecological, social, and economic conditions and trends in the planning area, and will identify best available scientific information including Native or Indigenous knowledge. Trends and conditions identified in the assessment will inform the need to change the existing plan as well as the subsequent revision process.

DATES: The public will be invited to engage and participate in the assessment phase of the revision process beginning in the spring of 2024 through winter of 2025. Engagement opportunities are posted on the Tongass National Forest Plan Revision website: *https://www.fs.usda.gov/detail/tongass/landmanagement/planning/?cid=fseprd1105492.* A draft assessment, which will reflect input received, is anticipated to be available for review and comment, in January 2025.

ADDRESSES: For questions about Land Management Plan revision or comments on initiating the assessment phase of plan revision, please address mail to: Tongass National Forest Supervisor's Office, Attn: Erin Mathews—Tongass Plan Revision Coordinator, 648 Mission Street, Suite 110, Ketchikan, AK 99901–6591, or via email to *SM.FS.TNFRevision@usda.gov.* All correspondence, including names and addresses, will be part of the public record. More information on the planning process can also be found on the Tongass Plan Revision website at *https://www.fs.usda.gov/detail/tongass/landmanagement/planning/?cid=fseprd1105492.*

FOR FURTHER INFORMATION CONTACT: Erin Mathews, Plan Revision Coordinator, at *erin.eathews@usda.gov* or by phone at 907–419–8347. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

Information will be shared through electronic mailing lists, social media, and media outlets. If members of the public are interested in learning more, please visit the website listed above and select the link to subscribe to updates on the Tongass Plan Revision. The public can also sign up to receive regular updates by sending an email to *SM.FS.TNFRevision@usda.gov.*

SUPPLEMENTARY INFORMATION: The 2012 Planning Rule (36 CFR 219), which implements the National Forest Management Act (NFMA) of 1976, provides that the Forest Service develop, maintain and revise land management plans, often called a Forest Plan, for all national forests and grasslands. Land Management Plans provide a programmatic framework for management of forest resources and are amended as conditions change over time. The Tongass Land Management Plan was first approved in 1979, revised in 1997, and later amended in 2003, 2008, 2016, and 2020. The 2016 Land Management Plan amends the 2008 Tongass Land and Resource

Management Plan (2008 Forest Plan), incorporating changes made since 2008.

This notice announces initiates the assessment phase of the plan revision process, during which the Agency will identify and evaluate current information regarding the Tongass National Forest from the public, Tribes, Alaska Native Corporations, other government agencies, and non-governmental parties, 36 CFR 219.5(a)(1), 219.6, 219.19. The Tongass National Forest has initiated consultation with Tribes and Alaska Native Corporations for all phases of the planning process and will consult as part of the assessment phase of revision, 36 CFR 219.4. The Forest Service, Alaska Region, will build on the engagement efforts and the relationships developed as part of the Southeast Alaska Sustainability Strategy to ensure that a broad range of local voices contribute to the assessment and throughout the planning process. Information collected during the formation of the Sustainability Strategy will be utilized in the assessment where appropriate.

The 2012 Planning Rule requires the assessment to include information regarding the status and trends of ecological, social, and economic conditions within the planning area and across the broader landscape. In particular, the Agency must identify and evaluate information relevant to the plan area for the following: (1) Terrestrial ecosystems, aquatic ecosystems, and watersheds; (2) Air, soil, and water resources and quality; (3) System drivers, including dominant ecological processes, disturbance regimes, and stressors, such as natural succession, wildland fire, invasive species, and climate change, and the ability of terrestrial and aquatic ecosystems in the plan area to adapt to change; (4) Baseline assessment of carbon stocks; (5) Threatened, endangered, proposed, and candidate species, and potential species of conservation concern present in the plan area; (6) Social, cultural, and economic conditions; (7) Benefits people obtain from the National Forest System planning area (ecosystem services); (8) Multiple uses and their contributions to local, regional, and national economies; (9) Recreation settings, opportunities and access, and scenic character; (10); Renewable and nonrenewable energy and mineral resources; (11) Infrastructure, such as recreational facilities and transportation and utility corridors; (12) Areas of tribal importance; (13) Cultural and historic resources and uses; (14) Land status and ownership and access patterns; and (15) Existing designated areas located in the plan area including wilderness and wild and scenic rivers and potential need and opportunity for additional designated areas. (36 CFR 219.6.)

During this assessment phase, the Forest Service invites other government agencies, Tribes, Alaska Native Corporations, non-governmental parties, and the public to share information about social, economic, and environmental conditions of the Tongass National Forest and the broader landscape. Existing information about conditions on the Tongass National Forest, including information gathered through public engagement and tribal consultation, will be integrated into a draft resource assessment.

At 16.7 million acres, the Tongass National Forest is integral to social, ecological, economic and cultural values in Southeast Alaska. The Tongass is of immense cultural significance for Alaska Native peoples, and is within the traditional homelands of the Tlingit, Haida and Tsimshian peoples. It plays an important role in economic opportunity and social well-being for people and communities in Southeast Alaska. It also represents the largest intact coastal temperate rainforest on earth and is considered critical for carbon sequestration and carbon storage to help mitigate climate change. During this assessment phase, the Forest Service invites input on these and other distinctive roles and contributions of the Tongass to the local area, region, and nation (36 CFR 219.2(b)).

The Forest Service will review and incorporate public comments and additional information from tribal consultation on the draft assessment and produce a final assessment that will inform the Agency's understanding of the need to change the plan for the Tongass National Forest. The Forest Service may then initiate the planning phase, which will include development of an environmental impact statement, pursuant to the National Environmental Policy Act (NEPA).

Responsible Official: The responsible official for the revision of the land management plan for the Tongass National Forest is Frank Sherman, Forest Supervisor.

Dated: April 22, 2024.

Troy Heithecker,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–08957 Filed 4–25–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Kootenai National Forest; Montana; Kootenai National Forest Over-Snow Motorized Use Travel Plan

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service (Forest Service), United States Department of Agriculture, will prepare an environmental impact statement (EIS) to inform a decision about the designation of trails and areas of the Kootenai National Forest which would be open to motorized over-snow use. The environmental impact statement will also inform a decision about the classes of vehicles and times of year for which motorized over-snow use will be allowed on designated trails and areas. Trails and areas designated for motorized over-snow vehicle use will be identified on an Over-Snow Vehicle Use Map which will specify the classes of vehicles and the time of year for which use is designated on the Kootenai National Forest.

DATES: The draft environmental impact statement is expected early in 2025, with a 45-day public comment period immediately following publication of this project's Notice of Availability of Draft Environmental Impact Statement in the **Federal Register**. The final environmental impact statement is expected by summer of 2025.

FOR FURTHER INFORMATION CONTACT: Kootenai National Forest, *SM.FS.knfcontactus@usda.gov,* 406–283–7740, or Stephani Rust, *stephani.rust@usda.gov.* Individuals may also visit the project's web page at *https://www.fs.usda.gov/project/kootenai/?project=64358.* Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service at 800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

Pursuant to the Travel Management Rule at 36 CFR 212 subpart C, the Forest Service must designate trails and areas to be open for motorized over-snow vehicle use. Once designated, trails and areas open to motorized over-snow vehicle use need to be identified on an Over-Snow Vehicle Use Map (36 CFR 212.81). Over-Snow Vehicle Use Maps must specify the classes of vehicles and the time of year for which use is

designated (36 CFR 212.81(c)). The public shall be allowed to participate in the designation of National Forest System roads, trails, and areas, consistent with the National Environmental Policy Act (36 CFR 212.52).

On the 2.2-million-acre Kootenai National Forest, there is a need to designate trails and areas which would be open to motorized over-snow vehicle use. There is also a need to designate trails and areas open to motorized over-snow vehicle use within the Ten Lakes Wilderness Study Area of the Kootenai National Forest.

Proposed Action

The Forest Service proposes to designate approximately 1,302,000 acres of the Kootenai National Forest, including the Ten Lakes Wilderness Study Area, as areas open to cross-country motorized over-snow vehicle use. Approximately 987,000 acres are proposed as areas open for all classes of cross-country motorized over-snow travel from December 1 to May 31 each year. Approximately 315,000 acres are proposed as areas open for all classes of cross-country motorized over-snow travel from December 1 to March 31 and would be closed to motorized over-snow vehicle use on March 31 each year to accommodate grizzly bear den emergence. Areas designated for over-snow vehicle use would be identified on an Over-Snow Vehicle Use Map, in accordance with 36 CFR 212.81. Over-Snow Vehicle Use Maps would specify the classes of vehicles and the time of year for which use is designated (36 CFR 212.81(c)).

Additionally, the Forest Service proposes to designate approximately 380 miles of trails in the Kootenai National Forest, including in the Ten Lakes Wilderness Study Area, as open to motorized over-snow vehicle use. Approximately 285 miles of groomed over-snow trails and approximately 49 miles of ungroomed over-snow trails are proposed to be open to any over-snow vehicle class between December 1 and March 31 each year. Approximately 16 miles of groomed over-snow trails and 30 miles of ungroomed over-snow trails are proposed to be open to any over-snow vehicle class between December 1 and March 31 each year. Trails designated for over-snow vehicle use would be identified with the publication of an Over-Snow Vehicle Use Map, in accordance with 36 CFR 212.81.

An amendment to the Kootenai National Forest 2015 Land Management Plan may be considered to modify the boundaries of management area 5a (Backcountry-Non-motorized Year-round).

Expected Impacts

The minimization criteria were applied to the identification of the National Forest System areas and trails. Impacts to wolverine, grizzly bear, Canada lynx, and whitebark pine will be assessed in a biological assessment, and consultation with U.S. Fish and Wildlife Service is expected to occur. An amendment to the Kootenai National Forest 2015 Land Management Plan may be considered to modify the boundaries of management area 5a (Backcountry-Non-motorized Year-round) as it currently is mapped in the 2015 Land Management Plan. The following substantive requirements are likely to apply (219.13(b)(2)) to the potential amendment: 36 CFR 219.8(b) to guide the plan area's contribution to social and economic sustainability, taking into account: (1) social, cultural, and economic conditions relevant to the area influenced by the plan; (2) sustainable recreation; (3) multiple uses that contribute to local, regional, and national economies in a sustainable manner; and 36 CFR 219.9(a)(2) the plan must include plan components that maintain or restore the diversity of ecosystems and habitat types throughout the plan area.

Responsible Official

Kootenai National Forest Supervisor.

Scoping Comments and the Objection Process

Public scoping of this project occurred in April 2015 and July through September 2023; those scoping efforts have informed this proposed action. Public scoping will not be repeated; however, additional opportunities for public comment will be provided when the Draft EIS is available.

Any decision about this project may be subject to 36 CFR 218 and/or 36 CFR 219 pre-decisional review (objection). Unless received anonymously, public comments received during the scoping period from July 13, 2023 through September 29, 2023 or other designated opportunities for public comment may establish eligibility for participation in pre-decisional administrative review. Issues raised in an objection must be based on previously submitted comments, unless based on new information arising after designated opportunities.

Nature of Decision To Be Made

The decision will determine the designation of trails and areas of the Kootenai National Forest which will be open to motorized over-snow use, as well as determining the classes of vehicles and times of year for which motorized over-snow use will be allowed on designated trails and areas.

Substantive Provisions

An amendment to the Kootenai National Forest 2015 Land Management Plan may be considered to modify the boundaries of management area 5a (Backcountry-Non-motorized Year-round) as it currently is mapped in the 2015 Land Management Plan. The following substantive requirements are likely to apply (219.13(b)(2)) to the potential amendment: 36 CFR 219.8(b) to guide the plan area's contribution to social and economic sustainability, taking into account: (1) social, cultural, and economic conditions relevant to the area influenced by the plan; (2) sustainable recreation; (3) multiple uses that contribute to local, regional, and national economies in a sustainable manner; and 36 CFR 219.9(a)(2) the plan must include plan components that maintain or restore the diversity of ecosystems and habitat types throughout the plan area.

Dated: April 22, 2024.

Troy Heithecker,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–08951 Filed 4–25–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Nez Perce-Clearwater National Forests; Idaho; End of the World Project

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service (''Forest Service''), United States Department of Agriculture, is giving notice of its intent to prepare an environmental impact statement (EIS) for the End of the World Project on the Salmon River Ranger District of the Nez Perce-Clearwater National Forests in Idaho. The Forest received an unpublished order in Friends of the Clearwater v. Cheryl F. Probert. The court ordered the environmental assessment (EA), decision notice (DN), and finding of no significant impact (FONSI) for the End of the World project to be remanded to the United States Forest Service for further evaluation under the National Forest Management Act (NFMA) and National Environmental Policy Act

(NEPA). The EIS will further analyze old growth in the project area and evaluate the cumulative impacts with the neighboring Hungry Ridge Project to ensure old growth was retained per the 1987 Nez Perce National Forest land management plan requirements.

DATES: The Forest Service is not conducting a scoping period because we are using the information we collected during the development of the previous EA. The draft EIS will be published for public comment as required by 40 CFR 1503.1. Notice of the draft EIS availability will be announced for public review and comment in the **Federal Register** and on the Nez Perce-Clearwater National Forests' project website, as well as other local media. The comment period for the draft EIS will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**. The Forest Service anticipates that the draft EIS will be available for public review in spring/summer 2024.

ADDRESSES: Nez Perce Clearwater National Forests, 1008 Highway 64, Kamiah, Idaho 83536.

FOR FURTHER INFORMATION CONTACT: Jeff Shinn, Salmon District Ranger, *jeffrey.shinn@usda.gov* or 208–839–2103. Individuals who use telecommunications devices for the hearing impaired may call 711 to reach the Telecommunications Relay Service, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The End of the World project area is located approximately six (6) miles south of Grangeville, Idaho. The name of this project is a tribute to local community members who often gather at the previous Fish Creek Lookout site (located prominently within the project area) which they affectionately call ''The End of the World'' because of the extensive viewscape. The EIS will expand the analysis from the End of the World Final EA (January 2021) by providing an updated analysis of the environmental effects related to old growth and analysis of cumulative effects of the Hungry Ridge and End of the World projects. The End of the World Final EA evaluated the potential effects of three alternatives, including No Action and two action alternatives. The final Decision Notice was signed January 25, 2021. The EIS will provide updated information about the project's ability to meet Forest Plan standards for old growth in the project area and the cumulative effects between the End of the World and Hungry Ridge projects. Other resources will be addressed by following 40 CFR 1502.2(b).

The Forest Supervisor of the Nez Perce-Clearwater National Forests will issue a Record of Decision (ROD) after evaluating the EIS and public comments.

Purpose and Need for Action

The End of the World Project area is designated as part of an insect and disease treatment program in accordance with Title VI, Section 602, Healthy Forest Restoration Act (HFRA), as amended by Section 8204 of the Agriculture Act (Farm Bill) of 2014. Based on observed existing conditions, as well as other supporting information (*e.g.,* annual insect and disease aerial detection surveys, national insect and disease risk maps, community wildfire protection plan (CWPP), and input from local community members), there is a need to:

- Change the nature and arrangement of fuels to reduce wildfire risk to the local communities and surrounding Federal lands;
- Reduce the risk or extent of, or increase resilience to, insect or disease infestation;
- Restore forest vegetation, dry meadows, and grasslands to a healthy condition; and
- Improve water quality and aquatic habitats.

This project is in the heart of the Forests' Wildland Fire Crisis Emergency Landscape. The project lies entirely within the Wildland Urban Interface (WUI) for the Grangeville area as defined by the CWPP of Idaho County. It was originally authorized as part of an insect and disease treatment program in accordance with title VI, section 602, HFRA, as amended by section 8204 of the Agriculture Act (Farm Bill) of 2014. This project meets Executive Order (E.O.) 14072 because it was created using science-based modelling that indicated that this area is in high need for treatment through sustainable forest and land management activities. The project conserves America's mature and old-growth forests through authorization under title VI, section 602, HFRA as well as application of the 1987 Nez Perce Forest Plan Standards. Proposed activities will improve the resilience of our lands, waters, wildlife, and communities in the face of increasing disturbances and chronic stress arising from climate impacts.

Proposed Action

The goal of this project is to treat at a landscape scale to increase the resilience of the forest to insects, disease, fire, and future climate impacts. The project is also designed to improve water quality, aquatic habitats, and resources important to the Nez Perce Tribe (project area is fully within the ceded territory). Finally, the project is adjacent to the community of Grangeville, Idaho, and actions are designed to reduce the threat of catastrophic wildfires to both private residences in and adjacent to the Forest and to the community of Grangeville.

Pre-commercial thinning, intermediate harvest, regeneration harvest, and aquatic improvements are proposed to change the nature and arrangement of fuels and reduce wildfire risk. The project proposes to remove hazard trees in campgrounds and dispersed camping areas, create a fuel break on Forest Service Road 221, conduct prescribed landscape burning, treat invasive plant species, improve range conditions and restore dry meadows, conduct trail restoration or reconstruction, decommission roads, replace culverts, improve cross drains, and complete stream crossing hardening. There will be no regeneration harvest in old growth. Project activities will maintain or promote old growth characteristics consistent with the regional definition of old growth.

The EIS will provide updated information about the project's ability to meet the 1987 Forest Plan standards for old growth in the project area and the cumulative effects on old growth between the End of the World and Hungry Ridge projects as directed by the court.

Preliminary Alternatives

The alternatives from the EA will be incorporated into the EIS. The End of the World EA (January 2021) evaluated the potential effects of three alternatives, including No Action and two action alternatives. Both the Proposed Action and Alternative B meet the purpose and need of the project. Alternative B was created in direct response to collaboration and public comments that requested alternative treatments near private properties, less harvest, fewer temporary roads, and less potential sediment production. The No Action alternative provided the baseline for the comparison of the environmental effects of the action alternatives to the existing condition. The No Action Alternative would continue to elevate the risk of uncharacteristic wildfire and would not address fuel accumulations in the WUI, nor would it respond to the priority landscapes identified by the Governor of Idaho. It would not further implementation of the National Wildfire Crisis or National Cohesive Strategies.

Expected Impacts

The Forest Service will evaluate potential impacts to old growth in the project area and cumulative effects on old growth by the End of the World and Hungry Ridge projects.

Responsible Official

Cheryl F. Probert, Nez Perce—Clearwater Forest Supervisor, Nez Perce-Clearwater National Forests Supervisor's Office, 1008 Highway 64, Kamiah, Idaho 83536.

Comments and the Objection Process

A legal notice was published in the *Lewiston Tribune* on February 16, 2018. This notice started a 30-day scoping/comment period. In accordance with 40 CFR 1502.9(d)(3), there will be no scoping conducted for this EIS. The scope of the End of the World final EA established the scope for this EIS. The Forest Service will be seeking comments on the draft EIS. The Forest Supervisor will be requesting Emergency Action Determination authority under the Bipartisan Infrastructure Law, section 40807, since the project is within two of the 250 high-risk western firesheds. If the Emergency Action Determination authority is approved, the End of the World project would not be subject to the pre-decisional objection review process pursuant to 36 CFR 218 subparts A and B.

The Forest Service will be soliciting future participation via the GovDelivery email notification system, rather than postal mail. Details about the upcoming project will be sent through GovDelivery. To sign up for GovDelivery and take advantage of electronic notifications, visit the End of the World Project web page at: *https://www.fs.usda.gov/project/?project=52541.* On the right side of the screen, under ''Get Connected,'' select ''Subscribe to Email Updates.'' When you click on that item, you will be prompted to provide your email address and select a password in the GovDelivery program. Once you have logged in, you will be able to manage your account by subscribing to projects by National Forest, Ranger District, project type, or project purpose. Select the Nez Perce-Clearwater National Forests, Salmon River Ranger District, and/or End of the World Project to receive any updates on the project. Once you are subscribed, you will continue to receive all project information and updates via email. Updates will not be sent via postal mail.

Nature of Decision To Be Made

The Responsible Official will review the information and analysis in the EIS to determine whether direct, indirect, and cumulative effects on old growth in the End of the World project area meet the requirements of appendix N of the 1987 Nez Perce National Forest Land and Resource Management Plan (Plan); if there are cumulative impacts to old growth by the End of the World Restoration Project and the Hungry Ridge Restoration Project; and which alternative best meets the purpose and need of the project and complies with the Plan.

Dated: April 22, 2024.

Troy Heithecker,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024–08954 Filed 4–25–24; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD878]

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The South Atlantic Fishery Management Council (Council) will host a Seminar Series presentation on Electronic Self-Reporting Programs in Recreational Fisheries via webinar on May 14, 2024.

DATES: The webinar presentation will be held on Tuesday, May 14, 2024, from 1 p.m. until 2:30 p.m.

ADDRESSES: The presentation will be provided via webinar. The webinar is open to members of the public. Information, including a link to webinar registration will be posted on the Council's website at: *https://safmc.net/safmc-seminar-series/* as it becomes available.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8439 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: The Council will host a presentation on electronic self-reporting programs in U.S. marine recreational fisheries by staff from The Nature Conservancy. The presentation will present information on the ''appscape'' used to collect information from recreational fisheries and identify successes, challenges, and lessons learned. A question-and-answer session will follow the presentation. Members of the public will have the opportunity to participate in the discussion. The presentation is for informational purposes only and no management actions will be taken. The presentation is part of an ongoing Seminar Series hosted by the Council featuring scientific studies relevant to fisheries in federal waters of the South Atlantic.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: April 22, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–08960 Filed 4–25–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD897]

Permanent Advisory Committee To Advise the U.S. Commissioners to the Western and Central Pacific Fisheries Commission; Meeting Announcement

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

ACTION: Notice of public meeting.

SUMMARY: NMFS announces a public meeting of the Permanent Advisory Committee (PAC) to advise the U.S. Commissioners to the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (WCPFC) on May 13, 2024. Meeting topics are provided under the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: The meeting of the PAC will be held via web conference on May 13, 2024, from 10 a.m. to 1 p.m. Hawaii standard time (HST) (or until business is concluded). Members of the public

may submit written comments on meeting topics or materials; comments must be received by May 6, 2024.

ADDRESSES: The public meeting will be conducted via web conference. For details on how to call into the web conference or to submit comments, please contact Katrina Poremba, NMFS Pacific Islands Regional Office; telephone: 808–725–5096; email: *katrina.porembas@noaa.gov.* Documents to be considered by the PAC will be sent out via email in advance of the conference call. Please submit contact information to Katrina Poremba (telephone: 808–725–5096; email: *katrina.poremba@noaa.gov*) at least 3 days in advance of the call to receive documents via email. The audio portion of this meeting may be recorded for the purposes of generating notes of the meeting. As public comments will be made publicly available, participants and public commenters are urged not to provide personally identifiable information (PII) at this meeting. Participation in the meeting by web conference, or by telephone, constitutes consent to the audio recording.

FOR FURTHER INFORMATION CONTACT: Katrina Poremba, NMFS Pacific Islands Regional Office; 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818; telephone: 808–725–5096; email: *katrina.poremba@noaa.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Western and Central Pacific Fisheries Convention Implementation Act (16 U.S.C. 6901 *et seq.*), the PAC has been formed to advise the U.S. Commissioners to the WCPFC. The PAC is composed of: (i) no less than 15 nor more than 20 individuals appointed by the Secretary of Commerce in consultation with the U.S. Commissioners to the WCPFC; (ii) the chair of the Western Pacific Fishery Management Council's Advisory Committee (or the chair's designee); and (iii) officials from the fisheries management authorities of American Samoa, Guam, and the Northern Mariana Islands (or their designees). The PAC supports the work of the U.S. National Section to the WCPFC in an advisory capacity. The U.S. National Section is made up of the U.S. Commissioners, the Department of State, and the U.S. head of delegation. NMFS Pacific Islands Regional Office provides administrative and technical support to the PAC in cooperation with the Department of State. More information on the WCPFC, established under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean, can be found on the WCPFC website: *https://www.wcpfc.int.*

Meeting Topics

The purpose of the May 13, 2024 meeting is to discuss U.S. objectives and priorities leading up to WCPFC 21 and its Subsidiary Body Meetings.

Special Accommodations

The web conference is accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Katrina Poremba at 808–725–5096 by May 6, 2024.

Authority: 16 U.S.C. 6902 *et seq.*

Dated: April 23, 2024.

Everett Wayne Baxter,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–08981 Filed 4–25–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD886]

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold four port meetings gathering input on Atlantic king mackerel and Atlantic Spanish mackerel as managed by the Fishery Management Plan for Coastal Migratory Pelagic Resources in the Gulf of Mexico and Atlantic Region.

DATES: The port meetings will take place May 14–16, 2024, and June 4, 2024. The port meetings will begin at 6 p.m., local time. For specific dates and times, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES:

Meeting addresses: The port meetings will be held via webinar May 14–16, 2024 and in-person in Riverhead, New York on June 4, 2024 in conjunction with the Mid-Atlantic Fishery Management Council Meeting. For specific locations, see **SUPPLEMENTARY INFORMATION**.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Christina Wiegand, Fishery Social Scientist, SAFMC; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *christina.wiegand@safmc.net.*

SUPPLEMENTARY INFORMATION: The Council is hosting a series of port meetings along the Atlantic coast throughout 2024 in order to take a focused look at the Atlantic king mackerel and Atlantic Spanish mackerel fisheries. The webinar port meetings on May 14–16, 2024 will focus on gathering input from fishermen in the New England region, specifically Connecticut, Rhode Island, and Massachusetts. The in-person port meeting on June 4, 2024 will focus on gathering input from fishermen in the state of New York.

The agenda for the port meetings is as follows:

Council staff will briefly introduce port meetings and the Council's goals and objectives. Attendees will then have the opportunity to provide input on a variety of issues related to the Atlantic king mackerel and Spanish mackerel fisheries including changing environmental conditions, needed management changes, commercial and recreational fishery dynamics, and the goals and objectives of the Coastal Migratory Pelagics Fishery Management Plan. Information provided during port meetings will be summarized and presented to the Council for use in management decision-making. Additional port meetings will be scheduled along the Atlantic coast throughout the remainder of 2024.

Webinar Information

The May 14–16, 2024 port meetings will be conducted via webinar. The port meetings will begin at 6 p.m. Registration for the webinars is required. Registration information will be posted on the Council's website at *https://safmc.net/king-and-spanish-mackerel-port-meetings/* as it becomes available.

In-Person Location

Tuesday, June 4, 2024: Atlantis Banquets and Events, 431 East Main Street, Riverhead, New York, 11901; phone: (631) 574–8008.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aid should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: April 22, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–08961 Filed 4–25–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD862]

Fisheries of the Gulf of Mexico and South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 79 Assessment Webinar III for Gulf of Mexico and South Atlantic Mutton Snapper.

SUMMARY: The SEDAR 79 assessment process of Gulf of Mexico and South Atlantic mutton snapper will consist of a Data Workshop, and a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION.**

DATES: The SEDAR 79 Assessment webinar III will be held May 13, 2024, from 1 p.m. to 3 p.m., Eastern Time. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop, (2) a series of assessment webinars, and (3) A Review Workshop. The product of the Data Workshop is a report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The assessment webinars produce a report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The product of the Review Workshop is an Assessment Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion during the Assessment webinar are as follows:

Panelists will review and discuss assessment modeling to date.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: April 22, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–08959 Filed 4–25–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD907]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of hybrid meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Bering Sea Aleutian Islands Crab Plan Team (BSAI CPT) will meet May 14, 2024 to May 16, 2024.

DATES: The meeting will be held on Tuesday, May 14, 2024 through Thursday, May 16, 2024, from 9 a.m. to 5 p.m., AK time.

ADDRESSES: The meeting will be a hybrid meeting. Attend in-person at the North Pacific Fishery Management Council office, 1007 West Third Ave, Suite 400 Anchorage, AK 99501, or join the meeting online through the link at *https://meetings.npfmc.org/Meeting/Details/3043*.

Council address: North Pacific Fishery Management Council, 1007 W Third Ave, Suite 400, Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Sarah Rheinsmith, Council staff; phone: (907) 271–2809; email: *sarah.rheinsmith@noaa.gov.* For technical support, please contact our admin Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, May 14, 2024 Through Thursday, May 16, 2024

The agenda will include: (a) Aleutian Island Golden King Crab 2024 SAFE; (b) Council updates; (c) proposed model runs for Bristol Bay red king crab, Eastern Bering Sea snow crab, Tanner crab, and Saint Matthew blue king crab; (d) ecosystem and socioeconomic profile updates; (e) Bering Sea Fisheries Research Foundation (BSFRF); (f)

economic impacts of the snow crab closure; (g) research updates; and (h) other business. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/3043* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone, or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/3043.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/3043.*

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

Dated: April 22, 2024.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2024–08962 Filed 4–25–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Privacy Act of 1974; System of Records

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of a modified system of records.

SUMMARY: The Department of Commerce (Department)/United States Patent and Trademark Office (USPTO) is issuing this notice of its intent to modify the Privacy Act system of records under ''COMMERCE/PAT–TM–10, Deposit Accounts and Electronic Funds Transfer Profiles.'' This system of records allows the USPTO to collect and maintain personal and financial information on customers who submit payments for services and processing fees to the USPTO.

DATES: The modified system of records notice (SORN) will become effective upon its publication, except that new routine uses 2, 3, 9, 11, 15, 16, and 17 and significant modifications to routine uses 4, 5, 6, 7, 10, 13, and 14 are subject to a public comment period of 30 days from the date of publication and will become effective at the end of that period. Any subsequent changes to a routine use in response to comments received, or other revisions to the system, will be subject to the requirements for further notice, as applicable, as set forth in OMB Circular A–108, section 6. To be considered, written comments must be submitted on or before May 28, 2024.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Email: SORN@USPTO.gov.* Include ''USPTO–10 comment'' in the subject line of the message.
- *Federal e-Rulemaking Portal: https://www.regulations.gov.*
- *Mail:* Justin Isaac, Office of the Chief Administrative Officer, USPTO, P.O. Box 1450, Alexandria, VA 22313–1450.

The USPTO will make all comments it receives available for public inspection at the Federal e-Rulemaking Portal located at *https://www.regulations.gov.* Before including your address, phone number, email address, or other personal identifying information, you should be aware that your entire comment, including any personal identifying information you provide, may be made publicly available. You may request in your comment that the USPTO withhold your personal identifying information from public review; however, the USPTO cannot guarantee it will be able to do so. Therefore, do not submit personal identifying information, Confidential Business Information, or otherwise sensitive or protected information that you do not want made public.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Matthew Lee, Director of the Receipts Accounting Division, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at (571) 272–6343, by email to *Matthew.Lee@uspto.gov* with ''Fee Management Products—System of Records'' in the subject line.

SUPPLEMENTARY INFORMATION: In accordance with the requirements of the Privacy Act of 1974, as amended, and the Office of Management and Budget (OMB) Circular A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,'' the USPTO is modifying the system of records currently listed under ''COMMERCE/PAT–TM–10, Deposit Accounts and Electronic Funds Transfer Profiles.'' This system of records was last amended on August 10, 2007 (72 FR 45009). The changes are needed to ensure that the notice for this system of records is up-to-date, accurate, and current, as required by the Privacy Act, 5 U.S.C. 552a(e)(4).

The USPTO is modifying this system of records due to changes in how it collects, uses, maintains, and retrieves personally identifiable information (PII) from its customers to administer transactions for services and processing fees related to patents, trademarks, and information products. The USPTO charges both service and processing fees, such as, but not limited to, patent and trademark application filing fees, patent examination fees, patent trial and appeal fees, trademark trial and appeal fees, and processing of refused payment and charge-back fees. Customers are able to choose from several methods of payment to pay for services and processing fees related to patents, trademarks, and information products. The USPTO is updating the system of records to include users of credit cards, debit cards, and paper checks, and/or their associated transactions.

To implement these updates, the USPTO is modifying this system of records to expand the categories of individuals covered by this system and the categories of records maintained in the system to reflect current users and the types of information collected. The USPTO also proposes modifying the record source categories to include records derived from financial entities and the Department of the Treasury or Bureau of the Fiscal Service-designated fiscal and financial agents of the United States that process payments and collections, and to update the appropriate sections to address credit card, debit card, and paper check users and/or the associated transactions.

The USPTO is modifying the routine uses for this system of records to expressly describe and consolidate all applicable routine uses into one notice instead of relying on a cross-reference to other **Federal Register** (FR) notices. In the last full publication of this system of records notice on July 6, 2006 at 71 FR 38387, the USPTO incorporated by reference some of the Prefatory Statement of General Routine Uses published on December 31, 1981 at 46 FR 63501–63502. Instead of relying on the incorporation by reference, the USPTO expressly incorporates in modified form eight General Routine Uses as Routine Uses 4 (formerly 3), 5 (formerly 2), 6 (formerly 1), 7 (formerly 10), 10 (formerly 4), 12 (formerly 9), 13 (formerly 5), and 14 (formerly 13) in this system of records. Of these eight, the USPTO is modifying Routine Uses 4, 5, 6, 7, 10, 13, and 14 to make administrative changes, address the expanded needs of the USPTO and reflect current authorities and practices; and Routine Use 12 to make non-substantive changes for clarity. Each

Routine Use has also been updated with minor editorial changes throughout, including the addition of descriptive headings. In addition, the USPTO proposes revising for clarity a previously unnumbered routine use (Routine Use 1) regarding the disclosure of financial information to financial institutions, including banks and credit unions, and credit card companies for the purpose of revenue collections and/or investigating the accuracy of information required to complete transactions. Also, the USPTO expressly incorporates, but in a modified form, a routine use published on August 10, 2007 at 72 FR 45009 (Routine Use 8) to comport with the USPTO's standards and routine disclosure practices and OMB guidance.

The USPTO is adding seven new routine uses to the system of records. The USPTO proposes adding a routine use (Routine Use 2) to cover the administrative needs of disclosing the information to the Department of Treasury. The USPTO is adding a new routine use (Routine Use 3) to disclose information to any agency, organization, or individual for audit/oversight functions of this system of records, such as to an accreditation entity, but only when such information is necessary and relevant to such function. The USPTO is adding a new routine use (Routine Use 9) to allow the USPTO to provide assistance to other agencies in responding to a data breach, if appropriate, in compliance with OMB Memorandum M–17–12. The USPTO is adding new routine uses (Routine Uses 11 and 15) to describe how the USPTO provides information to other Federal agencies for litigation purposes and in connection with the legislative coordination and clearance process. This includes providing the Department of Justice with information when litigation involves the USPTO (Routine Use 11) and allowing the USPTO to provide information related to private relief legislation to OMB in conjunction with that agency's legislative coordination and clearance functions (Routine Use 15). The USPTO is adding a routine use (Routine Use 16) to cover disclosures of information to officials of labor organizations, and a routine use (Routine Use 17) that describes how and when information may be disclosed to the news media and the public.

Finally, the USPTO is making minor administrative updates to certain sections to reflect current practice and enhance clarity; reorganizing the system of records in accordance with reissued OMB Circular A–108; and modifying the system of records name from ''COMMERCE/PAT–TM–10, Deposit Accounts and Electronic Funds Transfer Profiles'' to ''COMMERCE/USPTO–10, Fee Management Products'' to more accurately reflect the system and breadth of information maintained in the system of records.

The Privacy Act also requires each agency that proposes to establish or significantly modify a system of records to provide adequate advance notice of any such proposal to the OMB, the Committee on Oversight and Accountability of the House of Representatives, and the Committee on Homeland Security and Governmental Affairs of the Senate (5 U.S.C. 552a(r)). The USPTO filed a report describing the modified system of records covered by this notice with the Chair of the Senate Committee on Homeland Security and Governmental Affairs, the Chair of the House Committee on Oversight and Accountability, and the Deputy Administrator of the Office of Information and Regulatory Affairs at OMB.

The modified Privacy Act system of records, ''COMMERCE/USPTO–10, Fee Management Products,'' is published in its entirety below.

Charles R. Cutshall,

Senior Agency Official for Privacy, Chief Privacy Officer and Director of Open Government. Department of Commerce.

SYSTEM NAME AND NUMBER:

Fee Management Products, COMMERCE/USPTO–10.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

- Office of Finance, Receipts Accounting Division, USPTO, Madison East Building, 600 Dulany Street, Alexandria, VA 22314;
- Office of the Chief Information Officer, USPTO, Madison West Building, 600 Dulany Street, Alexandria, VA 22314.

SYSTEM MANAGER(S):

Director, Office of Finance, USPTO, Madison East Building, 600 Dulany Street, Alexandria, VA 22314.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 1113, Public Law 112–29, and 35 U.S.C. 2 and 41.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to collect, maintain, use, and retrieve personal and financial records of patent and trademark customers to process fees related to patents, trademarks, and information products.

This system of records contains the information necessary to allow customers to establish deposit accounts at USPTO, maintain existing accounts, charge the appropriate deposit account, or receive refunds if applicable. This system of records allows customers to establish and maintain a user profile to make fee payments from their bank accounts by electronic funds transfer (EFT), credit cards, debit cards, paper checks, or equivalent methods.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Registered patent attorneys and agents and other members of the public who maintain deposit accounts or submit payments, including those completed through their user profile, for the cost of products and services rendered by the USPTO.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in the system include:

1. Biographic information, including the account holder's first and last name, company or organization.

2. Contact information, including account holder's address and email address.

3. User information, including the user identification (ID), file/case ID number, and username and password.

4. Financial information, including deposit account number, financial account, financial transaction, credit card number, debit card number, paper check, bank name, bank routing number, bank account number, type of account, and payment transaction irregularities.

RECORD SOURCE CATEGORIES:

Information in this system of records is derived from subject individuals, those authorized by the individual to furnish information, including appropriate financial entities, and the Department of the Treasury or Bureau of the Fiscal Service-designated fiscal and financial agents of the United States that process payments and collections.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under the Privacy Act of 1974, as amended, 5 U.S.C. 552a(b), records maintained as part of this system of records may be routinely disclosed pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. *Financial Institutions*—A record from this system of records may be disclosed to financial institutions and other financial services companies, including banks, credit unions, and credit card companies, for the purpose of revenue collections, refunds, and/or

investigating the accuracy of information required to complete transactions using electronic methods and for administrative purposes, such as resolving questions, problems, or irregularities about a transaction.

2. *Department of the Treasury*—A record from this system of records may be disclosed to the Department of the Treasury, as well as its fiscal agents and financial agents, for the purpose of performing financial management services, including, but not limited to, processing payments, investigating and rectifying possible erroneous reporting information, creating and reviewing statistics to improve the quality of services provided, or conducting debt collection services.

3. *Audit Disclosure*—A record from this system of records may be disclosed to an agency, organization, or individual for the purpose of performing an audit or oversight operation as authorized by law, but only such information as is necessary and relevant to such audit or oversight function to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to the USPTO officers and employees.

4. *Governments Disclosure*—A record from this system of records may be disclosed to a Federal, State, local, Tribal, or international agency, in response to its request, in connection with (1) the assignment, hiring, or retention of an individual, (2) the issuance of a security clearance, (3) the letting of a contract, or (4) the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

5. *Record Informational Inquiries*—A record in this system of records may be disclosed to a Federal, State, local, Tribal, or international agency, maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a USPTO decision concerning (1) the assignment, hiring, or retention of an individual, (2) the issuance of a security clearance, (3) the letting of a contract, or (4) the issuance of a license, grant, or other benefit.

6. *Law Enforcement and Investigation*—A record in this system of records may be disclosed to a Federal, State, local, Tribal, or foreign agency or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by (1) general statute or particular program statute or contract, (2) rule, regulation, or order issued pursuant thereto, or (3) the necessity to protect an interest of the USPTO or the Department of Commerce. The agency receiving the record(s) must be charged with the responsibility of investigating or prosecuting such violations or with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto, or protecting the interest of the USPTO or the Department of Commerce.

7. *Non-Federal Personnel*—A record in this system of records may be disclosed to individuals, contractors, agents, grantees, experts, consultants, student volunteers, and other workers who technically do not have the status of Federal employees, performing or working on a contract, service, grant, cooperative agreement, or other work assignment for the USPTO or the Department of Commerce, to the extent needed to perform their assigned functions. These individuals or entities may have a need for information from the system of records: (1) in the course of operating or administrating the system of records; (2) in the course of fulfilling an agency function, but only to the extent necessary to fulfill that function; or (3) in order to fulfill their contract(s), but who do not operate the system of records within the meaning of 5 U.S.C. 552a(m).

8. *Data Breach Notification*—A record in this system of records may be disclosed to appropriate agencies, entities, and persons when (1) the USPTO suspects or has confirmed that there has been a breach of the system of records; (2) the USPTO has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, USPTO (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the USPTO's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

9. Data Breach Assistance—A record in this system of records may be disclosed to another Federal agency or Federal entity when the USPTO determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) 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. *Adjudication and Litigation*—A record in this system of records may be disclosed to a court, magistrate, or administrative tribunal during the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations where use of such records by the court or the USPTO is deemed by the USPTO to be relevant and necessary to the litigation, provided, however, that in each case, the USPTO determines that disclosure of the records to the court is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

11. *Department of Justice Litigation*—To the U.S. Department of Justice (DOJ), or in a proceeding before a court, adjudicative body, or other administrative body in which the USPTO is authorized to appear, when

(1) The USPTO;

(2) Any employee of the USPTO in their official capacity; or

(3) Any employee of the USPTO in their individual capacity where the DOJ or the USPTO has agreed to represent the employee; or

(4) The United States, when the USPTO determines that litigation is likely to affect the USPTO; is a party to litigation or has an interest in such litigation, and the use of such records by the DOJ or the USPTO is deemed by the USPTO to be relevant and necessary to the litigation, provided, however, that in each case, the USPTO determines that disclosure of the records to DOJ is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

12. *Freedom of Information Act Assistance from Department of Justice*—A record in this system of records may be disclosed to the Department of Justice in connection with determining whether disclosure thereof is required by the Freedom of Information Act (5 U.S.C. 552).

13. *Congressional Inquiries*—A record in this system of records may be disclosed to a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

14. *National Archives and Records Administration*—A record in this

system of records may be disclosed to the Administrator of the National Archives and Records Administration (NARA), or said administrator's designee, during an inspection of records conducted by NARA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with NARA regulations governing inspection of records for this purpose, and any other relevant directive. Such disclosure shall not be used to make determinations about individuals.

15. *Office of Management and Budget*—A record in this system of records may be disclosed to the Office of Management and Budget (OMB) in connection with the review of private relief legislation as set forth in OMB Circular No. A–19 at any stage of the legislative coordination and clearance process.

16. *Labor Organizations*—A record in this system of records may be disclosed to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation.

17. *Media and the Public*—A record in this system of records may be disclosed to the news media and the public, with the approval of the USPTO's Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of USPTO or is necessary to demonstrate the accountability of USPTO's officers, employees, or individuals covered by the system; except to the extent the USPTO determines that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The USPTO maintains records in this system in electronic form.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The USPTO retrieves records in this system by one or more of the following: registered user name or email address, account holder name, deposit account number, bank account number, bank routing number, credit or debit card number, name on card, check number, and by other transaction numbers or information. The files are searchable in a database available only to authorized personnel.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records in the system are maintained in accordance with the NARA approved USPTO Records Controls Schedules N1–241–05–001:5; N1–241–06–002:4; N1–241–06–002:6; N1–241–10–001:10.3; and General Records Schedules 1.1 and 3.2.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The USPTO safeguards records in this system according to applicable rules and policies, including all applicable automated systems security and access policies. Information systems are maintained in areas accessible only to authorized personnel and in buildings protected by security systems and security guards. The electronic records stored in this system of records can be accessed for maintenance only by authorized personnel. The USPTO has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to the information system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

Individuals can access their records by logging into their account to view, modify, or retrieve records.

Individuals can also request access to their records by mailing a written request to the Privacy Act Officer, Office of General Law, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450. The request should include the information requested pursuant to the provisions for making requests for records appearing at 37 CFR 102.24.

CONTESTING RECORD PROCEDURES:

The procedures for contesting or requesting amendment of information by the individual concerned appear in 37 CFR 102.27. Requests from individuals should be submitted as stated in the Record Access Procedures section above.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether this system of records contains information about themselves can send a written request to the System Manager at the address above or to the address provided in 37 CFR 102.23, which sets forth procedures for making inquiries about records covered by the Privacy Act. Requesters should include all required information in accordance with 37 CFR 102.23.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

COMMERCE/PAT–TM–10, Patent Deposit Accounts System, 72 FR 45009 (August 10, 2007); COMMERCE/PAT–TM–10, Deposit Accounts and Electronic Funds Transfer Profiles, 71 FR 38387 (July 6, 2006).

[FR Doc. 2024–08734 Filed 4–25–24; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes product(s) and service(s) to the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date deleted from the Procurement List:* May 26, 2024.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION:

Deletions

On March 22, 2024 (89 FR 20456), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product(s) and service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product(s) and service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following product(s) and service(s) are deleted from the Procurement List:

Product(s)

NSN(s)—Product Name(s):
7910–00–685–3910—Pad, Machine, Polishing, Floor, 18″ × 1/4″
Authorized Source of Supply: Beacon Lighthouse, Inc., Wichita Falls, TX
Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FORT WORTH, TX

Service(s)

Service Type: Embroidery Service
Mandatory for: Embroidery of Urban Name Tapes: U.S. Marine Corps, Arlington, VA
Authorized Source of Supply: LIONS INDUSTRIES FOR THE BLIND, INC, Kinston, NC
Contracting Activity: DEPT OF THE ARMY, W40M RHCO–ATLANTIC USAHCA
Service Type: Management of State Dept High Threat Division Kit
Mandatory for: Department of State, High Threat Division, 2216 Gallows Road, Dunn Loring, VA
Authorized Source of Supply: Virginia Industries for the Blind, Charlottesville, VA
Contracting Activity: STATE, DEPARTMENT OF, ACQUISITIONS—AQM MOMENTUM

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2024–09004 Filed 4–25–24; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes product(s) previously furnished by such agencies.

DATES: *Comments must be received on or before:* May 26, 2024.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 785–6404, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

In accordance with 41 CFR 51–5.3(b), the Committee intends to add this services requirement to the Procurement List as a mandatory purchase only for DEPT OF THE NAVY at NAVSUP FLT LOG CTR PEARL HARBOR with the proposed qualified nonprofit agency as the authorized source of supply. Prior to adding the service to the Procurement List, the Committee will consider other pertinent information, including information from Government personnel and relevant comments from interested parties regarding the Committee's intent to geographically limit this services requirement.

Service(s)

Service Type: Verbatim Transcription Service
Mandatory for: COMPACFLT, Commander, U.S. Pacific Fleet, Pearl Harbor, HI
Designated Source of Supply: Lighthouse for the Blind of Houston, Houston, TX
Contracting Activity: DEPT OF THE NAVY, NAVSUP FLT LOG CTR PEARL HARBOR

Deletions

The following product(s) are proposed for deletion from the Procurement List:

Product(s)

NSN(s)—Product Name(s): 7510–01–383–7680—Grips, Pencil, Cusheeze
Authorized Source of Supply: West Texas Lighthouse for the Blind, San Angelo, TX
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR(2, NEW YORK, NY

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2024–09005 Filed 4–25–24; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Changes

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed changes to the Procurement List.

SUMMARY: The Committee is proposing to change requirements for products already existing on the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: May 26, 2024.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 489–1322, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Changes

If the Committee approves the proposed changes, the entities of the Federal Government identified in this notice will be required to procure the product(s) listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Product(s)

NSN(s)—Product Name(s):
8415–01–670–5110—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XS–XS
8415–01–670–6243—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XL–XXL
8415–01–670–6251—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XXL–XS
8415–01–670–6337—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XXL–S
8415–01–670–6339—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XXL–R
8415–01–670–6344—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XXL–L
8415–01–670–6346—Trouser, Improved Hot Weather Combat Uniform (IHWCU),

Permethrin, Unisex, Army, OCP 2015, XXL–XL
8415–01–670–6349—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XXL–XXL
8415–01–670–6171—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, L–XL
8415–01–670–5165—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, M–XS
8415–01–670–5119—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XS–S
8415–01–670–5127—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XS–L
8415–01–670–5128—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XS–XL
8415–01–670–5133—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XS–XXL
8415–01–670–5135—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, S–XS
8415–01–670–5140—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, S–S
8415–01–670–5146—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, S–R
8415–01–670–5150—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, S–L
8415–01–670–5154—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, S–XL
8415–01–670–5157—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, S–XXL
8415–01–670–5507—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, M–S
8415–01–670–5511—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, M–R
8415–01–670–5515—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, M–L
8415–01–670–5518—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, M–XL
8415–01–670–5520—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, M–XXL
8415–01–670–5523—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, L–XS
8415–01–670–5527—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, L–S
8415–01–670–6164—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, L–R
8415–01–670–6169—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, L–L
8415–01–670–6179—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XL–XS
8415–01–670–6181—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XL–S
8415–01–670–6192—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XL–R
8415–01–670–6195—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XL–L
8415–01–670–6198—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XL–XL
8415–01–670–5124—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XS–R
8415–01–670–6174—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, L–XXL
8415–01–670–5110—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Unisex, Army, OCP 2015, XS–XS
8415–01–687–1339—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 31-Short
8415–01–687–1353—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 31-Regular
8415–01–687–1971—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 31–X Short
8415–01–687–2060—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 35-Regular
8415–01–687–1345—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 35-Long
8415–01–687–2126—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 31–X Long
8415–01–687–3100—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 25-Regular
8415–01–687–4018—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 35–X Long
8415–01–687–6147—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 35-Short
8415–01–687–6180—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 28-Long
8415–01–687–6201—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 28-Short
8415–01–687–6651—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 25–X Short
8415–01–687–6659—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 28–X Short
8415–01–687–6669—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 25-Short
8415–01–687–6673—Trouser, Improved Hot Weather Combat Uniform (IHWCU), Permethrin, Women's, Army, 31-Long

Authorized Source of Supply: Goodwill Industries of South Florida, Inc., Miami, FL

Authorized Source of Supply: ReadyOne Industries, Inc., El Paso, TX

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT

The Unisex Improved Hot Weather Combat Uniform (IHWCU) Permethrin Trousers were administratively added to the Procurement List 11/20/2017 in accordance with 41 CFR 51–6.13(b), as an additional size, color or other variation) of an existing PL product to meet 50% of the requirement for the Army Contracting Command—Aberdeen Proving Ground, Natick Contracting Division, with DLA Troop Support added later. However, when possible and to ensure clarity on existing PL requirements for military garments, or other applicable products, the Committee is departing from stating the mandatory purchase requirement as a percentage of a contracting activity's overall requirement and is instead stating the mandatory purchase requirement as a specified annual quantity of a garment or product. For the Trouser, IHWCU, Permethrin, Unisex, the contracting activity and the authorized sources of supply, assisted by the central nonprofit agency, have agreed that the mandatory purchase requirement is 94,896 units annually for the Unisex trousers and 151,104 units annually for the Women's trousers. The Committee intends to amend the Procurement List and reflect the agreed annual quantity. Additionally, for administrative purposes, the Committee is assigning a new PL number to the IHWCU Trouser, Unisex, which will sever the Unisex IHWCU garments as a legacy from garments no longer being produced and increase the Committee's overall efficiency when processing future transactions.

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2024–09003 Filed 4–25–24; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 1:00 p.m. EDT, Friday, May 3, 2024.

PLACE: Virtual meeting.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement matters. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.cftc.gov/.*

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202–418–5964.

(Authority: 5 U.S.C. 552b)

Dated: April 24, 2024.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2024–09131 Filed 4–24–24; 4:15 pm]

BILLING CODE 6351–01–P

DEPARTMENT OF EDUCATION

National Board for Education Sciences

AGENCY: National Board for Education Sciences, U.S. Department of Education, Institute of Education Sciences (IES).

ACTION: Notice of an open meeting.

SUMMARY: This notice sets forth the agenda, time, and instructions to access or participate in the National Board for Education Sciences (hereafter referred to as NBES or Board) open virtual meeting scheduled for May 13, 2024. This notice provides information about the meeting to members of the public who may be interested in virtually attending the meeting and/or how to provide written comment(s).

DATES: The NBES meeting will be held on Monday, May 13, 2024, from 11:00 a.m. to 12:30 p.m. (EDT).

ADDRESSES: The meeting will be conducted virtually via Microsoft Teams.

FOR FURTHER INFORMATION CONTACT: Ellie Pelaez, DFO for NBES, U.S. Department of Education, IES: 550 12th Street SW, Office 4126–1, Washington, DC 20202, telephone: (202) 987–0359, email: *ellie.pelaez@ed.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority and Function: The Board is authorized by § 116 of the Education Sciences Reform Act of 2002 (20 U.S.C. 9516). The Board is established as part of the U.S. Department of Education, IES, and shall, consistent with 20 U.S.C. 9514, 9515(b)–(c), and 9516 function as a board of directors for IES. The mission of IES is to provide national leadership in expanding fundamental knowledge and understanding of education from early childhood through postsecondary study, in order to provide parents, educators, students, researchers, policymakers, and the general public with reliable information about the condition and progress of education in the United States; educational practices that support learning and improve academic achievement and access to educational opportunities for all students; and the effectiveness of Federal and other education programs.

The Board's responsibilities are: (1) advise and consult with the Director of IES (Director) on the policies of IES; (2) consider and approve priorities proposed by the Director under 20 U.S.C. 9515 to guide the work of IES; (3) transmit approved priorities to the appropriate congressional committee (20 U.S.C. 9515(b)); (4) ensure that the priorities of IES and the National Education Centers are consistent with the mission of IES (20 U.S.C. 9515(c)); (5) review and approve procedures for technical and scientific peer review of the activities of IES; (6) advise the Director on the establishment of activities to be supported by IES, including the general areas of research to be carried out by the National Center for Education Research (NCER) and the National Center for Special Education Research (NCSER) (20 U.S.C. 9567); (7) present to the Director such recommendations as it may find appropriate for (a) the strengthening of education research, and (b) the funding of IES; (8) advise the Director on the funding of applications for grants, contracts, and cooperative agreements for research, after the completion of peer review; (9) review and regularly evaluate the work of IES, to ensure that scientifically valid research, development, evaluation, and statistical analysis are consistent with the standards for such activities under this title; (10) advise the Director on ensuring that activities conducted or supported by IES are objective, secular, neutral, and non-ideological, and are free of partisan political influence and racial, cultural, gender, or regional bias; (11) solicit advice and information from those in the educational field, particularly practitioners and researchers, to recommend to the Director topics that require long-term, sustained, systematic, programmatic, and integrated research efforts, including knowledge utilization and wide dissemination of research, consistent with the priorities and mission of IES; (12) advise the Director on opportunities for the participation in, and the advancement of, women, minorities, and persons with disabilities in education research, statistics, and evaluation activities of IES; (13) recommend to the Director ways to enhance strategic partnerships and collaborative efforts among other Federal and State research agencies; (14) recommend to the Director individuals to serve as Commissioners of the National Education Centers; and (15) make recommendations to the President with respect to the appointment of the Director. Notice of this meeting is required by Section 1009(a)(2) of 5 U.S.C. Chapter 10 (Federal Advisory Committees).

Meeting Agenda: The agenda for the meeting is as follows: (1) Call to order and welcome remarks by the Chairwoman of the Board; (2) Member roll call; (3) Board member approval of meeting transcript from the March 29, 2024 meeting; (4) Board member approval of meeting agenda; (5) Discussion of NBES recommendations for the criteria to select a new permanent IES Director; (6) Discussion of the Board's views on Senator and Ranking Member Bill Cassidy's Report to the Senate Health, Education, Labor, and Pensions Committee; (7) Closing remarks and adjournment.

Instructions for Accessing the Meeting: Members of the public interested in virtually attending this meeting may email the DFO listed in this notice no later than 11:59 p.m. Eastern Time (ET) on Thursday, May 9, 2024. The DFO will provide a link and instructions on how to access the meeting via Microsoft Teams.

Public Comment: Members of the public interested in submitting written comments related to the work of NBES may do so by emailing their comments to the DFO listed in this notice no later than 11:59 p.m. ET on Thursday, May 9, 2024. Written comments should pertain to the mission and function of NBES.

Reasonable Accommodations: The virtual meeting is accessible to individuals with disabilities. If you will need an auxiliary aid or service for the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the DFO listed in this notice no later than Thursday, May 9, 2024.

Access to Records of the Meeting: The official transcript of this meeting will be available for public review on the IES website, *https://ies.ed.gov/director/board/index.asp,* no later than 90 days after the meeting. Pursuant to 5 U.S.C.

1009(b), the public may also inspect NBES records at the U.S. Department of Education, IES, 550 12th Street SW, Washington, DC 20202, Monday–Friday, 8:30 a.m. to 5:00 p.m. ET. Please email *ellie.pelaez@ed.gov* to schedule an appointment.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You also may access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: § 116 of the Education Sciences Reform Act of 2002 (20 U.S.C. 9516).

Matthew Soldner,

Acting Director, Institute of Education Sciences.

[FR Doc. 2024–08977 Filed 4–25–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Weatherization Assistance Program: Notice of Listening Session

AGENCY: Office of State and Community Energy Programs, Department of Energy.

ACTION: Notice of virtual listening session.

SUMMARY: This notice announces an upcoming listening session hosted by the U.S. Department of Energy's (DOE) Weatherization Assistance Program (WAP). This session will be held virtually via webinar.

DATES: DOE will hold a listening session via webinar on Wednesday, May 8, 2024, from 2 p.m.–5 p.m. ET.

ADDRESSES: For webinar registration information, participant instructions, and information about the capabilities available to webinar participants, please visit *https://us06web.zoom.us/webinar/register/WN_W7RoXnkTTG-jsLdrvzaOLg*

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Smith, Program Manager Readiness and Retrofit, Weatherization Assistance Program, U.S. Department of Energy, Weatherization Assistance Program, 1000 Independence Avenue SW, Washington, DC 20585–0121, email: *Carrie.Smith@hq.doe.gov,* Phone: (240) 982–0033.

SUPPLEMENTARY INFORMATION: The primary focus of this listening session will be to discuss potential updates to WAP's regulations at 10 CFR part 440. WAP is in the process of considering various regulatory updates in response to recent congressional direction and previously received stakeholder feedback. The listening session will be held virtually via webinar.

Signing Authority

This document of the Department of Energy was signed on April 22, 2024, by David Crane, Under Secretary for Infrastructure, 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 April 23, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–08987 Filed 4–25–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–124–000]

Colorado Interstate Gas Company, L.L.C.; Notice of Application and Establishing Intervention Deadline

Take notice that on April 8, 2024, Colorado Interstate Gas Company, L.L.C., (CIG), P. O. Box 1087, Colorado Springs, Colorado 80944, filed an application under sections 7(b) and 7(c) of the Natural Gas Act (NGA), and part 157 of the Commission's regulations requesting authorization for its Totem Enhanced Deliverability Project (Project) at its Totem Storage Field (Totem) in Adams County, Colorado. The Project consists of: (1) the installation of six new injection and withdrawal (I/W) wells and connecting lateral pipelines; (2) replacement and installation of various sections of storage field pipeline; (3) reclassification of an existing I/W well to an observation well and abandon in-place the associated connecting lateral pipeline; (4) installation of various appurtenant and auxiliary facilities; and (5) injection of approximately one billion cubic feet (Bcf) of additional base gas into Totem. CIG states that the Project will improve the overall performance of Totem and increase both the maximum total inventory and base gas capacity of the field by one Bcf and maximum withdrawal rate by approximately 50 million cubic feet per day. CIG estimates the total cost of the Project to be $79,528,414 and proposes to make the new additional incremental withdrawal deliverability available to customers through a new rate schedule, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

Any questions regarding the proposed project should be directed to Francisco Tarin, Director, Regulatory, P. O. Box 1087, Colorado Springs, Colorado 80944, by phone at (719) 667–7517, or by email at *francisco_tarin@kindermorgan.com.*

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this

[1] 18 CFR (Code of Federal Regulations) 157.9.

Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to intervene is 5:00 p.m. Eastern Time on May 13, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)[2] and 385.211[3] of the Commission's regulations under the NGA, any person[4] may file a protest to the application. Protests must comply with the requirements specified in section 385.2001[5] of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before May 13, 2024.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP24–124–000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at *www.ferc.gov* under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP24–124–000).

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other courier: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,[6] has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure[7] and the regulations under the NGA[8] by the intervention deadline for the project, which is May 13, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP24–124–000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select ''General'' and then select ''Intervention.'' The eFiling feature includes a document-less intervention option; for more information, visit

[2] 18 CFR 157.10(a)(4).

[3] 18 CFR 385.211.

[4] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[5] 18 CFR 385.2001.

[6] 18 CFR 385.102(d).

[7] 18 CFR 385.214.

[8] 18 CFR 157.10.

https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP24–124–000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other courier: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

Protests and motions to intervene must be served on the applicant either by mail or email at: Francisco Tarin, Director, Regulatory, P. O. Box 1087, Colorado Springs, Colorado 80944 or at *francisco_tarin@kindermorgan.com.* Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed [9] motions to intervene are automatically granted by operation of Rule 214(c)(1).[10] Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[11] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Intervention Deadline: 5:00 p.m. Eastern Time on May 13, 2024.

Dated: April 22, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08997 Filed 4–25–24; 8:45 am]

BILLING CODE 6717–01–P

[9] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[10] 18 CFR 385.214(c)(1).

[11] 18 CFR 385.214(b)(3) and (d).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG24–164–000.

Applicants: High River Energy Center, LLC.

Description: High River Energy Center, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 4/19/24.

Accession Number: 20240419–5198.

Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: EG24–165–000.

Applicants: Liberty County Solar Project, LLC.

Description: Liberty County Solar Project, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 4/19/24.

Accession Number: 20240419–5238.

Comment Date: 5 p.m. ET 5/10/24.

Take notice that the commission received the following electric rate filings:

Docket Numbers: ER11–2376–003.

Applicants: Orange and Rockland Utilities, Inc.

Description: Notice of Non-Material Change in Status of Orange and Rockland Utilities, Inc.

Filed Date: 4/19/24.

Accession Number: 20240419–5232.

Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: ER19–289–008; ER19–2462–006; ER18–2264–002.

Applicants: Macquarie Energy Trading LLC, Energy LLC, Cleco Cajun LLC.

Description: Amendment to June 30, 2022 Triennial Market Power Analysis for the Northwest Region of Cleco Cajun LLC, et al.

Filed Date: 4/19/24.

Accession Number: 20240419–5231.

Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: ER24–609–002.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Amendment to Filing, WMPA SA No. 5545; Queue No. AE2–125 to be effective 2/7/2024.

Filed Date: 4/19/24.

Accession Number: 20240419–5195.

Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: ER24–1278–001.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.17(b): Amber Meadow Solar LGIA Amendment Filing to be effective 2/7/2024.

Filed Date: 4/18/24.

Accession Number: 20240418–5206.

Comment Date: 5 p.m. ET 5/9/24.

Docket Numbers: ER24–1791–000.

Applicants: Public Service Company of New Mexico.

Description: § 205(d) Rate Filing: Certificate of Concurrence to Rate Schedule No. 160 to be effective 5/1/2024.

Filed Date: 4/18/24.

Accession Number: 20240418–5232.

Comment Date: 5 p.m. ET 5/9/24.

Docket Numbers: ER24–1792–000.

Applicants: Cald BESS LLC.

Description: Baseline eTariff Filing: Baseline FERC Market-Based Rate Tariff to be effective 4/19/2024.

Filed Date: 4/18/24.

Accession Number: 20240418–5243.

Comment Date: 5 p.m. ET 5/9/24.

Docket Numbers: ER24–1793–000.

Applicants: Northern Indiana Public Service Company LLC.

Description: § 205(d) Rate Filing: Timmons CIAC Agreement to be effective 4/21/2024.

Filed Date: 4/18/24.

Accession Number: 20240418–5245.

Comment Date: 5 p.m. ET 5/9/24.

Docket Numbers: ER24–1794–000.

Applicants: New York Independent System Operator, Inc.

Description: Tariff Amendment: Notice of Cancellation of LGIA SA 2672 among NYISO, LIPA, and Peconic to be effective 6/19/2024.

Filed Date: 4/19/24.

Accession Number: 20240419–5065.
Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: ER24–1795–000.
Applicants: ESV Energy Management, LLC.
Description: Baseline eTariff Filing: ESV Energy Management, LLC MBR Tariff to be effective 6/19/2024.
Filed Date: 4/19/24.
Accession Number: 20240419–5083.
Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: ER24–1796–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2024–04–19_Schedule 27 DAMAP STR Correction to be effective 6/19/2024.
Filed Date: 4/19/24.
Accession Number: 20240419–5087.
Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: ER24–1797–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: Perry Alabama Solar (Perry Solar) LGIA Filing to be effective 4/5/2024.
Filed Date: 4/19/24.
Accession Number: 20240419–5105.
Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: ER24–1798–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: Russell County Solar (Russell Solar) LGIA Filing to be effective 4/5/2024.
Filed Date: 4/19/24.
Accession Number: 20240419–5107.
Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: ER24–1799–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: Alabama Creek Solar LGIA Filing to be effective 4/5/2024.
Filed Date: 4/19/24.
Accession Number: 20240419–5110.
Comment Date: 5 p.m. ET 5/10/24.

Docket Numbers: ER24–1800–000.
Applicants: New York Independent System Operator, Inc.
Description: New York Independent System Operator filed Prospective Waiver Request of MST 5.11.4 and 5.11.4(c) clarifying NYISO may revise Locational Minimum Installed Capacity Requirement for Load Zone J for the 2024–2025 Capability Year.
Filed Date: 4/18/24.
Accession Number: 20240418–5321.
Comment Date: 5 p.m. ET 4/23/24.

Docket Numbers: ER24–1801–000.
Applicants: Public Service Company of Colorado.
Description: Formula Rate Charges and Transmission Formula Rate Charges for 2023 Post-Retirement Benefits Other than Pensions of Public Service Company of Colorado.
Filed Date: 4/16/24.
Accession Number: 20240416–5288.
Comment Date: 5 p.m. ET 5/7/24.

Take notice that the commission received the following electric securities filings:

Docket Numbers: ES24–25–000.
Applicants: PJM Settlement, Inc.
Description: Amendment to Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of PJM Settlement, Inc and Update to Exbibits, C, D & E.
Filed Date: 4/18/24.
Accession Number: 20240418–5324.
Comment Date: 5 p.m. ET 4/29/24.

Docket Numbers: ES24–35–000; ES24–36–000.
Applicants: ATC Management Inc., American Transmission Company LLC.
Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of American Transmission Company LLC, et al.
Filed Date: 4/18/24.
Accession Number: 20240418–5326.
Comment Date: 5 p.m. ET 5/9/24.

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, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Dated: April 19, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08924 Filed 4–25–24; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 6055–008]

Jeffersonville Hydroelectric Co.; Notice of Intent To Prepare an Environmental Assessment

On January 3, 2023, and supplemented May 23, 2023, August 18, 2023, September 19, 2023, and November 6, 2023, Jeffersonville Hydroelectric Co. filed an application for surrender of exemption for the Lake Jefferson Project No. 6055. The project is located on the East Branch Callicoon Creek, in Sullivan County, New York, and does not occupy Federal lands.

The exemptee proposes to surrender the exemption by: (1) leaving the turbines and all generating equipment disconnected from the grid and (2) securing the power generation area of the powerhouse/residence by means of a locked barricade. The exemptee filed the surrender application in response to an ongoing compliance proceeding for the project. The exemptee has been working with the U.S. Fish and Wildlife Service and American Rivers to develop its surrender application. On December 20, 2023, the Commission issued a public notice of the surrender application. On January 19, 2024, the Department of the Interior, on behalf of its component bureau, the Fish and Wildlife Service (FWS), the New York Department of Environmental Conservation, and American Rivers filed notices of intervention. Also on January 19, 2024, the FWS, Markus Booms, and Patrick Boittiaux filed comments.

This notice identifies Commission staff's intention to prepare an environmental assessment (EA) for the project. The planned schedule for the completion of the EA is April 19, 2025.[1]

[1] 42 U.S.C. 4336a(g)(1)(B) requires lead Federal agencies to complete EAs within 1 year of the agency's decision to prepare an EA. This notice

Revisions to the schedule may be made as appropriate. The EA will be issued and made available for review by all interested parties. All comments filed on the EA will be reviewed by staff and considered in the Commission's final decision on the proceeding.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members, and others to access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Any questions regarding this notice may be directed to Jeremy Jessup at (202) 502–6779 or *Jeremy.Jessup@ferc.gov*.

Dated: April 19, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08922 Filed 4–25–24; 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: RP24–677–000.

Applicants: East Cheyenne Gas Storage, LLC.

Description: Annual Gas Report of Operational Purchases and Sales of East Cheyenne Gas Storage, LLC.

Filed Date: 4/19/24.

Accession Number: 20240419–5250.

Comment Date: 5 p.m. ET 5/1/24.

Docket Numbers: RP24–678–000.

Applicants: Eastern Gas Transmission and Storage, Inc.

Description:§ 4(d) Rate Filing: EGTS—April 22, 2024 Administrative Change to be effective 5/22/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5059.

Comment Date: 5 p.m. ET 5/6/24.

Docket Numbers: RP24–679–000.

Applicants: Cove Point LNG, LP.

Description: § 4(d) Rate Filing: Cove Point—April 22, 2024 Administrative Change to be effective 5/22/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5142.

Comment Date: 5 p.m. ET 5/6/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

Filings in Existing Proceedings

Docket Numbers: PR24–53–001.

Applicants: Enable Oklahoma Intrastate Transmission, LLC.

Description: § 284.123(g) Rate Filing: Metadata filing 4–19–24 to be effective 4/1/2024.

Filed Date: 4/19/24.

Accession Number: 20240419–5132.

Comment Date: 5 p.m. ET 5/3/24.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: April 22, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08994 Filed 4–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2736–046]

Idaho Power Company; Notice of Intent To Prepare an Environmental Assessment

On February 14, 2023, Idaho Power Company filed an application for a new major license for the 67.5-megawatt American Falls Hydroelectric Project (American Falls Project; FERC No. 2736). The American Falls project is located on the Snake River in Power County, Idaho, near the city of American Falls, about 25 miles southwest of Pocatello. The project is located at the American Falls Dam, owned and operated by the United States Bureau of Reclamation. The project occupies 7.37 acres of United States land administered by the U.S. Bureau of Reclamation in Power County, Idaho.

In accordance with the Commission's regulations, on February 7, 2024, Commission staff issued a notice that the project was ready for environmental analysis (REA Notice). Based on the information in the record, including comments filed on the REA Notice, staff does not anticipate that licensing the project would constitute a major Federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare a draft and final Environmental Assessment (EA) on the application to relicense the American Falls Project.

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202)502–6595 or *OPP@ferc.gov.*

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

establishes the Commission's intent to prepare an EA for the project; therefore, the EA must be issued within 1 year of the issuance date of this notice.

Milestone	Target date
Commission issues draft EA.	October 2024.
Comments on draft EA due	November 2024.
Commission issues final EA.	April 2025.[1]

Any questions regarding this notice may be directed to Golbahar Mirhosseini at *Golbahar.Mirhosseini@ferc.gov*.

Dated: April 22, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08995 Filed 4–25–24; 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: RP24–675–000.

Applicants: East Cheyenne Gas Storage, LLC.

Description: § 4(d) Rate Filing: ECGS 2024–04–18 Administrative Changes to be effective 5/18/2024.

Filed Date: 4/18/24.

Accession Number: 20240418–5129.

Comment Date: 5 p.m. ET 4/30/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov*.

Dated: April 19, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08923 Filed 4–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–1792–000]

Cald BESS 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 Cald BESS 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 May 13, 2024.

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.

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Dated: April 22, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08989 Filed 4–25–24; 8:45 am]

BILLING CODE 6717–01–P

[1] The Council on Environmental Quality's (CEQ) regulations under 40 CFR 1501.10(b)(1) (2022) require that EAs be completed within 1 year of the Federal action agency's decision to prepare an EA. *See* National Environmental Policy Act, 42 U.S.C. 4321 *et seq., as amended by* section 107(g)(1)(B)(iii) of the Fiscal Responsibility Act of 2023, Pub. L. 118–5, sec. 4336a, 137 Stat. 42.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–1795–000]

ESV Energy Management, 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 ESV Energy Management, 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 May 13, 2024.

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.

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Dated: April 22, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08990 Filed 4–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL24–94–000]

Glover Creek Solar, LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On April 22, 2024, the Commission issued an order in Docket No. EL24–94–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation to determine whether Glover Creek Solar, LLC's Rate Schedule is unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful. *Glover Creek Solar, LLC,* 187 FERC ¶ 61,029 (2024).

The refund effective date in Docket No. EL24–94–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL24–94–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2023), within 21 days of the date of issuance of the order.

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. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202)502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission strongly encourages electronic filings of comments, protests, and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

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Dated: April 22, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08991 Filed 4–25–24; 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 exempt wholesale generator filings:

Docket Numbers: EG24–166–000.

Applicants: North Fork Solar Project, LLC.

Description: North Fork Solar Project, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 4/19/24.

Accession Number: 0240419–5246.

Comment Date: 5 p.m. ET 5/10/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER06–613–000; ER06–613–012.

Applicants: ISO New England Inc., New England Power Pool.

Description: ISO New England Inc. and New England Power Pool Submit semi-annual compliance report re forward reserve market with a motion to terminate.

Filed Date: 4/18/24.

Accession Number: 20240418–5320.

Comment Date: 5 p.m. ET 5/9/24.

Docket Numbers: ER24–1763–001.

Applicants: FRP Tupelo Solar, LLC.

Description: Tariff Amendment: Cost-Based PPA with Seminole Electric Coop., Inc. (ER24–1763–) Amend Metadata to be effective 8/15/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5138.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1780–000.

Applicants: Lake Erie Connector Transmission, LLC.

Description: Lake Erie Connector Transmission, LLC submits a Request for Order Confirming Negotiated Rate Authority and waiver of previously granted reporting requirements.

Filed Date: 4/12/24.

Accession Number: 20240412–5378.

Comment Date: 5 p.m. ET 5/3/24.

Docket Numbers: ER24–1803–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Implementation of Capacity Market Rules Applicable to DER Under Order No. 2222 to be effective 7/1/2023.

Filed Date: 4/22/24.

Accession Number: 20240422–5081.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1804–000.

Applicants: Clearwater Wind III, LLC.

Description: Baseline eTariff Filing: Clearwater Wind III, LLC Application for Market-Based Rate Authorization to be effective 6/22/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5133.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1805–000.

Applicants: ISO New England Inc., New England Power Company.

Description: § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: NEP; Filing of Revisions to Schedule 20A–NEP to be effective 5/1/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5165.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1806–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Initial Filing of Letter Agreement Related to Last Hour to be effective 4/30/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5166.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1807–000.

Applicants: Consolidated Edison Company of New York, Inc.

Description: § 205(d) Rate Filing: Combined RDM Update and Idlewild Cost Recovery 4–2024 to be effective 4/22/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5182.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1808–000.

Applicants: ISO New England Inc., England Power Company.

Description: § 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii: NEP; Filing of Revisions to Schedule 21–NEP to be effective 5/1/2024.

Filed Date: 4/22/24,

Accession Number: 20240422–5188.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1809–000.

Applicants: AEP Texas Inc.

Description: § 205(d) Rate Filing: AEPTX-Oncor Carbon Facilities Development Agreement to be effective 4/5/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5197.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1810–000.

Applicants: FirstEnergy Pennsylvania Electric Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: FirstEnergy Pennsylvania Electric Company submits tariff filing per 35.13(a)(2)(iii: FE PA submits Amended IA, SA No. 4161 re: FirstEnergy Reorganization to be effective 1/1/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5201.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1811–000.

Applicants: AEP Texas Inc.

Description: § 205(d) Rate Filing: AEPTX–BRP Antlia BESS 3rd Amended Generator Interconnection Agreement to be effective 4/5/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5206.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1812–000.

Applicants: AES Redondo Beach, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of MBR Tariff to be effective 4/23/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5226.

Comment Date: 5 p.m. ET 5/13/24.

Docket Numbers: ER24–1813–000.

Applicants: Hoosier Wind Project, LLC.

Description: Tariff Amendment: Notice of Cancellation of MBR Tariff to be effective 4/23/2024.

Filed Date: 4/22/24.

Accession Number: 20240422–5227.

Comment Date: 5 p.m. ET 5/13/24.

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, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

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information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: April 22, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08996 Filed 4–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Staff Attendance at North American Electric Reliability Corporation Working Group and Standard Drafting Meetings

The Federal Energy Regulatory Commission hereby gives notice that members of the Commission and/or Commission staff may attend the following meetings:

North American Electric Reliability Corporation: System Planning Impacts from DER Working Group, WebEx

April 30, 2024 | 9:00 a.m.–5:00 p.m. Eastern

May 1, 2024 | 9:00 a.m.–5:00 p.m. Eastern

Further information regarding this meeting may be found at: *https://www.nerc.com/comm/RSTC/SPIDERWG/SPIDERWG_May_Agenda.pdf.*

North American Electric Reliability Corporation: Project 2022–02 Modifications to PRC–024 (Generator Ride-through) and Project 2023–02 Analysis and Mitigation of BES IBR Performance Issues Joint Drafting Team Meeting, Hybrid

May 7, 2023 | 8:30 a.m.–4:30 p.m. Eastern (Joint Meeting)

North American Electric Reliability Corporation: Project 2022–02 Modifications to PRC–024 (Generator Ride-through) Standard Drafting Team Meeting, Hybrid

May 8, 2023 | 8:30 a.m.–4:30 p.m. Eastern

May 9, 2023 | 8:30 a.m.–4:30 p.m. Eastern

North American Electric Reliability Corporation: Project 2023–02 Analysis and Mitigation of BES Inverter-Based Resource Performance Issues Standard Drafting Team Meeting, Hybrid

May 8, 2023| 9:00 a.m.–5:00 p.m. Eastern

May 9, 2023 | 9:00 a.m.–5:00 p.m. Eastern

Further information regarding these meetings and how to join remotely may be found at: *http://www.nerc.com/Pages/Calendar.aspx.*

The discussions at the meetings, which are open to the public, may address matters at issue in the following Commission proceedings:

Docket No. RR24–2–000 North American Electric Reliability Corporation

For further information, please contact Leigh Anne Faugust (202) 502–6396 or *leigh.faugust@ferc.gov.*

Dated: April 22, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08993 Filed 4–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 703–001, 20–117]

PacifiCorp; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC) regulations, 18 CFR part 380, Commission staff reviewed PacifiCorp's applications, filed with the Commission on March 16, 2023, to decommission project facilities and surrender the Paris Hydroelectric Project (P–703) conduit exemption, and to amend Article 408(b) of its license for the Bear River Hydroelectric Project (P–20) to adjust minimum instream flows in the Grace Development's bypass reach. Commission staff have prepared a single Environmental Assessment (EA) for the proposed surrender of conduit exemption and amendment of license given the inter-relatedness of the proposals. The Paris Hydroelectric Project is located on Paris Creek in Bear Lake County, Idaho and does not occupy Federal lands. The Bear River Hydroelectric Project is located on Bear River is Franklin and Caribou counties, Idaho and occupies Federal lands administered by the Bureau of Land Management.

The EA contains Commission staff's analysis of the potential environmental effects of the proposed surrender of conduit exemption and amendment of license, alternatives to the proposed action, and concludes that the proposed surrender and amendment, with appropriate environmental protective measures, would not constitute a major Federal action that would significantly affect the quality of the human environment.

The EA may be viewed on the Commission's website at *http://www.ferc.gov* using the ''elibrary'' link. Enter the docket numbers (P–703–001 for the Paris Hydroelectric Project, or P–20–117 for the Bear River Hydroelectric Project) in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

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For further information, contact Jennifer Ambler at 202–502–8586 or *jennifer.ambler@ferc.gov,* or Holly Frank at 202–502–6833 or *holly.frank@ferc.gov.*

Dated: April 22, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–08992 Filed 4–25–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–1–000]

Cameron Interstate Pipeline, LLC; Notice of Availability of the Environmental Assessment for the Proposed Holbrook Expansion Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Holbrook Expansion Project, proposed by Cameron Interstate Pipeline, LLC

(CIP) in the above-referenced docket. CIP requests authorization to construct and operate two new natural gas compressor units (42,000 horsepower and 5,350 horsepower), associated aboveground facilities, 1,100 feet of 36-inch-diameter pipeline, and ancillary and auxiliary equipment at its existing Holbrook Compressor Station in Calcasieu Parish, Louisiana. CIP's stated purpose for this Project is to provide up to 1,079,000 dekatherms per day of firm natural gas transportation capacity to the CIP system. This capacity would supply feed gas to the Cameron LNG Terminal (in Cameron Parish, Louisiana) to meet shippers' incremental demand.

The EA assesses the potential environmental effects of the construction and operation of the Holbrook Expansion Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

The Commission mailed a copy of the *Notice of Availability* of the EA to Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; potentially interested Native American Tribes; affected landowners; and newspapers and libraries in the Project area. The EA is only available in electronic format. It may be viewed and downloaded from the FERC's website (*www.ferc.gov*), on the natural gas environmental documents page (*https://www.ferc.gov/industries-data/natural-gas/environment/environmental-documents*). In addition, the EA may be accessed by using the eLibrary link on the FERC's website. Click on the eLibrary link (*https://elibrary.ferc.gov/eLibrary/search*), select ''General Search'' and enter the docket number in the ''Docket Number'' field, excluding the last three digits (*i.e.,* CP24–1). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

The EA is not a decision document. It presents Commission staff's independent analysis of the environmental issues for the Commission to consider when addressing the merits of all issues in this proceeding. Any person wishing to comment on the EA may do so. Your comments should focus on the EA's disclosure and discussion of potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this project, it is important that we receive your comments in Washington, DC on or before 5 p.m. eastern time on May 20, 2024.

For your convenience, there are three methods you can use to file your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. This is an easy method for submitting brief, text-only comments on a project;

(2) You can also file your comments electronically using the eFiling feature on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP24–1–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered. Only intervenors have the right to seek rehearing or judicial review of the Commission's decision. At this point in this proceeding, the timeframe for filing timely intervention requests has expired. Any person seeking to become a party to the proceeding must file a motion to intervene out-of-time pursuant to Rule 214(b)(3) and (d) of the Commission's Rules of Practice and Procedures (18 CFR 385.214(b)(3) and (d)) and show good cause why the time limitation should be waived. Motions to intervene are more fully described at *https://www.ferc.gov/how-intervene.*

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the eLibrary link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

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In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

Dated: April 19, 2024.

Debbie-Anne A. Reese.

Acting Secretary.

[FR Doc. 2024–08925 Filed 4–25–24; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2022–0971; FRL–10181–02–OLEM]

Response to Petition To Classify Discarded Polyvinyl Chloride as RCRA Hazardous Waste

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final petition response.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is responding to a rulemaking petition

from the Center for Biological Diversity requesting that discarded polyvinyl chloride be listed as a hazardous waste under the Resource Conservation and Recovery Act. The Agency published a tentative denial of the rulemaking petition on January 12, 2023. Today, after review of the public comments, EPA is affirming that decision. The petition is denied.

DATES: This final action is effective on April 26, 2024.

FOR FURTHER INFORMATION CONTACT: Daniel Lowrey, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery, (5304T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 202–566–1015; email address: *lowrey.daniel@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

A. Does this action apply to me?

The Agency is not proposing any regulatory changes at this time. Entities that may be interested in this denial of the petition include any facility that manufactures, uses, or generates as waste any materials containing polyvinyl chloride (PVC) or its components. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. How can I get copies of this document and other related information?

1. Docket. EPA has established a docket for this action under Docket ID No. EPA–HQ–OLEM–2022–0971. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays). For further information on the EPA Docket Center services and the current status, see: *https://www.epa.gov/dockets.*

2. Electronic Access. You may access this **Federal Register** document electronically from *https://www.federalregister.gov/documents/current.*

C. List of Abbreviations and Acronyms

CBD Center for Biological Diversity
BBP Butyl benzyl phthalate
DBP Dibutyl phthalate
DEP Diethyl phthalate
DEHP Diethylhexyl phthalate
DIDP Diisodecyl phthalate
DINP Diisononyl phthalate
DMP Dimethyl phthalate
DnOP Di-n-octyl phthalate
EPA Environmental Protection Agency
L liter
mg milligram
PVC Polyvinyl chloride
RCRA Resource Conservation and Recovery Act
TC Toxicity characteristic
TCLP Toxicity characteristic leaching procedure

D. What action is the EPA taking?

The EPA is providing notice of and finalizing its denial of CBD's 2014 rulemaking petition concerning the regulation of discarded polyvinyl chloride (PVC) and associated chemical additives under the Resource Conservation and Recovery Act (RCRA). With this action, the Agency is also publishing its response to public comments on the tentative denial.

E. What is the EPA's authority for taking this action?

On July 24, 2014, the Center for Biological Diversity (CBD) petitioned the EPA to list discarded PVC as a hazardous waste under RCRA (''Petition''). The Agency is responding to this Petition for rulemaking pursuant to 42 U.S.C. 6903, 6921 and 6974, and EPA's implementing regulations at 40 CFR part 260.20, 261.3, 261.10, and 261.11. Authority for the identification and listing of hazardous wastes is granted pursuant to 42 U.S.C. 6903 and 6921, and implementing regulations 40 CFR parts 260 and 261.

F. What are the incremental costs and benefits of this action?

As this action proposes no regulatory changes, this action will have neither incremental costs nor benefits.

II. Background

A. Background on Polyvinyl Chloride

PVC is one of the most common plastics, used in a variety of applications—primarily in the construction industry, but also in packaging and consumer goods (OECD 2022). PVC is formed from the polymerization of vinyl chloride monomer and additives. Additives include stabilizers that limit degradation from sources such as oxygen, heat, light, and flame, and plasticizers that make the PVC more flexible.

All PVC contains stabilizers. Some PVC contains stabilizers containing metals such as barium, cadmium, and/or lead. Other PVC contains stabilizers based on calcium, zinc, and/or tin (Hahladakis et al. 2018; European Commission 2022).

PVC may contain plasticizers, with the concentration and identity of plasticizers varying widely based on the desired properties of the final material. Plasticizers that are phthalates include but are not limited to: di(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), diethyl phthalate (DEP), dimethyl phthalate (DMP), di-n-octylphthalate (DnOP), benzyl butyl phthalate (BBP), diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP) (Hahladakis et al. 2018; Czogała, Pankalla, and Turczyn 2021). Other plasticizers that are not phthalates include adipates and trimellitates. Rigid forms of PVC contain little to no plasticizers while more flexible forms require the addition of more plasticizers.

It is difficult to determine the proportion of PVC products that contain plasticizers because PVC manufacturers and PVC product manufacturers are not generally required to report this information. Typically, plasticizers constitute from zero up to about 50 percent of the product by weight, although higher concentrations have been reported (Hahladakis et al. 2018; Kim et al. 2020; European Commission 2022). Voluntary data from 2000 indicates at least two thirds of PVC is of rigid grades that do not typically contain any amount of plasticizers (Borrelli et al. 2005).

B. How is the EPA addressing discarded PVC?

Separate from the Petition and EPA's action on it, the EPA regulates the management of solid waste, including discarded plastics such as PVC, under RCRA. EPA has established different standards for units accepting different types of non-hazardous waste, see 40

CFR parts 257–258, and RCRA generally prohibits non-compliant ''open dumping'' of non-hazardous solid waste. 42 U.S.C. 6945(a).

The EPA Strategic Plan of 2022–2026 (U.S. EPA 2022) sets forth priorities to reduce waste and prevent environmental contamination (Objective 6.2) including that ''EPA will administer grant programs to improve Tribal, state, and local solid waste management programs and infrastructure and education and outreach on waste prevention. EPA also will address land-based contributions to the mismanagement of post-consumer materials and plastic waste.'' Further information about the management of discarded plastic, including discarded PVC, can be found at *https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/advancing-sustainable-materials-management.*

The EPA Strategic Plan also sets priorities to protect and restore waterbodies and watersheds (Objective 5.2) including that ''EPA also will engage in both domestic and international partnerships to support trash pollution prevention programs, recycling efforts in rural and suburban communities, and waterfront revitalization'' and that EPA will ''[i]mplement programs to prevent or reduce nonpoint source pollution, including nutrients and plastic pollution.'' Further information about the EPA's actions on plastic pollution in bodies of water, including marine plastic pollution as directed by the Save Our Seas 2.0 Act of 2020 (Pub. L. 116–224) signed into law in December 2020, can be found at *https://www.epa.gov/trash-free-waters/trash-free-waters-projects* (EPA 2024a).

In April of 2023 the EPA released for public comment and peer review a draft national strategy to prevent plastic pollution (EPA 2023). Proposed actions from the draft national strategy to prevent plastic pollution (EPA 2024b) include to:

- Reduce the production and consumption of single-use, unrecyclable, or frequently littered plastic products.
- Minimize pollution across the life cycle of plastic products.
- Increase public understanding of the impact of plastic mismanagement and how to appropriately manage plastic products and other waste.
- Identify and implement policies, programs, technical assistance, and compliance assurance actions that effectively prevent trash/microplastics from getting into waterways or remove such waste from waterways once it is there.

C. Regulatory Background

EPA defines hazardous waste for purposes of the RCRA hazardous waste regulations in 40 CFR 261.3. There are three ways by which a solid waste may be listed as hazardous waste under the RCRA hazardous waste regulations. See 40 CFR 261.11(a). Two of these are relevant to the Petition: 40 CFR 261.11(a)(1) and (a)(3).

A solid waste may be listed as a hazardous waste pursuant to 40 CFR 261.11(a)(1) if it ''exhibits any of the characteristics of a hazardous waste.'' The four characteristics of a hazardous waste are found in 40 CFR 261.21–24. The most relevant to the Petition is the toxicity characteristic, found in 40 CFR 261.24. A solid waste exhibits the characteristic of toxicity if it leaches specified toxic contaminants in the toxicity characteristic leaching procedure (TCLP) in excess of the regulatory limit listed in Table 1 of 40 CFR 261.24. See 40 CFR 261.24(a).

A solid waste may be listed as a hazardous waste pursuant to 261.11(a)(3) if ''it contains any of the toxic constituents listed in Appendix VIII [to 40 CFR part 261],'' and the Administrator concludes, after considering eleven factors, that it ''is capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported or disposed of, or otherwise managed.'' 40 CFR 261.11(a)(3). EPA lists hazardous constituents on Appendix VIII to 40 CFR part 261.

Pursuant to 42 U.S.C. 6974, any person may petition the Administrator to conduct a RCRA rulemaking, including requesting a listing of a hazardous waste. EPA's regulations require that ''[a]fter evaluating all public comments the Administrator will make a final decision [on the petition] by publishing in the **Federal Register** a regulatory amendment or a denial of the petition.'' 40 CFR 260.20(e). The regulations require that every petition must include ''a statement of the need and justification for the proposed action, including any supporting tests, studies, or other information.'' 40 CFR 260.20(b)(4). While 40 CFR 260.20 does not provide specific information requirements for hazardous waste listing petitions, EPA has clarified that the information relevant to the listing criteria set forth in 261.11(a) is useful for petitioners to include in such a petition. See 45 FR 33070. Therefore, when a petition requesting a listing of a substance as a hazardous waste, as supplemented by the public comments, provides insufficient information to consider all of the relevant listing criteria under 261.11(a), EPA is not required to grant the petition and may deny the petition as a matter of its discretion for having provided an insufficient justification as required by 260.20(b)(4). EPA's discretion under 260.20 includes the choice of whether to pursue a matter beyond what is provided in the petition and any subsequent public comments, where they fail to provide sufficient indicia of a hazard to human health or the environment.

III. Petition for Rulemaking, EPA's Tentative Denial, and Comments Received

A. Summary of the Petitioner's Requested Changes and EPA's Tentative Denial

On July 24, 2014, the Center for Biological Diversity (CBD) petitioned the EPA to ''promulgate regulations governing the safe treatment, storage and disposal of PVC, vinyl chloride and associated dialkyl- and alkylarylesters of 1,2-benzenedicarboxylic acid, commonly known as phthalate plasticizers.'' In doing so, CBD requested that discarded PVC be listed as a hazardous waste, which would require a narrative listing of discarded PVC from non-specific sources be added to the ''F'' list under 40 CFR 261.31.

On January 12, 2023, the Agency published a tentative denial of the Petition. In the denial, the Agency explained that petitioners had not provided sufficient evidence to support a listing of discarded PVC as a RCRA hazardous waste as the Petition did not provide sufficient information that discarded PVC, under current waste management practices, ''present[s] a substantial present or potential hazard to human health or the environment when solid waste is improperly treated, stored, transported or disposed of, or otherwise managed (40 CFR 261.11).'' Rather, much of the information provided in the Petition concerned potential exposures during the use of PVC as a product. Based on the information provided in the Petition, the Agency proposed to determine that a listing of discarded PVC was unwarranted at this time.

B. Summary of Comments Received

The Agency received public comments on the tentative denial during the 30-day comment period that ran from January 12, 2023, through February 13, 2023. On February 23, 2023, after the comment period had closed, the

Agency received a request to extend the comment period for an additional thirty days following the train derailment in East Palestine, Ohio. The Agency chose not to reopen the comment period because the release in East Palestine, Ohio did not have a direct bearing on the Petition. Furthermore, the Agency had entered into a consent decree with the Center for Biological Diversity (see docket EPA–HQ–OGC–2022–0406) in which the EPA had committed to sign the final determination on the Petition by April 12, 2024 (which the parties subsequently stipulated to extend to April 26, 2024). The requested extension of the comment period could have interfered with meeting that commitment.

The Agency received 4,543 comments on the tentative denial. 63 comments supported the tentative denial, including 2 letter writing campaigns representing approximately 52 of the comments, with 10 substantive and distinct comments. 4,480 comments were opposed to the denial, including a letter writing campaign covering approximately 4464 of the comments, with 3 substantive and distinct comments.

The comments supporting the tentative denial largely echoed the language of EPA's tentative denial, including the lack of evidence in the Petition that discarded PVC meets the 40 CFR 261.11 listing criteria, Agency discretion, the variable composition of PVC, other EPA efforts addressing plastic pollution, and the existing regulations on landfills, incinerators, and toxic contaminants. These commenters also cited recent EPA actions under the Toxic Substances Control Act (TSCA) related to the risk evaluations of vinyl chloride and phthalates and noted that the studies provided by the petitioner related to direct phthalate exposure which, the commenters argued, cannot substitute for evidence of potential exposure or effects from discarded PVC. Additional comments expressed concern about the potential regulatory burden and/or complexity of complying with the changes requested by the Petition, particularly with regard to generator status, regulated medical waste, and recycling/sustainability efforts.

The comments opposed to the denial of the Petition echoed the language of CBD's petition, expressing concern about potential releases of toxic constituents during the manufacture, use, and disposal of PVC. Specific concerns regarding disposal of PVC included plastic pollution and its effect on the environment, the scope of existing regulations, presence in landfills and incinerators, and potential release of hazardous constituents from landfill leachate and incineration. Commenters expressed concern about the potential toxicity of discarded PVC resin apart from any consideration of additives (*i.e.,* phthalate plasticizers and metals from heat stabilizers). Additionally, the petitioner submitted 30 additional scientific studies as support.

Responses to specific comments may be found in the response to comments document published separately in this docket.

IV. Reasons for EPA's Final Denial of the Petition

Pursuant to 40 CFR 260.20, the Petition, as supplemented by public comments, must provide sufficient information to justify the listing of discarded PVC as a hazardous waste. The Petition and public comments fail to do so.

The Petition does not specifically request that EPA list discarded PVC as a hazardous waste pursuant to 40 CFR 261.11(a)(1). However, it does provide some information that could be construed as relevant to a request for such a listing. The Petition does specifically request that EPA conduct a hazardous waste listing pursuant to 40 CFR 261.11(a)(3). Accordingly, EPA has considered information to be relevant to the Petition if it is relevant to either 261.11(a)(1) or (a)(3). EPA proposed to deny the Petition based on the lack of information provided by Petitioners. After considering public comment on the tentative denial, EPA concludes that the Petition, even as supplemented by the information received through the public comment period, still provides insufficient information to justify a listing of discarded PVC as a hazardous waste at this time under either 261.11(a)(1) or 261.11(a)(3).

With respect to 40 CFR 261.11(a)(1), the Petition states that PVC may contain any of the following hazardous contaminants found in Table 1 of 40 CFR 261.24: vinyl chloride monomer (D043), barium (D005), cadmium (D006), and lead (D008). Under EPA's regulations, a solid waste exhibits the hazardous waste characteristic of toxicity (TC) when the values in Method 1311 (TCLP) exceed 0.2 milligrams per liter (mg/L), 100 mg/L, 1 mg/L, and 5 mg/L, respectively, for these contaminants. However, the Petition and comments are insufficient because they do not provide evidence that discarded PVC leaches these hazardous contaminants in excess of their TC regulatory levels. Additionally, EPA is also aware of at least one study suggesting that discarded PVC may not exhibit the hazardous waste characteristic of toxicity for vinyl chloride. Specifically, a survey of American vinyl producers conducted in 2000 found concentrations of residual vinyl chloride monomer to be too low to exceed the vinyl chloride TC regulatory level (Borrelli et al. 2005). That is, the study found that residual vinyl chloride concentrations were less than twenty times the TC regulatory level for vinyl chloride (20×0.2 mg/L = 4 mg/L), which according to agency guidance may be classified as non-hazardous with respect to the presence of vinyl chloride without having to conduct a TCLP test (*https://www.epa.gov/hw-sw846/hazardous-waste-characteristics#question23*). Therefore, given the insufficient information to determine whether hazardous contaminants in discarded PVC exceed their TC regulatory levels, EPA denies the Petition to the extent it requests a listing under 40 CFR 261.11(a)(1).

With respect to 40 CFR 261.11(a)(3), the Petition does provide some evidence that discarded PVC may contain one or more toxic constituents listed in Appendix VIII. Specifically, petitioner provided evidence that discarded PVC contains residual vinyl chloride monomer, and may contain barium, cadmium, lead, DEHP, DBP, DEP, DMP, DnOP, and BBP.

Nevertheless, the Petition, even as supplemented by the information received through the public comment period, does not provide sufficient information that discarded PVC is ''capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported or disposed of, or otherwise managed'' based on the eleven factors provided in 40 CFR 261.11(a)(3). 40 CFR 261.11(a)(3). To determine whether discarded PVC meets the 261.11(a)(3) criteria, EPA must consider eleven factors. The discussion below focusses on factors (ii), (iii), (vii), and (ix), detailing how the Petition and comments received provide insufficient information relevant to these criteria. Petitioner's failure to provide compelling information on these factors is sufficient to support EPA's final denial. EPA is not relying on an evaluation of, and does not intend to imply the sufficiency of, the evidence provided to support the other factors.

EPA received mixed information relevant to factor (ii). Factor (ii) specifies that EPA will consider the concentration of the Appendix VIII constituent in the waste. The petitioner

provided some evidence that discarded PVC may contain residual vinyl chloride monomer, and that the following toxic constituents may be present due to additives: barium, cadmium, lead, DEHP, DBP, DEP, DMP, DnOP, and BBP. To support this, petitioner claimed that barium, cadmium and lead additives are often present in PVC. Petitioner also made generalized claims from a number of limited sources that the listed phthalates are often used by the PVC industry and may constitute up to eighty percent by weight of certain PVC products. However, EPA also received public comments explaining that all of the toxic constituents that petitioners describe have been largely phased out of PVC in the United States over decades, such that, for example, less than 9 percent of new PVC contains any phthalates (including phthalates not listed on Appendix VIII), and the concentration of residual vinyl chloride monomer may be so low as to not be detectable (Vinyl Institute 2023 p 4, 13–14). Given the conflicting information on the prevalence and concentrations constituents in PVC, EPA has determined that the Petition and comments received provide insufficient information to consider the concentration of Appendix VIII constituents in discarded PVC.

EPA received insufficient information relevant to factor (vii). Factor (vii) specifies that EPA will consider plausible types of improper management to which discarded PVC could be subjected. In evaluating this factor, EPA does not consider spills, accidents, or other unlikely scenarios. *See Dithiocarbamate Task Force* v. *EPA,* 98 F.3d 1394, 1400–1401 (D.C. Cir. 1996); 63 FR 64383. Rather, EPA considers the current management practices for the waste at-issue and must identify ''some factual support for a conclusion that a particular mismanagement scenario is plausible.'' *Dithiocarbamate Task Force* at 1400. The Petition relies on the presence of plastic pollution and evidence of phthalate exposure as evidence that mismanagement of discarded PVC has occurred and characterizes—without further elaboration—a limited number of sources for the proposition that marine pollution results from flawed waste management techniques.

These claims are insufficiently supported in several respects. First, management of discarded PVC depends on the type and source of PVC, but may include disposal in construction and demolition landfills, municipal solid waste landfills, or incineration as municipal solid waste. The Petition fails to distinguish between the management practices applicable to the different sources of this PVC waste,[1] and therefore, fails to properly identify potential improper management scenarios, or evaluate their plausibility. Second, the Petition fails to explain what amount of plastic pollution, including marine litter, can be attributed to PVC, as opposed to other forms of plastic. Third, the Petition also fails to explain the extent that this pollution has resulted from mismanagement of discarded PVC, as opposed to other sources such as uncontrolled litter or product use that occurs outside of the current waste management regime.[2] For all of these reasons, the Petition and comments received provide insufficient evidence for EPA to consider the plausible types of improper management to which discarded PVC could be subjected.

EPA also received insufficient information relevant to factors (iii) and (ix). Factor (iii) specifies that EPA will consider the potential of the constituent or any toxic degradation product of the constituent to migrate from the waste into the environment under the types of improper management considered in factor (vii); and factor (ix) specifies that EPA will consider the nature and severity of the human health and environmental damage that has occurred as a result of the improper management of wastes containing the constituent(s). Both of these factors require consideration of plausible mismanagement scenarios. However, as explained above, EPA received insufficient information about the plausible types of mismanagement to which discarded PVC could be subjected. The Petition and comments provided information about potential exposures from the use of PVC products. However, they did not explain why the information is germane to evaluating the potential of the constituent or any toxic degradation product of the constituent to migrate from waste (*i.e.,* discarded PVC) into the environment under the particular environments found in waste management scenarios. Nor did they explain how it is relevant to human health or environmental damage occurring as a result of improper waste management. Finally, the Petition and comments fail to identify any cases or situations where substantial human health or environmental damage has occurred from exposure to hazardous constituents in PVC resulting from the management of discarded PVC.

As such, the Petition fails to provide enough information to compel EPA to list discarded PVC as a hazardous waste. Nor do the Petition and comments include sufficient information of a potential hazard to human health or the environment that would otherwise justify, in the Agency's discretion, initiating a rulemaking procedure to supplement the insufficient information provided in the petition and public comments. Accordingly, EPA has determined that the Petition, even as supplemented by the information received through the public comment period, provides insufficient information to justify granting the petition under 260.20. The petition is denied.

[1] For example, as noted in unit II.B. of this notice, different federal standards apply to different classifications of non-hazardous waste landfills.

[2] See Figure 10 of OECD 2022 for sources of aquatic plastic including product use; See also Table 8 of U.S. EPA 2020, which shows that discarded PVC is less than 3% of the plastic in municipal solid waste.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by the EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. CBD. Petition for Rulemaking Pursuant to Section 7004(a) of the Resource Conservation and Recovery Act, 42 U.S.C. 6974(A), and Section 21 of the Toxic Substances Control Act, 15 U.S.C. 2620, Concerning the Regulation of Discarded Polyvinyl Chloride and Associated Chemical Additives. July 29, 2014.
2. Borrelli, F., de la Cruz, P., and Paradis, R. 2005. Residual Vinyl Chloride Levels in U.S. PVC Resins and Products: Historical Perspective and Update. Journal of Vinyl & Additive Technology, June 2005 65–69. *https://doi.org/10.1002/vnl.20040.*
3. Czogała, J., Pankalla, E., and Turczyn, R. 2021. Recent Attempts in the Design of Efficient PVC Plasticizers with Reduced Migration. Materials (Basel, Switzerland) 14(4): 844. *https://doi.org/10.3390/ma14040844.*
4. European Commission, Directorate-General for Environment. 2022. The use of PVC (poly vinyl chloride) in the context of a non-toxic environment: final report. Publications Office of the European Union. *https://data.europa.eu/doi/10.2779/375357.*
5. Hahladakis, J., Velis, C., Weber, R., Iacovidou, E., and Purnell, P. 2018. An overview of chemical additives present in plastics: Migration, release, fate and environmental impact during their use, disposal and recycling. Journal of

Hazardous Materials 344, 179–199. *https://doi.org/10.1016/j.jhazmat.2017.10.014.*

6. Kim, D.Y.; Chun, S.-H.; Jung, Y.; Mohamed, D.F.M.S.; Kim, H.-S.; Kang, D.-Y.; An, J.-W.; Park, S.-Y.; Kwon, H.-W.; Kwon, J.-H.. 2020. Phthalate Plasticizers in Children's Products and Estimation of Exposure: Importance of Migration Rate. International Journal of Environmental Research. and Public Health, 202017(22) 8582. *https://doi.org/10.3390/ijerph17228582.*
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8. United States Environmental Protection Agency. 2020. Advancing Sustainable Materials Management: Facts and Figures Report, December 2020. *https://www.epa.gov/facts-and-figures-about-materials-waste-and-recycling/advancing-sustainable-materials-management.*
9. United States Environmental Protection Agency. 2022. FY 2022–2026 EPA Strategic Plan. Washington, DC: U.S. Environmental Protection Agency, March 2022. Periodical. *https://www.epa.gov/system/files/documents/2022-03/fy-2022-2026-epa-strategic-plan.pdf.*
10. United States Environmental Protection Agency. 2023. Draft National Strategy to Prevent Plastic Pollution: Executive Summary, April 2023. *https://www.epa.gov/system/files/documents/2023-04/Draft_National_Strategy_to_Prevent_Plastic_Pollution_Executive_Summary.pdf.*
11. United States Environmental Protection Agency. 2024a. Trash Free Waters Projects, Retrieved March 28, 2024. *https://www.epa.gov/trash-free-waters/trash-free-waters-projects.*
12. United States Environmental Protection Agency. 2024b. Draft National Strategy to Prevent Plastic Pollution, Retrieved March 28, 2024. *https://www.epa.gov/circulareconomy/draft-national-strategy-prevent-plastic-pollution.*
13. Vinyl Institute. 2023. Public Comment. EPA–HQ–OLEM–2022–0971–0028 Attachment 1.

Michael S. Regan,

Administrator.

[FR Doc. 2024–09031 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2003–0033; FRL—11929–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Modification of Secondary Treatment Requirements for Discharges Into Marine Waters (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Modification of Secondary Treatment Requirements for Discharges into Marine Waters (EPA ICR Number 0138.13, OMB Control Number 2040–0088) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through April 30, 2024. Public comments were previously requested via the **Federal Register** on August 4, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before May 28, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OW–2003–0033, to EPA online using *www.regulations.gov* (our preferred method), by email to *OW-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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.

FOR FURTHER INFORMATION CONTACT: Virginia Fox-Norse, Oceans, Wetlands and Communities Division, Office of Water, (4504T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202 566–1266; email address: *fox-norse.virginia@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through April 30, 2024. 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.

Public comments were previously requested via the **Federal Register** on August 4, 2023, during a 60-day comment period (88 FR 51813). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The Clean Water Act (CWA) section 301(h) allows for a case-by-case review of treatment requirements for publicly owned treatment works (POTW) discharges to marine waters. Eligible POTWs that met the set of environmentally stringent criteria in CWA section 301(h) received a modified National Pollutant Discharge Elimination System permit waiving the secondary treatment requirements for the conventional pollutants-biochemical oxygen demand, suspended solids, and pH. CWA section 301(h) only applies to the 25 POTWs that currently hold CWA 301(h) modified permits. No new applications are accepted. The CWA section 301(h) program involves collecting information from two sources: 1) the POTW, and 2) the state in which the POTW is located. The POTW holding or seeking to renew or revise a CWA section 301(h) modified permit provides application, reapplication, monitoring, and toxic control program information to demonstrate that its discharge meets and continues to meet all the CWA section 301(h) environmental criteria. The state provides state determination and certification information.

Form Numbers: None.

Respondents/affected entities: Municipalities that currently have CWA section 301(h) modifications from secondary treatment, or have applied for

a renewal of a CWA section 301(h) modified permit, and the states within which these municipalities are located.

Respondent's obligation to respond: Voluntary, required to obtain or retain a benefit. (40 CFR part 125 subpart G, 40 CFR 124.53 and 124.54).

Estimated number of respondents: 30 (total).

Frequency of response: From once every five years, to varies case-by-case, depending on the category of information.

Total estimated burden: 44,985 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $1,418,675 (per year), which includes no annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no increase in hours in the total estimated respondent burden compared with the ICR currently approved by OMB. There is no change in program requirements, nor program status, information needs, and use of technology.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–08983 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10891–01–OAR]

California State Nonroad Engine Pollution Control Standards; In-Use Diesel-Fueled Transport Refrigeration Units (TRU) and TRU Generator Sets and In-Use Off-Road Diesel Fueled Fleets; Requests for Authorization; Opportunity for Public Hearing and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of opportunity for public hearing and comment.

SUMMARY: The California Air Resources Board (CARB) has notified the EPA that it has adopted amendments to its In-Use Diesel-Fueled Transport Refrigeration Units (TRU) and TRU Generator Sets (collectively, ''TRU'') regulations. By letter dated December 29, 2022, CARB requested that the EPA authorize the amendments pursuant to section 209(e) of the Clean Air Act (CAA). CARB has also notified EPA that it has adopted amendments to its In-Use Off-Road Diesel-Fueled Fleets (''Offroad Fleets'') regulations. By letter dated November 2, 2023, CARB requested that the EPA authorize the amendments pursuant to section 209(e) of the CAA. This notice announces that the EPA will hold a public hearing to consider California's authorization requests and that the EPA is now accepting written comments on the requests.

DATES:

Comments: Written comments must be received on or before June 19, 2024.

Public Hearing: The EPA will hold public hearings on May 16, 2024, regarding each of CARB's authorization requests. See **SUPPLEMENTARY INFORMATION** for further information on the virtual public hearings, the specific time of day associated with each authorization request, and registration. Additional information regarding the virtual public hearing and the TRU action can be found at: *https://www.epa.gov/regulations-emissions-vehicles-and-engines/virtual-public-hearing-californias-tru.* Additional information regarding the virtual public hearing and the Offroad Fleets action can be found at: *https://www.epa.gov/regulations-emissions-vehicles-and-engines/virtual-public-hearing-californias-use-road-diesel.*

ADDRESSES:

Comments: You may submit your comments, identified by Docket ID No. EPA–HQ–OAR–2024–0030 (for the TRU action) and by Docket ID. No. EPA–HQ–OAR–2023–0581 (for the Offroad Fleets action) by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.*
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, OAR, Docket EPA–HQ–OAR–2024–0030 (for the TRU action) or Docket EPA–HQ–OAR–2023–0581 (for the Offroad Fleets action), Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier (by scheduled appointment only:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except federal holidays).

Instructions: All submissions received must include the Docket ID No. for one or both of these actions. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on the process for these actions, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. For the full EPA public comment policy, information about confidential business information (CBI) or multimedia submissions, and general guidance on making effective comments, please visit: *http://www.epa.gov/dockets/commenting-epa-dockets.*

Public Hearing: The virtual public hearings will be held on May 16, 2024. The hearing for the TRU authorization request will begin at 10:00 a.m. Eastern Daylight Time and will end approximately at 1:00 p.m. or when all parties who wish to speak have had an opportunity to do so. The hearing for the Offroad Fleets authorization request will begin at 2:00 p.m. Eastern Daylight Time and will end when all parties who wish to speak have had an opportunity to do so. All hearing attendees, for those wishing to attend either the morning hearing or afternoon hearing for the TRU or Offroad Fleets authorization request, respectively (including even those who do not intend to provide testimony), should register for the respective public hearing(s) by May 9, 2024. Information on how to register for the virtual public hearing regarding the TRU authorization request can be found at: *https://www.epa.gov/regulations-emissions-vehicles-and-engines/virtual-public-hearing-californias-tru.* Information on how to register for the virtual public hearing regarding the Offroad Fleets authorization request can be found at: *https://www.epa.gov/regulations-emissions-vehicles-and-engines/virtual-public-hearing-californias-use-road-diesel.*

FOR FURTHER INFORMATION CONTACT: Mark Coryell, Office of Transportation and Air Quality, U.S. Environmental Protection Agency; Telephone number: (734) 214–4446; Email address: *coryell.mark@epa.gov.* Jeremy O'Kelly, Office of Transportation and Air Quality, U.S. Environmental Protection Agency; Telephone number: (202) 250–8884; Email address: *okelly.jeremy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. CARB's TRU Authorization Request

CARB's December 29, 2022, letter to the EPA Administrator notified the EPA that CARB had amended its In-Use Diesel-Fueled Transport Refrigeration Units (TRU) and TRU Generator Sets (collectively, ''TRU'') regulations (the TRU Amendments).[1] The TRU Amendments, adopted by the Board on

[1] Title 13, California Code of Regulations, section 2477. EPA granted an authorization for California's initial set of TRU regulations on January 16, 2009. EPA also granted a within-the-scope authorization for amendments to the TRU regulations, adopted in 2010, on June 28, 2013 (78 FR 38970).

February 24, 2022, contain several provisions including, but not limited to, a requirement that certain TRUs manufactured after a certain date use a refrigerant less than or equal to a specified global warming potential (GWP), a requirement that non-truck TRUs meet specified particulate matter (PM) standards, a requirement that TRU owners transition a percentage of their truck fleet TRUs to zero-emission technology, and a requirement that owners of certain facilities are subject to registration and reporting requirements.[2]

II. CARB's Offroad Fleets Authorization Request

CARB's November 2, 2023, letter to the EPA Administrator notified the EPA that CARB had amended its In-Use Off-Road Diesel-Fueled Fleets regulations (Offroad Fleets Amendments).[3] The Offroad Fleets Amendments, adopted by the Board on December 8, 2022, primarily require fleets of in-use off-road diesel-fueled vehicles to phase out the operation of their oldest and highest-emitting diesel vehicles and prohibit such fleets from acquiring high-emitting vehicles. The Offroad Fleets Amendments also require fleets to fuel their vehicles with specified renewable diesel. Further, the Amendments establish administrative requirements for prime contractors and public works awarding bodies.[4]

III. Scope of Preemption and Criteria for an Authorization Under the Clean Air Act

Section 209(e)(1) of the CAA prohibits all states and local governments from adopting or attempting to enforce any standard or other requirement relating to the control of emissions from certain types of new nonroad engines or nonroad vehicles, including both ''(A) New engines which are used in construction equipment or vehicles or used in farm equipment or vehicles and which are smaller than 175 horsepower'' and ''(B) New locomotives or new engines used in locomotives.'' [5] Section 209(e)(2)(A) of the CAA, however, requires the Administrator, after notice and opportunity for public hearing, to authorize California to adopt and enforce standards and other requirements relating to the control of emissions from nonroad engines and vehicles otherwise not prohibited under section 209(e)(1) if California determines that California standards will be, in the aggregate, at least as protective of public health and welfare as are applicable Federal standards. However, the EPA shall not grant such authorization if it finds that (1) the determination of California is arbitrary and capricious; (2) California does not need such California standards to meet compelling and extraordinary conditions; or (3) California standards and accompanying enforcement procedures are not consistent with [CAA section 209].[6]

On July 20, 1994, the EPA promulgated a rule that sets forth, among other things, regulations providing the criteria, as found in section 209(e)(2)(A), that the EPA must consider before granting any California authorization request for nonroad engine or vehicle emission standards.[7] The EPA revised these regulations in 1997.[8] The criteria for granting California authorization requests, as reflected in section 209(e)(2)(A), can be found at 40 CFR 1074.105.

As stated in the preamble to the 1994 rule, the EPA has historically interpreted the section 209(e)(2)(A)(iii) ''consistency'' inquiry (see 40 CFR 1074.105(b)(3)) to require, at minimum, that California standards and enforcement procedures be consistent with section 209(a), section 209(e)(1), and section 209(b)(1)(C) (as the EPA has interpreted that subsection in the context of section 209(b) motor vehicle waivers).[9]

In order to be consistent with section 209(a), California's nonroad standards and enforcement procedures must not apply to new motor vehicles or new motor vehicle engines. To be consistent with section 209(e)(1), California's nonroad standards and enforcement procedures must not attempt to regulate engine categories that are permanently preempted from state regulation (such as ''. . . any standard or other requirement relating to the control of emissions from . . . (A) New engines which are used in construction equipments or vehicles or used in farm equipment or vehicles and which are smaller than 175 horsepower. (B) New locomotives or new engines used in locomotives.'').

To determine consistency with section 209(b)(1)(C), EPA typically reviews nonroad authorization requests under the same ''consistency'' criteria that are applied to motor vehicle waiver requests. Pursuant to section 209(b)(1)(C), the Administrator shall not grant California a motor vehicle waiver if he finds that California ''standards and accompanying enforcement procedures are not consistent with section 202(a)'' of the Act. Previous decisions granting waivers and authorizations have noted that state standards and enforcement procedures are inconsistent with section 202(a) if: (1) there is inadequate lead time to permit the development of the necessary technology giving appropriate consideration to the cost of compliance within that time, or (2) the federal and state testing procedures impose inconsistent certification requirements.[10]

III. EPA's Request for Comments

We request comment on whether the TRU Amendments meet the criteria for an EPA authorization. Specifically, we request comment on: (a) whether CARB's determination that its standards, in the aggregate, are at least as protective of public health and welfare as applicable federal standards is arbitrary and capricious, (b) whether California needs such standards to meet compelling and extraordinary conditions, and (c) whether California's standards and accompanying enforcement procedures are consistent with section 209 of the Act. As explained above, the EPA considers several provisions with regard to the consistency with section 209 of the Act criterion.

We also request comment on whether the Offroad Fleets Amendments meet the criteria for an EPA authorization. Specifically, we request comment on: (a) whether CARB's determination that its standards, in the aggregate, are at least as protective of public health and welfare as applicable federal standards is arbitrary and capricious, (b) whether California needs such standards to meet compelling and extraordinary conditions, and (c) whether California's standards and accompanying enforcement procedures are consistent with section 209 of the Act. As

[2] CARB's Authorization Support Document at 4–9 (EPA Docket: EPA–HQ–OAR–2024–0030). A description of CARB's 2022 TRU Amendments can be found in the Authorization Support Document submitted by CARB along with associated attachments that can be found in the EPA docket for this matter.

[3] Title 13, California Code of Regulations, sections 2449, 2449.1, and 2449.2. In 2013, EPA issued an authorization for CARB's initial Offroad Fleets adopted in 2007 and amended in 2009 and 2010 (78 FR 58090 (Sept. 20, 2013)).

[4] CARB's Authorization Support Document at 4–10 (EPA Docket: EPA–HQ–OAR–2023–0581). A description of CARB's Offroad Fleets Amendments can be found in the Authorization Support Document submitted by CARB along with associated attachments that can be found in the EPA docket for this matter.

[5] 42 U.S.C 7543(e)(1).

[6] 42 U.S.C. 7543(e)(2)(A).

[7] 59 FR 36969 (July 20, 1994).

[8] 62 FR 67733 (December 30, 1997). The preemption regulations were later transcribed at 40 CFR part 1074; see 73 FR 59034 (Oct. 8, 2008).

[9] 59 FR 36969 (July 20, 1994).

[10] 78 FR 58090, 58092 (September 20, 2013).

explained above, the EPA considers several provisions with regard to the consistency with section 209 of the Act criterion.

IV. Procedures for Public Participation

The virtual public hearings will be held on May 16, 2024. The hearing for the TRU authorization request will begin at 10:00 a.m. Eastern Daylight Time and will end approximately at 1:00 p.m. or when all parties who wish to speak have had an opportunity to do so. The hearing for the Offroad Fleets authorization request will begin at 2:00 p.m. Eastern Daylight Time and will end when all parties who wish to speak have had an opportunity to do so.

All hearing attendees, for those wishing to attend either the morning or afternoon hearings for TRU or Offroad Fleets, respectively (including even those who do not intend to provide testimony,) should register for the respective public hearing(s) by May 9, 2024. Information on how to register for the virtual public hearing regarding the TRU authorization request can be found at: *https://www.epa.gov/regulations-emissions-vehicles-and-engines/virtual-public-hearing-californias-tru.* Information on how to register for the virtual public hearing regarding the Offroad Fleets authorization request can be found at: *https://www.epa.gov/regulations-emissions-vehicles-and-engines/virtual-public-hearing-californias-use-road-diesel.*

Those seeking to register should do so by May 9, 2024. If you require the services of a translator or special accommodations such as American Sign Language, please pre-register for the hearing and describe your needs by May 9, 2024. The EPA may not be able to arrange accommodations without advance notice. Please note that any updates made to any aspect of the TRU authorization hearing will be posted online at: *https://www.epa.gov/regulations-emissions-vehicles-and-engines/virtual-public-hearing-californias-tru.* Please also note that any updates to any aspect of the Offroad Fleets authorization hearing will be posted online at: *https://www.epa.gov/regulations-emissions-vehicles-and-engines/virtual-public-hearing-californias-use-road-diesel.* While the EPA expects the hearings to go forward as set forth above, please monitor the respective hearing websites or contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

Each commenter will have 3 minutes to provide oral testimony. The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. The EPA recommends submitting the text of your oral comments as written comments to the docket for the respective authorization request. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the public hearing for the respective authorization request. The Agency will make a verbatim record of the proceedings at each hearing that will be placed in the respective TRU and Offroad Fleets dockets. The EPA will keep the record open until June 19, 2024, for each authorization request. After expiration of the comment period, the Administrator will render decisions on CARB's requests based on the record of the public hearing, relevant written submissions, and other information that he deems pertinent.

William Charmley,

Director, Assessment and Standards Division, Office of Transportation and Air Quality.

[FR Doc. 2024–08927 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2024–0192; FRL–11917–01–OGC]

Proposed Consent Decrees, Toxic Substances Control Act Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decrees; request for public comment.

SUMMARY: Notice is given of proposed consent decrees to address lawsuits filed by Community In-Power and Development Association Inc., Learning Disabilities Association of America, Louisiana Environmental Action Network, Sierra Club, and Texas Environmental Justice Advocacy Services (collectively, ''CIDA Plaintiffs'') in the United States District Court for the District of Columbia on September 18, 2023: *Community In-Power and Development Association Inc.* v. *EPA,* Case No. 1:23-cv-02715 (D.D.C.) (the ''CIDA action'') and by American Chemistry Council (''ACC'') in the same court on December 19, 2023: *ACC* v. *EPA,* Case No. 1:23-cv-03726 (D.D.C.) (the ''ACC action''). The cases were consolidated on January 17, 2024. The CIDA Plaintiffs and ACC filed the cases pursuant to the Toxic Substances Control Act (''TSCA''), alleging that EPA failed to perform non-discretionary duties under TSCA to timely complete several risk evaluations. EPA is providing notice of the proposed consent decrees, which would resolve all claims in both cases by establishing deadlines for EPA to take action on the subject risk evaluations.

DATES: Written comments on the proposed consent decrees must be received by May 28, 2024.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0192, online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Consent Decrees'' heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Stephanie Schwarz, Pesticides and Toxic Substances Law Office, Office of General Counsel, U.S. Environmental Protection Agency; telephone (202) 564–8496; email address *schwarz.stephanie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Copies of the Proposed Consent Decrees

The official public docket for this action (Docket ID No. EPA–HQ–OGC–2024–0192) contains copies of the proposed consent decrees. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the OEI Docket is (202) 566–1752.

The electronic version of the public docket for this action contains copies of the proposed consent decrees and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit

or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About Commenting on the Proposed Consent Decrees

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2024–0192, via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* 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. 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://www.epa.gov/dockets/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

In accordance with the EPA's ''Consent Decrees and Settlement Agreements to Resolve Environmental Claims Against the Agency'' (March 18, 2022), for a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to a proposed consent decrees for these claims. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decrees if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, or inadequate.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Randolph L. Hill,

Associate General Counsel.

[FR Doc. 2024–08936 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11921–01–R1]

2024 Annual Joint Meeting of the Ozone Transport Commission and the Mid-Atlantic Northeast Visibility Union

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; public meeting.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing the 2024 Annual Joint Meeting of the Ozone Transport Commission (OTC) and the Mid-Atlantic Northeast Visibility Union (MANEVU). The meeting agenda will include topics covering OTC and MANEVU activities to reduce regional ground-level ozone precursors and visibility-impairing fine particles.

DATES: The public meeting will be held on June 13, 2024, starting at 9 a.m. and ending at 3 p.m.

Location: Portland, Maine. Further information on the details is available at *http://otcair.org.*

FOR FURTHER INFORMATION CONTACT:

For documents and press inquiries contact: Ozone Transport Commission, 89 South St., Suite 602, Boston, MA 02111; (617) 259–2005; email: *ozone@otcair.org;* website: *http://www.otcair.org.*

For registration: To register for the meeting, please use the online registration form available at *http://otcair.org,* or contact the OTC at (617) 259–2005 or by email at *ozone@otcair.org.*

SUPPLEMENTARY INFORMATION: The Clean Air Act Amendments of 1990 contain section 184 provisions for the Control of Interstate Ozone Air Pollution. Section 184(a) establishes an Ozone Transport Region (OTR) comprised of the States of Connecticut, Delaware, Maine,[1] Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, parts of Virginia, and the District of Columbia. The purpose of the OTC is to address ground-level ozone formation, transport, and control within the OTR.

MANEVU was formed in 2001, in response to EPA's issuance of the Regional Haze Rule. MANEVU's members include Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, the Penobscot Indian Nation, and the St. Regis Mohawk Tribe, along with EPA and Federal Land Managers.

Type of Meeting: Open.

Agenda: Copies of the final agenda are available from the OTC office at (617) 259–2005, by email: *ozone@otcair.org,* or via the OTC website at *http://www.otcair.org.*

Dated: April 22, 2024.

David Cash,

Regional Administrator, EPA Region 1.

[FR Doc. 2024–08929 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P

[1] The geographic scope of Maine within the OTR was subsequently reduced to the portion of Maine encompassing 111 towns and cities comprising the Androscoggin Valley, Down East, and Metropolitan Portland Air Quality Control Regions, commonly referred to as the ''Portland and Midcoast Ozone Areas.'' 87 FR 7734 (February 10, 2022).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2019–0558, FRL–11931–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; RCRA Subtitle C Reporting Instructions and Forms (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), RCRA Subtitle C Reporting Instructions and Forms (EPA ICR Number 0976.20, OMB Control Number 2050–0024) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through April 30, 2024. Public comments were previously requested via the **Federal Register** on September 6, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before May 28, 2024.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OLEM–2018–0534, to EPA online using *www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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.

FOR FURTHER INFORMATION CONTACT: Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–566–0453; *vyas.peggy@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through December 31, 2023. 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.

Public comments were previously requested via the **Federal Register** on September 6, 2023 during a 60-day comment period (88 FR 60939). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: Under the authority of the Resource Conservation and Recovery Act of 1976 (RCRA), as amended, Congress directed the U.S. Environmental Protection Agency to implement a comprehensive program for the safe management of hazardous waste. In addition, Congress wrote that ''[a]ny person may petition the Administrator for the promulgation, amendment or repeal of any regulation'' under RCRA (section 7004(a)). 40 CFR parts 260 and 261 contain provisions that allow regulated entities to apply for petitions, variances, exclusions, and exemptions from various RCRA requirements.

The following are some examples of information required from petitioners under 40 CFR part 260. Under § 260.20(b), all rulemaking petitioners must submit basic information with their demonstrations, including name, address, and statement of interest in the proposed action. Under § 260.21, all petitioners for equivalent testing or analytical methods must include specific information in their petitions and demonstrate to the satisfaction of the Administrator that the proposed method is equal to, or superior to, the corresponding method in terms of its sensitivity, accuracy, and reproducibility. Under § 260.22, petitions to amend part 261 to exclude a waste produced at a particular facility (more simply, to delist a waste) must meet extensive informational requirements. When a petition is submitted, the Agency reviews materials, deliberates, publishes its tentative decision in the **Federal Register**, and requests public comment. The EPA also may hold informal public hearings (if requested by an interested person or at the discretion of the Administrator) to hear oral comments on its tentative decision. After evaluating all comments, the EPA publishes its final decision in the **Federal Register**.

With this renewal, this ICR will no longer include the burden associated with the disposal of coal combustion residuals (CCR) from electric utilities as solid waste under Subtitle D of RCRA, found at 40 CFR part 257, subpart D. That burden is covered by OMB Control No. 2050–0223.

Form Numbers: 8700–12; 8700–13 A/B; 8700–23.

Respondents/affected entities: Entities potentially affected by this action are the private sector, as well as State, Local, or Tribal Governments.

Respondent's obligation to respond: Required to obtain or retain a benefit (RCRA Sections 1008, 4004, 4005(a)).

Estimated number of respondents: 59,418.

Frequency of response: Biennially.

Total estimated burden: 730,323 hours. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $282,918 in annualized capital or O&M costs.

Changes in the Estimates: There is a decrease of 79,059 hours and $60,098 from the previously finalized/approved ICR. The reason for the decrease is largely because the burden associated with the CCR program was removed from this ICR and merged with OMB Control No. 2050–0223.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–09036 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11900–01–R8]

Clean Air Act Operating Permit Program; Order on Petition for Objection to State Operating Permits for Bonanza Creek Energy Operating Company, LLC: Antelope CPF 13–21 Production Facility, State Antelope O–1 Central Production Facility, State North Platte 42–26 Central Production Facility and State Pronghorn 41–32 Central Production Facility

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition.

SUMMARY: The Environmental Protection Agency (EPA) Administrator signed an order dated January 30, 2024, granting a petition dated August 7, 2023, from the Center for Biological Diversity, Public Employees for Environmental Responsibility, 350 Colorado, Sierra Club and Green Latinos. The petition requested that the EPA object to the Clean Air Act (CAA) operating permits issued by the Colorado Department of Public Health and Environment (CDPHE) to Bonanza Creek Energy Operating Company, LLC for its Antelope CPF 13–21 Production Facility, State Antelope O–1 Central Production Facility, State North Platte 42–26 Central Production Facility and State Pronghorn 41–32 Central Production Facility, all located in Weld County, Colorado.

FOR FURTHER INFORMATION CONTACT: Donald Law, EPA Region 8, telephone number: (303) 312–7015, email address: *law.donald@epa.gov*. The final order and petition are available electronically at: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.*

SUPPLEMENTARY INFORMATION: The EPA received a petition from the Center for Biological Diversity, Public Employees for Environmental Responsibility, 350 Colorado, Sierra Club and Green Latinos dated August 7, 2023, requesting that the EPA object to the issuance of operating permits no. 20OPWE417, 20OPWE418, 20OPWE419 and 20OPWE420 issued by CDPHE to Bonanza Creek Energy Operating Company, LLC in Weld, Colorado. On January 30, 2024, the EPA Administrator issued an order granting the petition. The order itself explains the basis for the EPA's decision.

Sections 307(b) and 505(b)(2) of the CAA provide that a petitioner may request judicial review of those portions of an order that deny issues in a petition. Any petition for review shall be filed in the United States Court of Appeals for the appropriate circuit no later than June 25, 2024.

KC Becker,

Regional Administrator, Region 8.

[FR Doc. 2024–09032 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL OP–OFA–123]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed April 15, 2024 10 a.m. EST

Through April 22, 2024 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxapps.epa.gov/cdx-enepa-II/public/action/eis/search*.

EIS No. 20240073, Final, BLM, AK, Central Yukon Resource Management Plan, Review Period Ends: 05/28/2024, Contact: Melinda Bolton 907–271–3342.

EIS No. 20240074, Final Supplement, BLM, AK, Ambler Road Final Supplemental Environmental Impact Statement, Review Period Ends: 05/28/2024, Contact: Stacie McIntosh 907–474–2398.

Dated: April 22, 2024.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2024–08972 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0678; FR ID 216076]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before May 28, 2024.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, and (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a)

whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–0678.

Title: Part 25 of the Federal Communications Commission's Rules Governing the Licensing of, and Spectrum Usage by, Commercial Earth Stations and Space Stations.

Form Number: FCC Form 312 (Main Form and Schedules A, B, and S), FCC Form 312–R.

Type of Review: Revision of an existing collection.

Respondents: Business or other for-profit entities, not-for-profit institutions.

Number of Respondents and Responses: 3,515 respondents and 3,567 responses.

Estimated Time per Response: 0.5–80 hours.

Frequency of Response: On occasion, one time, and annual reporting requirements; third-party disclosure requirement; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The Commission has statutory authority for the information collection requirements under 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, and 721.

Total Annual Burden: 27,176.

Annual Cost Burden: $3,923,887.

Needs and Uses: The Federal Communications Commission requests that the Office of Management and Budget (OMB) approve a revision of the information collection titled ''Part 25 of the Federal Communications Commission's Rules Governing the Licensing of, and Spectrum Usage By, Commercial Earth Stations and Space Stations'' under OMB Control No. 3060–0678, as a result of three recent rulemakings, as well as an update to the Commission's filing system for earth station and space station applications filed pursuant to part 25 of the Commission's rules.

On September 27, 2019, the Commission released a Report and Order, FCC 19–93, in IB Docket No. 06–160, titled ''Amendment of the Commission's Policies and Rules for Processing Applications in the Direct Broadcast Satellite Service'' (*DBS Licensing Report and Order*). The *DBS Licensing Report and Order* adopted a new licensing process for space stations in the Direct Broadcast Satellite Service (DBS). This new process allows applicants for DBS space station licenses to take advantage of a licensing process that parallels the Commission's streamlined part 25 satellite licensing rules for geostationary orbit (GSO) space stations in the fixed-satellite service (FSS). The Commission limited the regulatory burdens borne by applicants, while promoting new opportunities for efficient use of orbital spacing and spectrum by DBS licensees.

The Commission's action supports and encourages the increasing innovation in the DBS sector and helps to preserve U.S. leadership in space-based services and operations. This information collection will provide the Commission and the public with necessary information about this area of satellite operations. While this information collection represents an overall increase in the burden hours, the increase is due to an anticipated overall increase in number of applications as a result of additional applications being filed under the process adopted in the *DBS Licensing Report and Order.* This information collection serves the public interest by streamlining the collection of information and allowing the Commission to authorize DBS space stations under the new process established in the Report and Order. Specifically, the *DBS Licensing Report and Order* contains the following new or modified information collection requirements: space station applications for GSO space stations operating in the frequencies of the International Telecommunication Union (ITU) Appendices 30 and 30A (incorporated by reference, see 47 CFR 25.108) must include a statement that the proposed operation will take into account the applicable requirements of these Appendices of the ITU Radio Regulations and a demonstration that it is compatible with other U.S. ITU filings under Appendices 30 and 30A or, for any affected filings, a letter signed by the affected operator indicating that it consents to the new application. The changes adopted in the *DBS Licensing Report and Order* will result in a very small net annualized increase in burden hours to certain applicants and licensees under part 25. A request for revisions to the information collection resulting from *DBS Licensing Report and Order* was previously published in the **Federal Register** (see 85 FR 41980), but it has been updated and is now included in this revision request.

On November 19, 2020, the Commission released a Report and Order, FCC 20–159, in IB Docket No. 18–314, titled ''Further Streamlining Part 25 Rules Governing Satellite Services'' (*Satellite Services Report and Order*). The *Satellite Services Report and Order* streamlined the Commission's rules governing satellite services by creating an optional framework for authorizing both the blanket-licensed earth stations and space stations of a satellite system through a unified license. The *Satellite Services Report and Order* also permitted earth station applicants to certify compliance with relevant satellite licenses in lieu of providing duplicative or unnecessary technical demonstrations, aligned the build-out requirements for earth stations and space stations, and eliminated unnecessary reporting rules. These changes reduce regulatory burdens, simplify the Commission's licensing of satellite systems, and provide additional operational flexibility. The *Satellite Services Report and Order* affected two information collections: OMB Control Numbers 3060–1215 and 3060–0678. The Commission received OMB approval for changes under OMB Control No. 3060–1215 on August 26, 2021, as reported in 86 FR 52102. The Commission seeks approval for changes under OMB Control No. 3060–0678 through this request. The changes adopted in the *Satellite Services Report and Order* will result in a net annualized decrease in burden hours to applicants and licensees under part 25. This submission amends the previous submission to the OMB to reflect these changes.

On August 3, 2022, the Commission released a Report and Order, FCC 22–63, in IB Docket Nos. 20–330 and 22–273, titled ''Amendment of Parts 2 and 25 of the Commission's Rules to Enable GSO Fixed-Satellite Service (Space-to-Earth) Operations in the 17.3–17.8 GHz Band, to Modernize Certain Rules Applicable to 17/24 GHz BSS Space Stations, and to Establish Off-Axis Uplink Power Limits for Extended Ka-Band FSS Operations'' (*17 GHz Report and Order*). In the *17 GHz Report and Order,* the Commission amended its rules to permit geostationary satellite orbit (GSO) space stations to use the 17.3–17.7 GHz band by geostationary satellite orbit (GSO) space stations in the fixed-satellite

service (FSS) in the space-to-Earth direction on a co-primary basis with incumbent services and permit limited GSO FSS (space-to-Earth) use of the 17.7–17.8 GHz band on an unprotected basis with respect to fixed service operations. Specifically, the *17 GHz Report and Order* contains the following new or modified information collection requirements:

- Certification of frequency coordination with the operator of the co-frequency space station or submission of an interference analysis demonstrating the compatibility of the proposed system with the co-frequency space station;
- Information as to earth station antenna characteristics to ensure that antennas are properly aimed and configured and that their signals are not likely to interfere with other systems; and
- Information pertaining to implementation of interference detection and mitigation plans to prevent and resolve interference issues.

The changes adopted in the *17 GHz Report and Order* will result in a small net annualized increase in burden hours to certain applicants and licensees under part 25.

Finally, the Commission has updated the International Communications Filing System (ICFS)—which was formerly named the International Bureau Filing System, see 88 FR 21424—including updates to the Form 312, including Schedules A, B, and S, and Form 312–R. Applicants will be required to submit Form 312 (including Schedules A, B, and S) and Form 312–R through the updated, integrated web-based program. The updated version of Form 312 (including Schedules A, B, and S) and Form 312–R will include several minor changes to the information collection designed to provide clarity to applicants and Commission staff, reduce errors, and make overall improvements to the applicants' experience in completing the forms. Therefore, this supporting statement is being revised to reflect the new requirements, which are include the addition of several questions designed to better convey the overall information being requested in the form.

The changes will result in a very small net annualized increase in burden hours to certain applicants under part 25.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2024–09024 Filed 4–25–24; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Wednesday, May 1, 2024, at 10:00 a.m.

PLACE: Hybrid meeting: 1050 First Street NE Washington, DC (12>TH floor) and virtual.

Note: For those attending the meeting in person, current COVID–19 safety protocols for visitors, which are based on the CDC COVID–19 hospital admission level in Washington, DC, will be updated on the Commission's contact page by the Monday before the meeting. See the contact page at *https://www.fec.gov/contact/.* If you would like to virtually access the meeting, see the instructions below.

STATUS: This meeting will be open to the public, subject to the above-referenced guidance regarding the COVID–19 hospital admission level and corresponding health and safety procedures. To access the meeting virtually, go to the Commission's website *www.fec.gov* and click on the banner to be taken to the meeting page.

MATTERS TO BE CONSIDERED:

Draft Advisory Opinion 2024–03: PoliticalMeetings.com LLC
Draft Advisory Opinion 2024–04: Independence Blue Cross LLC Political Action Committee
Draft Advisory Opinion 2024–05: Nevadans for Reproductive Freedom
Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer Telephone: (202) 694–1220

Individuals who plan to attend in person and who require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Secretary and Clerk, at (202) 694–1040 or *secretary@fec.gov,* at least 72 hours prior to the meeting date. (Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Laura E. Sinram,

Secretary and Clerk of the Commission.

[FR Doc. 2024–09154 Filed 4–24–24; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the reporting, recordkeeping, and disclosure requirements associated with the Market Risk Capital Rule (FR 4201; OMB No. 7100–0314).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Collection title: Market Risk Capital Rule (see the *current actions* section for information about a change to the collection title and collection identifier).

Collection identifier: FR 4201.

OMB control number: 7100–0314.

Dates: The revisions are applicable as of April 26, 2024.

General description of collection: The market risk rule, which requires banking organizations to hold capital to cover their exposure to market risk, is a component of the Board's regulatory capital framework, Regulation Q—Capital Adequacy of Bank Holding

Companies, Savings and Loan Holding Companies, and State Member Banks (12 CFR part 217). The rule includes information collections that permit the Board to monitor the market risk profile of Board-regulated banking organizations that have significant market risk. These information collections provide current statistical data identifying market risk areas on which to focus onsite and offsite examinations. They also allow the Board to assess the levels and components of each reporting institution's risk-based capital requirements for market risk and the adequacy of the institution's capital under the market risk rule.

Frequency: Annual, quarterly, and on occasion.

Respondents: Bank holding companies, covered savings and loan holding companies,[1] U.S. intermediate holding companies of foreign banking organizations, and state member banks (collectively, banking organizations) that meet certain risk thresholds. The market risk rule applies to any such banking organization with aggregate trading assets and trading liabilities equal to (1) 10 percent or more of quarter-end total assets or (2) $1 billion or more.

Total estimated number of respondents: 37.

Total estimated change in burden: 592.

Total estimated annual burden hours: 36,236.[2]

Current actions: On December 4, 2023, the Board published a notice in the **Federal Register** (88 FR 84141) requesting public comment for 60 days on the extension, with revision, of the FR 4201. The Board proposed revising the FR 4201 to account for a recordkeeping requirement in section 217.203(b)(2) of Regulation Q that had not been previously cleared by the Board. The comment period for this notice expired on February 2, 2024. The Board did not receive any comments. The revisions will be implemented as proposed. This information collection is currently titled ''Market Risk Capital Rule'' with a collection identifier of ''FR 4201.'' As part of this clearance, the collection title will be changed to ''Reporting, Recordkeeping, and Disclosure Requirements Associated with Regulation Q (Market Risk Capital Rule)'' and the collection identifier will be updated to ''FR Q–2.'' The purpose of this non-substantive change is to implement consistent nomenclature for information collections contained within a rule. This change would not modify the reporting, recordkeeping, or disclosure requirements in any way.

Board of Governors of the Federal Reserve System, April 23, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–09020 Filed 4–25–24; 8:45 am]

BILLING CODE P

[1] For the definition of ''covered savings and loan holding company,'' see 12 CFR 217.2.

[2] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 4201.

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Reporting, Recordkeeping, and Disclosure Requirements Associated with Regulation WW (FR WW; OMB No. 7100–0367).

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, *nuha.elmaghrabi@frb.gov,* (202) 452–3884.

Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements (which contain more detailed information about the information collections and burden estimates than this notice), and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportingforms/review* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With Revision, of the Following Information Collection

Collection title: Reporting, Recordkeeping, and Disclosure Requirements Associated with Regulation WW.

Collection identifier: FR WW.

OMB control number: 7100–0367.

Dates: The revisions are applicable as of April 26, 2024.

General description of collection: The Board, Federal Deposit Insurance Corporation (FDIC), and Office of the Comptroller of the Currency (OCC) (collectively, the agencies) implemented a liquidity coverage ratio (LCR) requirement and a net stable funding ratio (NSFR) requirement, consistent with the international liquidity standards published by the Basel Committee on Banking Supervision (BCBS), for large and internationally active banking organizations. For the Board, these standards are implemented through Regulation WW—Liquidity Risk Measurement, Standards, and Monitoring (12 CFR part 249). The NSFR and LCR requirements in Regulation WW apply to certain large state member banks, covered depository institution holding companies, and U.S. intermediate holding companies of foreign banking organizations, as well as covered nonbank companies (together, covered companies). The reporting, recordkeeping, and disclosure requirements contained in FR WW are used to monitor covered companies' compliance with the LCR and NSFR.

Frequency: The reporting requirements of the FR WW information collection are submitted on an event-generated basis. The recordkeeping requirements of the FR WW information collection are both event-generated and ongoing. The disclosure requirements of the FR WW information collection must be met on a quarterly basis (relating to the LCR) as well as every second and fourth calendar quarter (relating to the NSFR) and must remain publicly available for at least five years after the initial disclosure date.

Respondents: The FR WW panel comprises covered companies, as defined above. Certain requirements apply only to covered holding and nonbank companies.

Total estimated number of respondents: 21.

Total estimated change in burden: (446).

Total estimated annual burden hours: 2,483.[1]

Current actions: On December 5, 2023, the Board published a notice in the **Federal Register** (88 FR 84328) requesting public comment for 60 days on the extension, with revision, of the FR WW. The Board proposed to revise the FR WW to account for three recordkeeping requirements in Regulation WW, contained in section 249.4(a) and sections 249.22(a)(1) and (a)(4), which had not been previously cleared by the Board under the PRA. In addition, the Board revised the estimated hours per response for several requirements which lead to a net decrease in the total burden hours. The comment period for this notice expired on February 5, 2024. The Board did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, April 23, 2024.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2024–09018 Filed 4–25–24; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice-MEG–2024–01; Docket No.2024–0002; Sequence No.15]

Notice of Intent To Establish a Federal Advisory Committee and Call for Nominations

AGENCY: Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Notice.

SUMMARY: The General Services Administration (GSA) announces its intent to establish the Open Government Federal Advisory Committee (hereinafter ''the Committee'' or ''the OG FAC'') and is requesting member nominations.

DATES: GSA will consider nominations that are submitted via email or postmarked by May 28, 2024.

ADDRESSES: Please submit nominations to Arthur Brunson, Designated Federal Officer (DFO), General Services Administration, Office of Government-wide Policy, 1800 F Street, NW Washington, DC 20405; or send by email having a subject line of ''OG FAC Nomination'' to *ogfac@gsa.gov.*

FOR FURTHER INFORMATION CONTACT: Arthur Brunson, DFO, Office of Government-wide Policy, 202–501–1126, or email having a subject line of ''OG FAC Nomination'': *ogfac@gsa.gov*

SUPPLEMENTARY INFORMATION: The Administrator of the U.S. General Services Administration (GSA) intends to establish the Open Government Federal Advisory Committee (OG FAC) as a discretionary advisory committee under agency authority in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. 10.

GSA's Open Government Secretariat supports ensuring a more transparent, responsive and inclusive Federal Government. This is done by providing channels for members of the public to regularly engage with their government. The OG FAC will advise GSA in its endeavor to increase the public's access to data, to better advance equity, engage the public in the regulatory process, make government records more accessible, and improve the delivery of government services and benefits through expert advice.

The OG FAC will serve as an advisory body to GSA on GSA Open Government initiatives including GSA's creation, implementation and monitoring of U.S. Open Government National Action Plans (NAPs)and commitment themes. The initial focus for the OG FAC will be to provide advice to GSA on the development of NAP 6, Open Government Policy, and Public Engagement. The OG FAC will advise GSA's Administrator on emerging open government issues, challenges and opportunities to support GSA's Open Government Secretariat.

The OG FAC is essential to conduct agency business for GSA and bring together civil society, Federal agencies, academia, industry, and other interested stakeholders. GSA needs a wide diversity of views on Open Government initiatives.

It is anticipated that the OG FAC will be comprised of no less than ten (10) and no more than twenty (20) Federal and non-Federal members, with a strong background and expertise in open government themes such as Access to Information, Anti-Corruption, Civic Space, Climate and Environment, Digital Governance, Fiscal Openness, Gender and Inclusion, Justice, Media Freedom, Public Participation, and improving the delivery of government services and benefits. The GSA Administrator will appoint all members. Members serve one (1) to three (3) year terms. No member will serve for more than six (6) consistent years. Membership balance is not static given the broad nature of the work, and the expertise or experience relevant to the function of this Committee may change over time, depending on the work of the Committee. GSA values opportunities to increase diversity, equity, inclusion and accessibility on its federal advisory committees.

Committee

The OG FAC will operate in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, (5 U.S.C. 10). The OG FAC will be solely advisory in nature. Consistent with FACA and its requirements, each meeting of the OG FAC will be open to the public unless otherwise notified in accordance with the Government in the Sunshine Act. A notice of each meeting will be published in the **Federal Register** at least fifteen (15) days in advance of the meeting. Records will be maintained for each meeting and made available for public inspection. All activities of the OG FAC will be conducted in an open, transparent, and accessible manner.

The OG FAC is expected to be a continuing entity with charter renewals every two years. The first meeting date and agenda topics will be announced in the **Federal Register** at least fifteen (15) days prior to the first meeting date. In addition, as needed, working groups or subcommittees will be established to facilitate the OG FAC's work. Special accommodations for meetings will be made available to individuals with disabilities upon request.

Members will be designated as Regular Government Employees (RGEs), Special Government Employees (SGEs), or Representative members as appropriate. GSA's Office of General Counsel will assist the DFO to determine the advisory committee member designations. In general, SGEs are experts in their field who provide Federal advisory committees with their own best independent judgment based on their individual expertise. Representatives are members selected to represent a specific point of view held by a particular group, organization, or association. Members who are full-time or permanent part-time Federal civilian officers or employees shall be appointed to serve as Regular Government Employee (RGE) members.

In accordance with OMB Final Guidance published in the **Federal**

[1] More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at *https://www.federalreserve.gov/apps/reportingforms/review.* On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR WW.

Register on October 5, 2011 and revised on August 13, 2014, federally registered lobbyists may not serve on the Committee in an individual capacity to provide their own individual best judgment and expertise, such as SGEs and RGEs members. This ban does not apply to lobbyists appointed to provide the Committee with the views of a particular group, organization, or association, such as a representative member.

Member Nominations

GSA invites nominations to serve on the Committee in the disciplines related to Open Government policy and initiatives such as, but not limited to: Access to Information, Anti-Corruption, Civic Space, Climate and Environment, Digital Governance, Fiscal Openness, Gender and Inclusion, Justice, Media Freedom, Public Participation, and improving the delivery of government services and benefits. In the selection of members for the Committee, GSA will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the Committee.

Membership will depend upon several factors, including: (i) The Committee's mission; (ii) The geographic, ethnic, social, economic, or scientific impact of the Committee's recommendations; (iii) The types of specific perspectives required, for example, such as those of consumers, technical experts, the public at-large, academia, business, or other sectors; (iv) The need to obtain divergent points of view on the issues before the Committee; and (v) The relevance of State, local, territorial, or Tribal governments to the development of the Committee's recommendations.

Member Selection Criteria

The following factors will be used to evaluate nominees:

Committee Members

a. Subject matter expertise in the key issue the OG FAC is examining for the current period;

b. Professional experiences and accomplishments (*e.g.,* projects, nature of work, or publications);

c. Current employment and membership in associations or other activities (*e.g.,* industry, academia, and civil society organizations); and

d. Willingness to commit time to the Committee and demonstrated ability to work constructively and effectively on committees;

Committee Chair and Any Co-chairs or Vice-Chairs

- Demonstrated credentials and interdisciplinary expertise in the open government themes such as Access to Information, Anti-Corruption, Civic Space, Climate and Environment, Digital Governance, Fiscal Openness, Gender and Inclusion, Justice, Media Freedom, Public Participation, and improving the delivery of government services and benefits.
- Willingness to commit substantial time to the Committee and demonstrated ability to work constructively and effectively on committees;
- Background and experience helping engage people from different backgrounds work towards common objectives;
- Demonstrated ability to assess and analyze policy challenges with objectivity and integrity;
- Excellent interpersonal, oral, and written communication skills; and
- Excellent leadership and consensus-building skills.

All members will be appointed by the GSA Administrator, who will also select the Chair and any Co-Chairs or Vice-Chairs from among the members.

Miscellaneous

The OG FAC will meet at least four times per year. Such meetings will be open to the public unless an appropriate authority determines, in accordance with FACA, as amended, that a meeting shall be closed or partially closed. The Committee will meet virtually or in person as agreed to by the Committee Chair and DFO.

Committee members (including the Committee Chair and any Co-Chairs or Vice-Chairs) will not be compensated for their services and may be allowed travel expenses, including per diem, in accordance with 5 U.S.C. 5703. Regardless of the type of committee membership appointment, any travel expenses shall be paid at rates equivalent to that allowable to Federal employees.

The GSA Open Government Secretariat will host a virtual Question and Answer (Q&A) session on May 10, 2024 at 1:00pm ET. The purpose of the Q&A session is to answer questions on the selection process and timeline. The Q&A session will be recorded and will be posted to the GSA YouTube Channel, on the Open Government Secretariat Playlist. To attend this virtual session please complete and submit a registration form at *https://gsa.zoomgov.com/meeting/register/vJItduyurz0jEvnY1VG4FD-PswDaufetOsc* or submit your contact information via email having a subject line of ''OG FAC Q&A Session Attendance'' to: *ogfac@gsa.gov.*

Nomination Submissions

Any interested person and/or organization may nominate qualified individuals for membership. Individuals are also encouraged to self-nominate. The following items must be submitted in a nomination package:

(1) A letter of nomination stating the nominee's name and organizational affiliation(s), nominee's field of expertise, specific qualifications to serve on the Committee, and a brief statement of interest, including if the nominee is interested in serving as the Chair of the Committee;

(2) A professional resume or curriculum vitae (CV); and

(3) A short biography (no more than two paragraphs) describing the nominee's professional and educational qualifications, including a list of relevant activities and any current or previous/current service on advisory committees.

The letter of nomination, resume or CV, and a short biography should include the candidate's full name, address of the current organization, position title, email address, and daytime telephone number(s) of the nominee and nominator.

In preparing the letter of nomination, please describe how the nominee's background, knowledge, and experience will bring value to the work of the Committee and how these qualifications would contribute to the overall diversity of the Committee. Also, describe any previous involvement with GSA through employment, grant funding, and/or contracting sources, if applicable.

Nominations are due by May 28, 2024 and must be submitted to Arthur Brunson, Designated Federal Officer (DFO), General Services Administration, Office of Government-wide Policy, 1800 F Street, NW Washington, DC 207405 having a postmarked date of no later than the due date or via email having a subject line of ''OG FAC Nomination'' to: *ogfac@gsa.gov.*

Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy, General Services Administration.

[FR Doc. 2024–08970 Filed 4–25–24; 8:45 am]

BILLING CODE 6820–UA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1500/1490S and CMS–R–234]

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 (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 June 25, 2024.

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–1500/1490 Health Insurance Common Claims Form and Supporting Regulations at 42 CFR part 424, subpart C

CMS–R–234 Subpart D—Private Contracts and Supporting Regulations in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, and 424.24

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:* Extension without change of a currently approved collection; *Title of Information Collection:* Health Insurance Common Claims Form and Supporting Regulations at 42 CFR part 424, subpart C; *Use:* The CMS–1500 and the CMS–1490S forms are used to deliver information to CMS for CMS to reimburse for provided services. Medicare Administrative Contractors use the data collected on the CMS–1500 and the CMS–1490S to determine the proper amount of reimbursement for Part B medical and other health services (as listed in section 1861(s) of the Social Security Act) provided by physicians and suppliers to beneficiaries. The CMS–1500 is submitted by physicians/suppliers for all Part B Medicare. Serving as a common claim form, the CMS–1500 can be used by other third-party payers (commercial and nonprofit health insurers) and other Federal programs (*e.g.,* TRICARE, RRB, and Medicaid). *Form Number:* CMS–1500/1490S (OMB control number: 0938–1197); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,507,992; *Total Annual Responses:* 994,038,623; *Total Annual Hours:* 17,328,912. (For policy questions regarding this collection contact Sadaf Ali-Simpson at 667–414–0004.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Subpart D-Private Contracts and Supporting Regulations in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, and 424.24; *Use:* Section 4507 of the Balanced Budget Act of 1997 (BBA 1997) amended section 1802 of the Social Security Act (the Act) to permit certain physicians and practitioners to opt-out of Medicare and to provide—through private contracts—services that Medicare would otherwise cover. Under such contracts, the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. CMS–R–234 allows certain physicians and practitioners to opt out of Medicare and furnish covered services to Medicare beneficiaries through private contracts. Physicians and practitioners use this information collection to comply with the applicable regulations. Physicians and practitioners entering private contracts with beneficiaries must file an affidavit with Medicare in which they agree to opt-out of Medicare for 2 years and to meet certain other criteria. In general, the applicable regulations require that during that 2-year period, physicians and practitioners who have filed affidavits opting out of Medicare must sign private contracts with all Medicare beneficiaries to whom they furnish services that Medicare would otherwise cover (except those who need emergency or urgently needed care). In addition, Medicare Administrative Contractors (MACs) use this information to determine if benefits should be paid or continued. *Form Number:* CMS–R–234 (OMB control number: 0938–0730);

Frequency: Occasionally; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents;* 78,258; *Total Annual Responses;* 78,258; *Total Annual Hours:* 22,780. (For policy questions regarding this collection contact Frank Whelan at 410–786–1302.)

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–09040 Filed 4–25–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3464–PN]

Medicare Program; Application by the National Association of Boards of Pharmacy (NABP) for Continued CMS Approval of its Home Infusion Therapy (HIT) Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from the National Association of Boards of Pharmacy (NABP) for continued approval by the Centers for Medicare & Medicaid Services (CMS) of NABP's national accrediting organization program for suppliers providing home infusion therapy (HIT) services and that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's complete application, CMS will publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by May 28, 2024.

ADDRESSES: In commenting, refer to file code CMS–3464–PN.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3464–PN, P.O. Box 8016, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3464–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Shannon Freeland, (410) 786–4348.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. We will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. We continue to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Home infusion therapy (HIT) is a treatment option for Medicare beneficiaries with a wide range of acute and chronic conditions. Section 5012 of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) added section 1861(iii) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines ''home infusion therapy'' as professional services, including nursing services; training and education not otherwise covered under the Durable Medical Equipment (DME) benefit; remote monitoring; and other monitoring services. HIT must be furnished by a qualified HIT supplier and furnished in the individual's home. The individual must:

- Be under the care of an applicable provider (that is, physician, nurse practitioner, or physician assistant); and
- Have a plan of care established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs under Part B, that prescribes the type, amount, and duration of infusion therapy services that are to be furnished.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that a qualified HIT supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and in reviewing and modifying the list of designated AOs. These statutory factors are as follows:

- The ability of the organization to conduct timely reviews of accreditation applications.
- The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).
- Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.
- Such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit HIT suppliers furnishing HIT no later than January 1, 2021. Section 1861(iii)(3)(D)(i)(III) of the Act requires a ''qualified home infusion therapy supplier'' to be accredited by a CMS-approved AO, pursuant to section 1834(u)(5) of the Act.

On March 1, 2019, we published a solicitation notice entitled, ''Medicare Program; Solicitation of Independent Accrediting Organizations to Participate in the Home Infusion Therapy Supplier Accreditation Program'' (84 FR 7057). This notice informed national AOs that accredit HIT suppliers of an opportunity to submit applications to participate in the HIT supplier accreditation program. We stated that complete applications would be considered for the January 1, 2021 designation deadline if received by February 1, 2020. Regulations for the approval and oversight of AOs for HIT organizations are located at 42 CFR part 488, subpart L. The requirements for HIT suppliers are located at 42 CFR part 486, subpart I.

II. Approval of Deeming Organization

Section 1834(u)(5) of the Act and regulations at 42 CFR 488.1010 require that our findings concerning review and approval of a national accrediting

organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data.

Our rules at 42 CFR 488.1020(a) require that we publish, after receipt of an organization's complete application, a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period. Pursuant to our rules at 42 CFR 488.1010(d), we have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of the National Association of Boards of Pharmacy's (NABP's) request for CMS' continued recognition of its HIT accreditation program. This notice also solicits public comment on whether NABP's requirements meet or exceed the Medicare requirements of participation for HIT services.

III. Evaluation of Deeming Authority Request

In the April 28, 2020 **Federal Register**, we published NABP's initial application for recognition as an accreditation organization for HIT (85 FR 23519). On September 28, 2020, we published notification of their approval as such an organization, effective September 26, 2020 through September 26, 2024 (85 FR 60793). NABP has since submitted all the necessary materials to enable us to make a determination concerning its request for continued recognition of its HIT accreditation program. This application was determined to be complete on February 28, 2024. Under section 1834(u)(5) of the Act and 42 CFR 488.1010 (Application and re-application procedures for national home infusion therapy accrediting organizations), our review and evaluation of NABP will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of NABP's standards for HIT as compared with CMS' HIT requirements for participation in the Medicare program.
- NABP's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of NABP's to CMS' standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ NABP's processes and procedures for monitoring a HIT supplier found out of compliance with NABP's program requirements.

++ NABP's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ NABP's capacity to provide CMS with electronic data and reports necessary for effective assessment and interpretation of the organization's survey process.

++ The adequacy of NABP's staff and other resources, and its financial viability.

++ NABP's capacity to adequately fund required surveys.

++ NABP's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced.

++ NABP's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

++ NABP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

++ NABP's agreement or policies for voluntary and involuntary termination of HIT suppliers.

++ NABP's agreement or policies for voluntary and involuntary termination of the HIT AO program.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–09044 Filed 4–25–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–P–0015A]

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 (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 June 25, 2024.

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–P–0015A Medicare Current Beneficiary Survey (MCBS)

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 previously approved collection; *Title of Information Collection:* Medicare Current Beneficiary Survey (MCBS); *Use:* The Medicare Current Beneficiary Survey (MCBS) is the most comprehensive and complete survey available on the Medicare population and is essential in capturing data not otherwise collected through our operations. The MCBS is a nationally-representative, longitudinal survey of Medicare beneficiaries that we sponsor and is directed by the Office of Enterprise Data and Analytics (OEDA). MCBS data collection includes both in-person and phone interviewing. The survey captures beneficiary information whether aged or disabled, living in the community or facility, or serviced by managed care or fee-for-service. Data produced as part of the MCBS are enhanced with our administrative data (*e.g.,* fee-for-service claims, prescription drug event data, enrollment, etc.) to provide users with more accurate and complete estimates of total health care costs and utilization. The MCBS has been continuously fielded for more than 30 years, encompassing over 1.2 million interviews and more than 140,000 survey participants. Respondents participate in up to 11 interviews over a four-year period. This gives a comprehensive picture of health care costs and utilization over a period of time.

The MCBS continues to provide unique insight into the Medicare program and helps CMS and our external stakeholders better understand and evaluate the impact of existing programs and significant new policy initiatives. In the past, MCBS data have been used to assess potential changes to the Medicare program. For example, the MCBS was instrumental in supporting the development and implementation of the Medicare prescription drug benefit by providing a means to evaluate prescription drug costs and out-of-pocket burden for these drugs to Medicare beneficiaries. *Form Number:* CMS–P–0015A (OMB control number: 0938–0568); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 35,015; *Total Annual Responses:* 35,015; *Total Annual Hours:* 35,212. (For policy questions regarding this collection contact: William Long at 410–786–7927.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–08921 Filed 4–25–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10437]

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 (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 June 25, 2024.

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–10437 Generic Social Marketing & Consumer Testing Research

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:* Generic Social Marketing & Consumer Testing Research; *Use:* The purpose of this submission is to extend the approval of the generic clearance for a program of consumer research aimed at a broad audience of those affected by CMS programs including Medicare, Medicaid, Children's Health Insurance Program (CHIP), and health insurance exchanges. This program extends strategic efforts to reach and tailor communications to beneficiaries, caregivers, providers, stakeholders, and any other audiences that would support the Agency in improving the functioning of the health care system, improve patient care and outcomes, and reduce costs without sacrificing quality of care. The information collected will be used to create a streamlined and proactive process for collection of data and utilizing the feedback on service delivery for continuous improvement of communication activities aimed at diverse CMS audiences. The generic clearance will allow rapid response to inform CMS initiatives using a mixture of qualitative and quantitative consumer research strategies (including formative research studies and methodological tests) to improve communication with key CMS audiences. As new information resources and persuasive technologies are developed, they can be tested and evaluated for beneficiary response to the materials and delivery channels. Results will inform communication development and information architecture as well as allow for continuous quality improvement. The overall goal is to maximize the extent to which consumers have access to useful sources of CMS program information in a form that can help them make the most of their benefits and options The activities under this clearance involve social marketing and consumer research using samples of self-selected customers, as well as convenience samples, and quota samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. All collection of information under this clearance will utilize a subset of items drawn from a core collection of customizable items referred to as the Social Marketing and Consumer Testing Item Bank. This item bank is designed to establish a set of pre-approved generic question that can be drawn upon to allow for the rapid turn-around consumer testing required for us to communicate more effectively with our audiences. The questions in the item bank are divided into two major categories. One set focuses on characteristics of individuals and is intended primarily for participant screening and for use in structured quantitative on-line or telephone surveys. The other set is less structured and is designed for use in qualitative one-on-one and small group discussions or collecting information related to subjective impressions of test materials. Results will be compiled and disseminated so that future communication can be informed by the testing results. We will use the findings to create the greatest possible public benefit. Form Number: CMS–10437 (OMB control number: 0938–1247); Frequency: Yearly; Affected Public: Individuals; Number of Respondents: 7,732; Number of Responses: 61,992; Total Annual Hours: 26,688. (For policy questions regarding this collection contact Hemalgiri Gosai at 410–786–0000.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–09041 Filed 4–25–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4597]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Shortages Data Collections

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 May 28, 2024.

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 0910–0491. 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.

Shortages Data Collections

OMB Control Number 0910–0491—Extension

Under section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)), the Commissioner of Food and Drugs is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. After the events of September 11, 2001, and as part of broader counterterrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable CDRH to anticipate and respond to medical device shortages that might arise in the context of federally declared disasters/emergencies or regulatory actions. In particular, CDRH identified the need to acquire and maintain detailed data on domestic inventory, manufacturing capabilities, distribution plans, and raw material constraints for medical devices that would be in high demand and/or would be vulnerable to shortages in specific disaster/emergency situations or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, support real-time decision making by the Department of Health and Human Services during actual emergencies or emergency preparedness exercises, and mitigate or prevent harm to the public health.

This voluntary data collection process consists of outreach to firms that have been identified as producing or distributing medical devices that may be considered essential to the response effort. In this initial outreach, the intent and goals of the data collection effort will be described, and the specific data request made. Data are collected, using the least burdensome methods, in a structured manner to answer specific questions. After the initial outreach, we will request updates to the information periodically to keep the data current and accurate. Additional followup correspondence may occasionally be needed to verify/validate data, confirm receipt of followup correspondence(s), and/or request additional details to further inform FDA's public health response.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136) was enacted on March 27, 2020. Section 3121 of the CARES Act amended the FD&C Act by adding section 506J to the FD&C Act (21 U.S.C. 356j). Section 506J of the FD&C Act provides FDA with new authorities intended to help prevent or mitigate medical device shortages by requiring medical device manufacturers to inform FDA about changes in device manufacturing that could potentially lead to a device shortage. Apprised with that information, section 506J of the FD&C Act authorizes FDA to take several actions that may help to mitigate or avoid supply disruptions.

Section 506J of the FD&C Act requires manufacturers of certain devices,[1] to notify FDA ''of a permanent discontinuance in the manufacture of the device'' or ''an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in supply of that device in the United States'' during or in advance of a declared public health emergency, and the reason for such discontinuance or interruption.[2] Section 506J of the FD&C Act requires FDA to take action based on that information, including (1) publicly posting a list of devices it determines to be in shortage, (2) publicly posting the reasons for the shortage, and (3) issuing letters to manufacturers that fail to comply with the notification requirements of section 506J of the FD&C Act.

On December 29, 2022, the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act was signed into law as part of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) (hereafter referred to as the ''FY 2023 Omnibus''). Section 2514(c) of the fiscal year (FY) 2023 Omnibus directed FDA to issue or revise guidance regarding requirements under section 506J of the FD&C Act and include a list of each device product code for which a manufacturer of such device is required to notify FDA in accordance with section 506J. Section 2514 of the FY 2023 Omnibus amended section 506J of the FD&C Act to add section 506J(h), ''Additional Notifications'' and directed FDA to issue guidance ''to facilitate voluntary notifications.''

In the **Federal Register** of November 17, 2023 (88 FR 80310), FDA announced the availability of the final guidance entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' [3] and the draft guidance entitled ''Select Updates for the 506J Guidance: 506J Device List and Additional Notifications.'' [4] The final guidance, ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' (hereafter referred to as the ''506J Guidance'') assists stakeholders in the Agency's implementation of section 506J of the FD&C Act. This final guidance serves as the baseline for information about notifications under section 506J of the FD&C Act during or in advance of any public health emergency (PHE). FDA provides additional clarification on who is required to notify FDA, when such notifications are required, what information FDA expects manufacturers to include in such notifications, and how to submit notifications. Additionally, FDA describes how FDA determines that a device is in shortage and additional actions FDA may take to help prevent or mitigate a potential device shortage.

In the draft guidance ''Select Updates for the 506J Guidance: 506J Device List and Additional Notifications,'' FDA proposes updates to the 506J Guidance. Specifically, FDA has developed a list of devices, by FDA product code, for which a manufacturer of such devices is required to notify FDA in accordance with section 506J of the FD&C Act (hereafter referred to as the ''506J Device List''). The 506J Device List is based on the requirements under section 506J(a) of the FD&C Act. In section 2514 of the FY 2023 Omnibus, Congress directed FDA to issue guidance on the requirements under section 506J of the FD&C Act and to include ''a list of each device product code for which a manufacturer of such device is required

[1] Under section 506J of the FD&C Act, manufacturers of the following devices must notify FDA of an interruption or permanent discontinuance in manufacturing:

- Devices that are critical to public health during a public health emergency, including those that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or
- Devices for which FDA determines information on potential meaningful supply disruptions is needed during a public health emergency. See section 506J(a)(1), (2) of the FD&C Act.

[2] See section 506J(a) of the FD&C Act.

[3] *https://www.fda.gov/media/155245/download.*

[4] *https://www.fda.gov/media/173800/download.*

to notify the Secretary in accordance with section 506J.'' Thus, manufacturers of a device on the 506J Device List must notify FDA in accordance with 506J of the FD&C Act for each such device. For more information, manufacturers should see the 506J Device List web page, available at *https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list.* Additionally, consistent with section 506J(h) of the FD&C Act, FDA is proposing to clarify for stakeholders that manufacturers may submit, and FDA may receive, voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a PHE.

The guidance documents include additional voluntary items that manufacturers could provide the Agency, including additional information about device manufacturing and supply, and updates to initial notifications.

Respondents may notify FDA about an interruption or permanent discontinuance in device manufacturing (506J notification) on our website at *https://fda-cdrh.my.salesforce-sites.com/shortages/.*

In the **Federal Register** of November 28, 2023 (88 FR 83134), 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	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Shortages outreach data collection	1,000	4	4,000	1	4,000
Information collection under section 506J	8,400	1	8,400	0.25 (15 minutes)	2,100
Additional voluntary collections related to section 506J	8,400	1	8,400	0.25 (15 minutes)	2,100
Total			20,800		8,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

I. Shortages Outreach Data Collection

FDA bases these estimates on our recent experience and informal direct contact with respondents. We estimate up to 1,000 manufacturers, distributors, healthcare systems, healthcare providers, group purchasing organizations, and sterilizers for which there may be targeted outreach because their devices may be essential to the response effort. This targeted outreach will be conducted periodically either to obtain primary data or to verify/validate updated data (although additional outreach may be undertaken as needed). The data being requested represent common data elements that respondents monitor and track as part of routine business operations and, therefore, are readily available. It is anticipated that for most respondents, the estimated time to fulfill CDRH's data request will not exceed 1 hour per request, or 4 hours per year.

II. Information Collection Under Section 506J of the FD&C Act and Related Voluntary Collections

Based on current registration and listing data (approved under OMB control number 0910–0625), we estimate the number of respondents that will submit a notification under section 506J of the FD&C Act to be approximately 20 percent of currently registered manufacturers. Data from our Registration and Listing system indicate that there are approximately 42,000 unique FDA Establishment Identification registered manufacturers. Therefore, we estimate 8,400 respondents per year. We believe that the burden, including the provision of required information under section 506J of the FD&C Act, as well as additional voluntary information (including additional issues that may impact the availability of the device, such as information about critical suppliers, potential mitigations, production capacity and market share, and notification updates), is minimal and such information is readily available to respondents. Therefore, we estimate the burden of this information collection to be 15 minutes or less per notification.

Since the last OMB approval, we have updated the Number of Respondents and Average Burden per Response for the Shortages Outreach Data Collection element based on our recent experience with the information collection and informal direct contact with respondents. The updates result in an adjustment of an additional 3,000 hours and 2,000 responses annually.

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09023 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3743]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Records: Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled ''Electronic Records: Electronic Signatures'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On January 22, 2024, the Agency submitted a proposed collection of information entitled ''Electronic Records: Electronic Signatures'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0303. The approval expires on March 31, 2027. A copy of the supporting statement for this information collection is available on the internet at *https://www.reginfo.gov/public/do/PRAMain.*

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08953 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1376]

Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications; Draft Guidance for Industry, Institutional Review Boards, and Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry, institutional review boards (IRBs), and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.'' This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation Research (CBER) for the treatment of cancer. Specifically, this draft guidance includes recommendations regarding the appropriate use of washout periods and concomitant medication exclusions.

DATES: Submit either electronic or written comments on the draft guidance by June 25, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–1376 for ''Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jamie Brewer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2319, Silver Spring, MD 20993, 240–402–4463; or Vishal Bhatnagar, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2113, Silver Spring, MD 20993, 240–402–3696; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry, IRBs, and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.'' The purposes of eligibility criteria are to select the intended patient population and reduce potential risks to trial participants. However, eligibility criteria are sometimes more restrictive than necessary, and expanding eligibility criteria to be more inclusive is one trial design consideration that may improve the diversity of clinical trial populations. This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by CDER and CBER for the treatment of cancer. Specifically, this draft guidance includes recommendations regarding the appropriate use of washout periods and concomitant medication exclusions and is intended to assist interested parties, including sponsors and IRBs, who are responsible for the development and oversight of clinical trials.

A clinical trial's eligibility criteria (for inclusion and exclusion) are essential components of the trial, defining the characteristics of the study population. Because there is variability in investigational drugs and trial objectives, eligibility criteria should be developed taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, the availability of adequate safety data, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. The Agency recognizes that some eligibility criteria may have become commonly accepted over time or used as a template across trials, but such criteria should be carefully considered and be appropriate for a specific trial context. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug.

Appropriately broadening cancer trial eligibility criteria can improve the generalizability of trial results and provide a more detailed characterization of the therapy's benefit-risk profile across the patient population likely to use the drug in clinical practice.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.'' 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. The previously approved collections of information are subject to review by Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, 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: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09038 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5303]

Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination and Removal of a Foreign Manufacturer's Goods From Detention Without Physical Examination; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration is reopening the comment period for the draft guidance for industry entitled ''Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination and Removal of a Foreign Manufacturer's Goods From Detention Without Physical Examination; Draft Guidance for Industry; Availability'' that published in the **Federal Register** of February 12, 2024. We are taking this action in response to a request to extend the comment period to allow additional time for interested parties to submit comments.

DATES: FDA is reopening the comment period for the draft guidance for industry announced in the **Federal Register** on February 12, 2024 (89 FR 9852). Submit either electronic or written comments on the draft guidance by June 25, 2024, to ensure that we consider your comments before we begin work on the final guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted,

such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

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

Instructions: All submissions received must include the Docket No. FDA–2023–D–5303 for ''Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination and Removal of a Foreign Manufacturer's Goods From Detention Without Physical Examination; Draft 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.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Steven Bloodgood, Division of Seafood Safety (HFS–325), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–5316, email: *Steven.Bloodgood@fda.hhs.gov;* or Holli Kubicki, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 12, 2024 (89 FR 9852), the Food and Drug Administration (FDA or we) published a notice announcing the availability of a draft guidance for industry entitled ''Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination and Removal of a Foreign Manufacturer's Goods From Detention Without Physical Examination; Draft Guidance for Industry.'' We provided a 60-day comment period for the draft guidance.

We have received a request for a 60-day extension of the comment period for the draft guidance to provide additional time to review and comment on the rationale for the sampling recommendations in the draft guidance. In the interest of balancing the public health importance of the sampling recommendations in the draft guidance and granting additional time to submit comments before we finalize the draft guidance, we have concluded that it is reasonable to reopen the comment period for 60 days, until June 25, 2024. We are reopening the comment period because the request for an extension of the comment period arrived too late for us to extend the comment period. We believe that an additional 60 days allows adequate time for interested persons to submit comments.

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08952 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1377]

Cancer Clinical Trial Eligibility Criteria: Performance Status; Draft Guidance for Industry, Institutional Review Boards, Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry, institutional review boards (IRBs), and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for the treatment of cancer. Specifically, this draft guidance includes recommendations regarding expanding eligibility criteria to include patients with a wider range of performance status.

DATES: Submit either electronic or written comments on the draft guidance by June 25, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

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

Instructions: All submissions received must include the Docket No. FDA–2024–D–1377 for ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul Kluetz, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2223, Silver Spring, MD 20993, 301–796–9567; or Harpreet Singh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2137, Silver Spring, MD 20993, 240–402–3561; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry, IRBs, and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' The purposes of eligibility criteria are to select the intended patient population and reduce potential risks to trial participants. However, eligibility criteria are sometimes more restrictive than necessary, and expanding eligibility criteria to be more inclusive is one trial design consideration that may improve the diversity of clinical trial populations. This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by CDER and CBER for the treatment of cancer. This draft guidance includes recommendations regarding expanding eligibility criteria to include patients with a wider range of performance status, and is intended to assist interested parties, including sponsors and IRBs, who are responsible for the development and oversight of clinical trials.

A clinical trial's eligibility criteria (for inclusion and exclusion) are essential components of the trial, defining the characteristics of the study population. Because there is variability in investigational drugs and trial objectives, eligibility criteria should be developed taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, the availability of adequate safety data, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. The Agency recognizes that some eligibility criteria may have become commonly accepted over time or used as a template across trials, but such criteria should be carefully considered and be appropriate for a specific trial context. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug.

Appropriately broadening cancer trial eligibility criteria can improve the generalizability of trial results and characterize the therapy's benefit-risk profile across the patient population

likely to use the drug in clinical practice.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Cancer Clinical Trial Eligibility Criteria: Performance Status.'' 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. The previously approved collections of information are subject to review by Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/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: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09037 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1592]

Promoting Effective Drug Development: Identifying Opportunities and Priorities for the Food and Drug Administration's Office of Clinical Pharmacology; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket entitled ''Promoting Effective Drug Development: Identifying Opportunities and Priorities for the Food and Drug Administration's Office of Clinical Pharmacology.'' The purpose of this docket is to solicit input from interested parties on specific and actionable policy topics that could be prioritized, developed, and implemented by the staff of the Center for Drug Evaluation and Research's (CDER's) Office of Clinical Pharmacology (OCP) to support effective drug development programs.

DATES: Although you can comment at any time, to ensure that the Agency considers your comment, submit either electronic or written comments by June 25, 2024.

ADDRESSES: You may submit comments 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–2024–N–1592 for ''Promoting Effective Drug Development: Identifying Opportunities and Priorities for the Food and Drug Administration's Office of Clinical Pharmacology.'' 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.

- 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.

FOR FURTHER INFORMATION CONTACT: Anuradha Ramamoorthy, Office of

Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1688, *anuradha.ramamoorthy@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Clinical pharmacology impacts many important aspects of drug development including, but not limited to, dose selection and optimization, clinical trial inclusion and exclusion criteria, and evidence generation for safety and effectiveness determinations. Clinical pharmacology derived recommendations are also critical for optimizing pharmacotherapy in clinical practice (*e.g.,* by informing patient-specific treatment strategies).

Within CDER, OCP leverages clinical pharmacology information on drug disposition, disease biology, pharmacology, and determinants of response variability to support risk/benefit determinations and therapeutic individualization recommendations for patients and practitioners. OCP's mission is to advance the development of innovative new medicines by applying state-of-the-art scientific principles and promoting therapeutic optimization and individualization. OCP fulfills this mission through its core functions of regulatory review, regulatory research, and development and implementation of scientific guidances and policies.

To facilitate effective and efficient drug development, FDA is engaged in multiple, high-priority policy initiatives. Consistent with FDA's broader initiatives and modernization efforts, OCP works collaboratively with stakeholders to develop and implement contemporary guidance and policy in the multidisciplinary field of clinical pharmacology to share the current regulatory thinking on a topic and promote effective drug development programs. FDA is establishing a public docket to solicit input from interested parties on specific and actionable clinical pharmacology-relevant policy topics that could be prioritized, developed, and implemented by OCP staff.

II. Request for Comments

FDA is soliciting specific, actionable policy suggestions that could be prioritized, developed, and implemented in the near-term by OCP staff to promote effective drug development programs. We emphasize that the focus of this request is to seek input in the multidisciplinary field of clinical pharmacology. The Agency welcomes any relevant information that interested parties wish to share in a submission to the docket. We are particularly interested in seeking input on:

1. Topics for development of new clinical pharmacology/translational medicine guidances to improve clarity and promote effective drug development. Please provide a rationale to support your suggestion and highlight relevant aspects that could be considered in guidance development.
2. Topics and concepts where further clarity on OCP's existing guidances may be warranted. Please provide a rationale to support your suggestions and actionable recommendations.
3. Topics that promote patient centricity in drug development and regulatory assessment. For FDA, patient-centric drug development and providing patient-centered clinical recommendations are important priorities.

III. Electronic Access

Persons with access to the internet may obtain relevant clinical pharmacology guidances at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08956 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1382]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic User Fee Payment Request Forms

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 electronic user fee payment request forms.

DATES: Either electronic or written comments on the collection of information must be submitted by June 25, 2024.

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 June 25, 2024. 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–

2024–N–1382 for ''Electronic User Fee Payment Request Forms.'' 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: 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: 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.

Electronic User Fee Payment Request Forms—Form FDA 3913 and Form FDA 3914

OMB Control Number 0910–0805—Extension

This information collection supports FDA user fee programs. Form FDA 3913, User Fee Payment Refund Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment refund. The information collected includes the organization, contact, and payment information. The information is used to determine the reason for the refund, the refund amount, and who to contact if there are any questions regarding the refund request. A submission of the User Fee Payment Refund Request form does not guarantee that a refund will be issued. FDA estimates an average of 0.40 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. The estimated hours are based on past FDA experience with the user fee payment refund request.

In fiscal year 2023, approximately 1,856 user fee refunds were processed for cover sheets and invoices including 2 for Animal Drug User Fees, 2 for Animal Generic Drug User Fees, 3 for Biosimilar Drug User Fees, 1 for Color Additive Certification Fees, 1 for Compounding Quality fees, 32 for Export Certificate Program Fees, 7 for Freedom of Information Act requests, 94 for Generic Drug User Fees, 730 for Medical Device User Fees, 219 for Medical Device Federal Unified Registration and Listing fees, 666 for Mammography inspection fees, 19 for Over-The-Counter Monograph Drug User Fees, 77 for Prescription Drug User Fees, and 3 for Tobacco product fees.

Form FDA 3914, User Fee Payment Transfer Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment transfer request. The information collected includes payment and organization information. The information is used to determine the reason for the transfer, how the transfer should be performed, and who to contact if there are any questions regarding the transfer request. A submission of the User Fee Payment Transfer Request form does not guarantee that a transfer will be performed. FDA estimates an average of 0.25 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. FDA estimated hours are based on past FDA experience with the user fee payment transfer requests.

In fiscal year 2023, approximately 86 user fee payment transfers were processed for cover sheets and invoices including 0 for Animal Drug User Fees, 0 for Animal Generic Drug User Fees, 1 for Biosimilar Drug User Fees, 2 for Compounding Quality fees, 4 for Export Certificate Program Fees, 20 for Generic Drug User Fees, 6 for Medical Device User Fees, 37 for Medical Device Federal Unified Registration and Listing fees, 8 for Mammography inspection fees, 8 for Over-The-Counter Monograph Drug User Fees, 0 for Prescription Drug User Fees, and 0 for Tobacco product fees.

Respondents for the electronic request forms include domestic and foreign firms (including pharmaceutical, biological, medical device firms, etc.). Specifically, refund request forms target respondents who submitted a duplicate payment or overpayment for a user fee cover sheet or invoice. Respondents

may also include firms that withdrew an application or submission. Transfer request forms target respondents who submitted payment for a user fee cover sheet or invoice and need that payment to be re-applied to another cover sheet or invoice (transfer of funds).

The electronic user fee payment request forms streamline the refund and transfer processes, facilitate processing, and improve the tracking of refund or transfer requests. The burden for this collection of information is the same for all customers (small and large organizations). The information being requested or required has been held to the absolute minimum required for the intended use of the data. Respondents are able to request a user fee payment refund or transfer online at *https://www.fda.gov/forindustry/userfees/default.htm.* This electronic submission is intended to reduce the burden for customers to submit a user fee payment refund and transfer request.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Payment Refund Request—Form FDA 3913.	1,856	1	1,856	0.40 (24 minutes)	742
User Fee Payment Transfer Request—Form FDA 3914.	86	1	86	0.25 (15 minutes)	22
Total	.....	.....	.....	.....	764

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 525 hours and a corresponding increase of 1,274 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08968 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1057]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pregnancy Exposure Registry Enrollment Project: A Survey of Healthcare Providers To Advance Pregnancy Safety Data Collection and Improve Health Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled ''Pregnancy Exposure Registry Enrollment Project: A Survey of Healthcare Providers To Advance Pregnancy Safety Data Collection and Improve Health Communications.''

DATES: Either electronic or written comments on the collection of information must be submitted by June 25, 2024.

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 June 25, 2024. 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–2024–N–1057 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Pregnancy Exposure Registry Enrollment Project: A Survey of Healthcare Providers To Advance Pregnancy Safety Data Collection and Improve Health Communications.'' 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 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.

Pregnancy Exposure Registry Enrollment Project: A Survey of Healthcare Providers To Advance Pregnancy Safety Data Collection and Improve Health Communications

(OMB Control Number 0910—NEW)

I. Background

FDA has a need for data on pregnancy exposure registries (registries). The goal of the proposed Pregnancy Exposure Registry Enrollment Project survey is to determine healthcare providers' (HCPs) perceived barriers to sufficient patient enrollment in pregnancy exposure registries. FDA's authority to conduct research related to drugs and other FDA-regulated products is set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act), (21 U.S.C. 393(d)(2)(C) and (D)).

To ensure that pregnancy information in product labeling is accurately communicated to HCPs so that they can make informed decisions about treatment options for their patients, human pregnancy safety data are collected postapproval. Registries are an important tool for pregnancy safety data collection in the postmarketing setting. Their prospective design and ability to collect detailed patient information are critical to obtain human data to inform pregnancy labeling in a timely manner.

The pharmaceutical industry typically sponsors registries often as a result of a postmarketing requirement (PMR) or commitment (PMC) FDA issues at the time of drug approval under section 505(o)(3) of the FD&C Act (21 U.S.C. 355(o)(3)). Under a PMR or PMC, pharmaceutical industry sponsors often work with private companies, nonprofits, and/or academic health centers to operate registries. Other times, private companies, nonprofits, Federal agencies other than FDA, or academic health centers may develop registries without FDA involvement to facilitate pregnancy-related research with other scientific goals. When developing registry protocols, sponsors and those who operate registries must comply with 45 CFR part 46 and meet the Criteria for IRB approval of research under 45 CFR 46.111, which provides protection of human research subjects, subjects' privacy, and the confidentiality of subjects' data.

Although registries are crucial to understanding the safety and potential toxicity of prescription products in the perinatal population, many registries fail to adequately enroll pregnant individuals. HCPs are a trusted source of information about health, and they serve as gatekeepers for recruiting pregnant individuals to enroll in clinical studies such as registries. Thus, HCPs are integral to the registry enrollment process. Publications suggest that low enrollment in registries may be related to HCPs' lack of awareness, time, incentives, and comfort with discussing clinical research with patients. Despite this speculation about the barriers that HCPs face, however, researchers have not surveyed HCPs to understand their challenges. FDA reviewed existing literature and engaged with other Offices and Centers within FDA and external experts and determined that this data collection is not duplicative.

During this voluntary, FDA-funded, qualitative survey, we will recruit through an existing panel of HCPs currently licensed to practice in clinical settings in the United States who routinely care for or counsel pregnant patients. We will engage three groups of HCPs: (1) primary HCPs (obstetrician/gynecologists, family practice physicians, certified nurse-midwives, physician assistants); (2) consulting HCPs (neurologists, infectious disease specialists, psychiatrists, rheumatologists, cardiologists, pulmonologists, dermatologists), and (3) pharmacists. To be eligible for the study, primary HCPs must routinely care for or counsel five or more pregnant patients per month, and consulting HCPs and pharmacists must routinely care for or counsel three or more pregnant patients per month. All eligible HCPs must have either a degree

as a Doctor of Medicine, a Doctor of Osteopathic Medicine, or a Doctor of Pharmacy. Although we will recruit with representativeness in mind, we will weigh the data to ensure a nationally representative sample of HCPs. Generated tables will compare the weighted distributions of the variables used for weighting against their corresponding benchmarks.

A contracted research firm will collect data through internet administration. One hundred percent (100%) of participants will self-administer the internet survey via a computer, which will record responses and provide appropriate probes when needed. We will use automated technology in data collection, data reduction, and analyses. To identify eligible HCPs, we will send a recruitment email that links to a prequalifying screener on the internet. The screener will include questions about the HCP's specialty, number of years in practice, number of pregnant patients counseled per month, and demographics (age, race/ethnicity, and gender) and will confirm that the respondent does not work for FDA or a pharmaceutical company. We will invite all respondents who meet eligibility requirements to participate in the survey within 24 hours of completing the screener and obtain informed consent from all survey participants. The survey will assess experienced HCPs' knowledge of registries, their attitudes toward them, the barriers they face to recruiting patients, and their ideas about improving registry enrollment. Results from this project will advance pregnancy safety data collection from registries and ultimately improve health communications through inclusion of human safety data in pregnancy labeling. The survey is available on request at *pedsdrugs@fda.hhs.gov.*

We have the following specific research questions:

1. What proportion of HCPs know about pregnancy exposure registries?
2. What proportion of HCPs have referred patients to pregnancy exposure registries?
3. What proportion of HCPs have provided information from patient medical records to pregnancy exposure registries?
4. What barriers to patient enrollment in pregnancy exposure registries are identified by HCPs?
5. What ideas do HCPs have to improve enrollment in pregnancy exposure registries?

The target sample size for this study is 400 completed surveys. The sample will include an equal number of primary HCPs, consulting HCPs, and pharmacists. Such a design will help to ensure assessment of not only HCPs' perceptions generally, but also potential variations between different types of HCPs. HCPs are a difficult group to recruit, so several strategies will be put into place to achieve a high response rate. These strategies include tailoring contact materials, disclosing FDA sponsorship on survey materials, and providing a cash incentive.

To obtain 400 completed surveys, we estimate that 2,000 experienced HCPs will need to be screened. We estimate that participation in the study will take 17 minutes.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	2,000	1	2,000	0.0333 (2 minutes)	67
Main Study Survey	400	1	400	0.25 (15 minutes)	100
Total	2,000				167

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Prior to the main analysis, an outlier analysis will be performed for the time spent on any screen visited and total time to complete the survey. Extreme survey time will be identified and appropriate adjustments will be made prior to the final data analysis. The extent of any missing information will also be assessed to determine the data quality. Descriptive statistics will afford a look at the frequency of responses. Assessment of potential differences between primary HCPs, consulting HCPs, and pharmacists can be accomplished with pairwise comparisons between groups. We will also produce national-level estimates about attitudes toward pregnancy exposure registries and other key questions.

An analysis of item nonresponse will be made in the screener, if needed, and in the main survey. Item nonresponse rates will be tabulated for the questionnaire items, allowing for skip patterns. An analysis will be made of any questionnaire items that register unusually high item nonresponse rates. Multivariate item nonresponse relationships will be evaluated, including monotonicity patterns such as breakoffs (all items dropped after a particular item), and other types of ''blocks'' of multivariate item nonresponse. High levels of item nonresponse in particular items will have their correlations with other questionnaire item results in both the screener and main survey analyzed (tabulating how much the item nonresponse is concentrating in a particular subgroup of health providers).

The FDA anticipates disseminating the results of the study after final analyses of the data are completed, reviewed, and cleared. The information gathered on this topic will be used to inform regulatory guidance to sponsors and investigators designing pregnancy exposure registry protocols.

II. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Gelperin, K., H. Hammad, K. Leishear, et al., ''A Systematic Review of Pregnancy Exposure Registries: Examination of Protocol-Specified Pregnancy Outcomes, Target Sample Size, and Comparator Selection,'' *Pharmacoepidemiology and Drug Safety,* 2017 Feb;26(2):208–214. doi: 10.1002/pds.4150. Epub 2016 Dec 27. PMID: 28028914.
2. FDA, ''Postapproval Pregnancy Safety Studies (May 2019).'' Available at: *https://www.fda.gov/media/124746/download.*
3. National Institutes of Health, Task Force on Research Specific to Pregnant Women

and Lactating Women (PRGLAC). Available at: *https://www.nichd.nih.gov/about/advisory/PRGLAC.*
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5. Daniels, J.L., D.A. Savitz, C. Bradley, et al., ''Attitudes Toward Participation in a Pregnancy and Child Cohort Study,'' *Paediatric and Perinatal Epidemiology,* 2006 May;20(3):260–266. doi: 10.1111/j.1365–3016.2006.00720.x. PMID: 16629701.
6. Hartman, R.I. and A.B. Kimball, ''Performing Research in Pregnancy: Challenges and Perspectives,'' *Clinics in Dermatology,* 2016 May–Jun;34(3):410–415. doi: 10.1016/j.clindermatol.2016.02.014. Epub 2016 Feb 11. PMID: 27265080.
7. Krueger, W.S., M.S. Anthony, C.W. Saltus, et al., ''Evaluating the Safety of Medication Exposures During Pregnancy: A Case Study of Study Designs and Data Sources in Multiple Sclerosis,'' *Drugs Real World Outcomes,* 2017 Sep;4(3):139–149. doi: 10.1007/s40801–017–0114–9. PMID: 28756575; PMCID: PMC5567459.
8. Sarker A., P. Chandrashekar, A. Magge, et al., ''Discovering Cohorts of Pregnant Women From Social Media for Safety Surveillance and Analysis,'' *Journal of Medical internet Research,* 2017 Oct 30;19(10):e361. doi: 10.2196/jmir.8164. PMID: 29084707; PMCID: PMC5684515.
9. Sinclair S., M. Cunnington, J. Messenheimer, et al., ''Advantages and Problems With Pregnancy Registries: Observations and Surprises Throughout the Life of the International Lamotrigine Pregnancy Registry,'' *Pharmacoepidemiology and Drug Safety,* 2014 Aug;23(8):779–786. doi: 10.1002/pds.3659. Epub 2014 Jun 27. PMID: 24974947; PMCID: PMC4406353.

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09028 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1402]

Cancer Clinical Trial Eligibility Criteria: Laboratory Values; Draft Guidance for Industry, Institutional Review Boards, and Clinical Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry, institutional review boards (IRBs), and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Laboratory Values.'' This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation Research (CBER) for the treatment of cancer. Specifically, this draft guidance includes recommendations for selecting appropriate laboratory values as trial eligibility criteria to avoid unjustified exclusions of diverse trial participants.

DATES: Submit either electronic or written comments on the draft guidance by June 25, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–1402 for ''Cancer Clinical Trial Eligibility Criteria: Laboratory Values.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

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

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2169, Silver Spring, MD 20993, 240–302–2942; or Abhilasha Nair, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2362, Silver Spring, MD 20993, 301–796–8317; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry, IRBs, and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Laboratory Values.'' The purposes of eligibility criteria are to select the intended patient population and reduce potential risks to trial participants. However, eligibility criteria are sometimes more restrictive than necessary, and expanding eligibility criteria to be more inclusive is one trial design consideration that may improve the diversity of clinical trial populations. This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by CDER and CBER for the treatment of cancer. Specifically, this draft guidance includes recommendations to consider appropriate use of laboratory values as trial eligibility criteria and intends to assist interested parties, including sponsors and IRBs, who are responsible for the development and oversight of clinical trials.

A clinical trial's eligibility criteria (for inclusion and exclusion) are essential components of the trial, defining the characteristics of the study population. Because there is variability in investigational drugs and trial objectives, eligibility criteria should be developed taking into consideration the mechanism of action of the drug, the targeted disease or patient population, the anticipated safety of the investigational drug, the availability of adequate safety data, and the ability to recruit trial participants from the patient population to meet the objectives of the clinical trial. The Agency recognizes that some eligibility criteria may have become commonly accepted over time or used as a template across trials, but such criteria should be carefully considered and be appropriate for a specific trial context. Unnecessarily restrictive eligibility criteria may slow patient accrual, limit patients' access to clinical trials, and lead to trial results that do not fully represent treatment effects in the patient population that will ultimately use the drug.

Appropriately broadening cancer trial eligibility criteria can improve the generalizability of trial results and provide a more detailed characterization of the drug's benefit-risk profile across the patient population likely to use the drug in clinical practice.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Cancer Clinical Trial Eligibility Criteria: Laboratory Values.'' 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. The previously approved collections of information are subject to review by Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, 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: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09039 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Inclusion of Terrain Factors in the Definition of Rural Area for Federal Office of Rural Health Policy Grants

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for public comment.

SUMMARY: HRSA's Federal Office of Rural Health Policy (FORHP) utilizes clear, consistent, and data-driven methods of defining rural areas in the United States for the purposes of determining eligibility for its rural health grant programs. FORHP monitors ongoing national research and, as appropriate, considers updates to its definition. Because access to needed health care is likely to be reduced when roads are most difficult to traverse, with this notice, FORHP proposes to modify the definition of rural areas by integrating the new Road Ruggedness Scale (RRS) released in 2023 by the Economic Research Service (ERS) of the U.S. Department of Agriculture, which characterizes topographic variability, or ruggedness, of roads. This proposal does not impact rural areas included in the current FORHP definition. This notice seeks public comment on FORHP's proposal. This notice also includes a technical clarification explaining how FORHP will use Census data to identify outlying Metropolitan Statistical Area counties that qualify as rural in future updates given the U.S. Census Bureau's 2020 Census terminology changes that removed the categories of Urban Clusters and Urbanized Areas.

DATES: Submit comments no later than May 28, 2024.

ADDRESSES: Comments should be submitted to *ruralpolicy@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Greta Stuhlsatz, Statistician, Policy Research Division, FORHP, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; (301) 443–0835; and *ruralpolicy@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 711 of the Social Security Act (42 U.S.C. 912) directs FORHP to advise the Secretary of HHS on policies affecting rural hospitals and health care and coordinating activities within HHS that relate to rural health care. Since the 1990s, FORHP has administered grants that support activities related to increasing access to health care in rural areas. FORHP's authorizing statute does not, however, include a definition of ''rural area.'' To carry out this charge, FORHP monitors ongoing national research and analysis efforts related to defining geographic areas and rurality. As new methods and data become available, FORHP may consider revisions to the definition.

Historically, there have been two principal definitions of ''rural'' that were in use by the Federal Government: The U.S. Census Bureau urban-rural classification (*https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html*) and the Office of Management and Budget's definition of metropolitan, also called metro, areas (*https://www.census.gov/programs-surveys/metro-micro.html*). Neither definition defined ''rural'' directly, but rather defined areas as either ''urban,'' with all other territory being ''rural,'' or as ''metro,'' with all other territory being ''non-metro.''

Current FORHP Definition of Rural Area

FORHP currently designates the following areas as rural for purposes of FORHP's grant programs: [1]

(1) All non-metro counties,

(2) All outlying metro counties without an Urbanized Area,

(3) All metro census tracts with Rural Urban Commuting Area (RUCA) codes 4–10, and

(4) Metro census tracts of at least 400 square miles in area with population density of 35 or less per square mile with RUCA codes 2–3.

FORHP's current definition finds that 19.7 percent of the population, or approximately 60.8 million people, live in rural areas, and classifies 86 percent of the land area of the United States as rural (based on 2010 Census data; all data will be updated when updated RUCA codes are available using data from the 2020 Census). Information on whether individual addresses are within a rural area can be identified in a search tool at the HRSA Data Warehouse.[2] HRSA updates the search tool as needed to assist rural health grant applicants.

Adding Rugged Terrain Data to the Definition of Rural Area

FORHP's definition of rural area was last updated in 2021.[3] At that time, some commenters suggested that FORHP should further modify the definition of rural area to account for difficult and mountainous terrain because travel on roads through such terrain is more difficult and time-consuming. FORHP did not have national data that could consistently identify areas of difficult terrain.

In 2023, the ERS published a report, *Characterizing Rugged Terrain in the United States,*[4] which describes the measurement of topographic variation using the Terrain Ruggedness Index. The ERS conducted a study to analyze how population, population density, and income vary by ruggedness and rurality. The ERS produced two scales:

(1) The Area Ruggedness Scale (ARS) measures the changes in elevation for all terrain and classifies census tracts as: (1) level, (2) nearly level, (3) slightly rugged, (4) moderately rugged, (5) highly rugged, and (6) extremely rugged. This characterizes overall ruggedness in the entire tract.

(2) The RRS measures the changes in elevation beneath roads and classifies census tracts as: (1) level, (2) nearly level, (3) slightly rugged, (4) moderately rugged, and (5) highly rugged. This characterizes overall ruggedness along roads in the tract.[5]

The RRS, or roads-only scale, helps to study the impact of rugged terrain on travel by vehicle. Based on the ERS analysis of the RRS, population density was highest, on average, for nearly level census tracts (5,514 people per square mile) and lowest for highly rugged census tracts (3,390 people per square mile).

TABLE 1—RRS CATEGORIES AND CENSUS TRACTS

RRS category	Number of census tracts	Percent of census tracts
1—Level	47,740	65.6
2—Nearly level	16,297	22.4
3—Slightly rugged	5,518	7.6
4—Moderately rugged	1,956	2.7
5—Highly rugged	1,254	1.7
Total	72,765	100.0

FORHP is proposing to expand its definition of rural by incorporating the RRS into the definition for purposes of FORHP's grant programs. All areas included in the current definition would remain included. The RRS focuses on roads and the difficulty of travelling in mountainous terrain, while the ARS more generally classifies the topography of the tract's terrain. Access to needed health care is likely to be reduced when the roads are most difficult to traverse. FORHP proposes including census tracts of at least 20 square miles in area in metro counties

[1] See the notice ''Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants,'' 85 FR 59806 (Sept. 23, 2020), for a full description of the methods and data sources used to develop FORHP's definition of rural areas. See the notice ''Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants,'' 86 FR 2418 (Jan. 12, 2021), for FORHP's current definition of rural areas. See Defining Rural Population, *https://www.hrsa.gov/rural-health/about-us/what-is-rural.*

[2] HRSA Data Warehouse: *https://data.hrsa.gov/tools/rural-health.*

[3] ''Response to Comments on Revised Geographic Eligibility for Federal Office of Rural Health Policy Grants.'' 86 FR 2418 (Jan. 12, 2021).

[4] Research Report No. ERR–322, August 2023. Available at *https://www.ers.usda.gov/publications/pub-details/?pubid=107027.*

[5] ARS and RRS data are available at *https://www.ers.usda.gov/data-products/area-and-road-ruggedness-scales/.*

with RRS 5 (highly rugged) and RUCA code 2 or 3 in our definition of rural area (tracts with RUCA codes 4–10 regardless of RRS are already included). Some small area tracts within or on the edge of cities can have rugged terrain (*e.g.,* State or local parks), but they are very small size and adjacent to major population centers.

FORHP estimates that including census tracts that are at least 20 square miles in area with RRS 5 and RUCA 2–3 in the definition of rural area would add 84 census tracts and approximately an additional 304,834 people to the 60,758,275 people currently living in FORHP-designated rural areas, an increase of 0.5 percent in the total number of people living in rural areas. The number of eligible census tracts by State is included in table 2.

Only tracts that meet all criteria—RRS 5 and RUCA 2–3 with an area over 20 square miles—would be newly eligible under this proposed update. Tracts with RRS 5 and RUCA code 1 could not be classified as rural areas as tracts with RUCA code 1 contain populations from urban areas with over 50,000 residents. Additionally, the RUCA code 1 tracts located in metro counties are part of the metropolitan area core and have primary commuting flow within the urban area.[6] For example, San Francisco, California has 31 census tracts with RRS 5 and RUCA code 1, and these small areas with rugged terrain inside the metropolitan area core are not rural in character.

TABLE 2—NUMBER OF CENSUS TRACTS WITH RRS 5 AND RUCA CODE 2 OR 3 AND AREA OVER 20 SQ. MILES, BY STATE

State	New tracts
CA	24
OR	16
NC	12
WA	9
TN	7
CO	6
WV	6
MT	2
AK	1
MD	1
Total	84

Note: Data in this table are based on 2010 census tract geographies. For a complete list of impacted census tracts see: *https://www.hrsa.gov/rural-health/about-us/what-is-rural/data-files.*

FORHP's proposal to modify our definition of rural area for purposes of FORHP's grant programs reflects efforts to be responsive to stakeholder feedback and target programs towards the intended communities. Other rural definitions for other purposes may be set by statute or regulation or be designed to meet different program goals.

Notification of FORHP's Technical Clarification in Response to the U.S. Census Bureau's 2020 Census Terminology Changes Removing Urban Clusters and Urbanized Areas

Prior to the 2020 Census, the U.S. Census Bureau designated two categories of urban areas—Urban Clusters (with a population of 2,500 to 49,999) and Urbanized Areas (with a population of 50,000 or more). With the elimination of these sub-categories to differentiate urban areas with large and small populations, the U.S. Census Bureau now only designates urban areas (population of 5,000 and up or housing units of 2,000 or more) and does not sub-categorize urban areas by size. FORHP's rural definition excludes outlying metro counties with an *Urbanized Area.* To retain the distinction between urban areas with population over and under 50,000 in FORHP's definition of rural area, FORHP will identify and categorize urban areas based on population size. With this technical clarification, the definition, ''all outlying metro counties with no urban population from an urban area of 50,000 or more people,'' will replace ''all outlying metro counties without an urbanized area.''

FORHP will use the urban area population counts published by the U.S. Census Bureau in the list of qualifying urban areas for the 2020 Census (*https://www.census.gov/programs-surveys/geography/guidance/geo-areas/urban-rural.html*) to sub-categorize urban areas as less than 50,000 people (*e.g.,* a population of 49,999 or fewer) and as 50,000 or more people in the next update to rural area data files. Consistent with our current definition, FORHP will consider outlying metro counties without population from urban areas with 50,000 or more people as rural areas, and the entire county would be considered a rural area for our grant programs.

There are 327 outlying metro counties in the Office of Management and Budget's Bulletin No. 23–01, released July 21, 2023, that have no population part of an urban area with 50,000 or more people. Outlying metro counties with any population from urban areas with 50,000 or more people would not be considered rural areas, however census tracts within those counties would be considered rural areas if they meet the RUCA criteria or the RUCA and RRS criteria, as applicable.

Proposed FORHP Definition of Rural Area Incorporating the RRS and the Technical Clarification in Response to Census Terminology Changes

FORHP proposes to designate the following areas as rural for purposes of FORHP's grant programs:

(1) Non-metro counties,

(2) Outlying metro counties with no urban population from an urban area of 50,000 or more people,

(3) Census tracts in metro counties with RUCA codes 4–10,

(4) Census tracts in metro counties of at least 400 square miles in area with population density of 35 or less per square mile with RUCA codes 2–3, and

(5) Census tracts in metro counties with RRS 5 and RUCA codes 2–3 that are at least 20 square miles in area.

Request for Public Comment

FORHP is proposing to modify the current definition of rural area for purposes of FORHP's grant programs. FORHP seeks comments from the public on the proposed use of the RRS to identify rural areas as described above.

This request for comments is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This request does not commit the Government to contract for any supplies or services or make a grant or cooperative agreement award or take any other official action. Further, HRSA is not seeking proposals through this request for comments and will not accept unsolicited proposals.

Carole Johnson,

Administrator.

[FR Doc. 2024–08931 Filed 4–25–24; 8:45 am]

BILLING CODE 4165–15–P

[6] See the description of Rural-Urban Commuting Area Codes at *https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to

recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities'' unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 12½%, as fixed by the Secretary of the Treasury, is certified for the quarter ended March 31, 2024. This rate is based on the Interest Rates for Specific Legislation, ''National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))'' and ''National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).'' This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

David C. Horn,

Director, Office of Financial Policy and Reporting.

[FR Doc. 2024–08939 Filed 4–25–24; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852 by contacting Dawn Taylor-Mulneix at 301–451–8021 or *dawn.taylor-mulneix@nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Human Monoclonal Antibodies That Target the RH5 Complex of Blood-Stage Plasmodium Falciparum

Description of Technology

249 million people were afflicted with malaria in 2022. There are five *Plasmodium* parasite species that cause malaria in humans. Of the five, *Plasmodium falciparum* causes most of the incidence of human disease. Most advanced malaria vaccine candidates can confer only partial, short-term protection in malaria-endemic areas. The pathogenesis of malaria is associated with blood-stage infection and antibodies specific to the parasite blood-stage antigens may be able to control parasitemia. To address this public health need, NIAID inventors have developed 35 human monoclonal antibodies that target the RH5 complex of blood-stage *Plasmodium falciparum* and were found to have potent activity in *in vitro* growth inhibition assays.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Method of prophylactic and/or therapeutic treatment by targeting blood-stage antigens of *Plasmodium.*

Competitive Advantages

- Most other commercially available antibodies targeting against *Plasmodium* target circumsporozoite protein (CSP) present in the sporozoite stage. These novel antibodies instead target a conserved and essential antigen present in the blood stage: RH5.
- These monoclonal antibodies can be used alone or in combination with existing antibodies.

Developmental Stage

- Pre-clinical.

Inventors: Joshua Tan, Ph.D., Lawrence Wang, Ph.D. and Andrew Cooper, Ph.D., all of NIAID.

Publications: Wang, L., Cooper, A., et al. ''Natural malaria infection elicits rare but potent neutralizing antibodies to the blood-stage antigen RH5.'' bioRxiv. *https://www.biorxiv.org/content/10.1101/2023.10.04.560669v1,* October 06, 2023.

Intellectual Property: HHS Reference No. E–014–2023; Provisional Patent Application No.: 63/468,740.

Licensing Contact: To license this technology, please contact Dawn Taylor-Mulneix at 301–451–8021 or *dawn.taylor-mulneix@nih.gov,* and reference E–014–2023.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Dawn Taylor-Mulneix at 301–451–8021 or *dawn.taylor-mulneix@nih.gov.*

Dated: April 19, 2024.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2024–08986 Filed 4–25–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket Number USCG–2024–0281]

Operational Adjustments Resulting From Workforce Shortages

AGENCY: Coast Guard, DHS.

ACTION: Notice and request for comments.

SUMMARY: We are requesting your comments on planned actions that will allow the Coast Guard to prioritize lifesaving missions and protection of the Marine Transportation System in light of current personnel shortages. Like other military services, the Coast Guard is facing an unprecedented workforce shortage that is impacting Service readiness. The current and forecasted extent of the shortage is prompting significant actions to best protect the American public and maintain Service readiness. If actions are not taken to adjust operations, we can anticipate longer-term impacts to mission effectiveness and increased risk to our service members, as well as to commercial mariners and private boaters. In addition to leveraging technology and enhancing recruitment and retention efforts, operational adjustments must be executed within the existing response system while maintaining standards and an adherence to core mission execution. These adjustments fall into two categories: First, in regions where multiple units could respond if they were resourced appropriately, boats and people will be consolidated at one or more units to ensure a robust response. Secondly, in areas where the Coast Guard operates

limited, or seasonal units that do not have sufficient personnel to respond, operations will be temporarily paused as resources are moved to higher priority areas. These adjustments will remain in effect until the Coast Guard has sufficient personnel to reconstitute these units.

DATES: Written comments and related material may be submitted to the Coast Guard personnel specified below. Your comments and related material must reach the Coast Guard on or before May 24, 2024.

ADDRESSES: You may submit comments identified by docket number USCG–2024–0281 using the Federal rulemaking portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document, please email Kiesha Miller (202–372–4632) at *SMB-COMDT-TempOpsAdjust@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
GAO Government Accountability Office

II. Background and Purpose

The Coast Guard continues to experience recruiting challenges, leading to workforce shortages impacting frontline operations and Service readiness. Personnel in impacted areas are largely boat operators and engineers, who form the bedrock of Coast Guard operations. The Coast Guard is proactively adjusting operations and prioritizing personnel assignments to specific operational units to ensure the Service remains always ready to serve the American public. This notice meets the requirements for 14 U.S.C. 910.

III. Discussion

The following units will transition for use as a forward operating location (*i.e.,* a staging area at unit commander discretion): Stations-Small Scituate, MA; East Moriches, NY; Great Egg, NJ; Beach Haven, NJ; Townsends Inlet, NJ; Stillpond, MD; Fortescue, NJ; Sodus Point, NY; Ashtabula, OH; Lorain, OH; Harbor Beach, MI; Muskegon, MI; Alpena, MI; Frankfort, MI; Ludington, MI; DuSable Harbor, IL; Wilmette Harbor, IL; Two Rivers, WI; Washington Island, WI; Green Bay, WI; Santa Cruz, CA; Coquille River, OR; and Rogue River, OR. These units already consolidate for some portion of the year.

The following units currently do not maintain a duty crew to conduct response operations, and will temporarily pause boat operations altogether: Stations Paducah, KY; Pittsburgh, PA; St. Louis, MO; Louisville; KY, and Memphis; TN and boat operations in Huntington, WV.

IV. Public Participation and Request for Comments

We encourage you to submit comments through the Federal portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. In your submission, please include the docket number for this notice and provide a reason for each suggestion or recommendation. We will review all comments received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

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

Jason C. Aleksak,

Captain, U.S. Coast Guard, Chief, Office of Boat Forces.

[FR Doc. 2024–08978 Filed 4–25–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6382–N–02]

Federal Housing Administration (FHA): Home Equity Conversion Mortgage (HECM) for Purchase-Acceptable Monetary Investment Funding Sources and Interested Party Contributions

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: On October 24, 2023, HUD published a **Federal Register** notice (October FR Notice) announcing and seeking public comment on changes to the Federal Housing Administration's (FHA) Home Equity Conversion Mortgage (HECM) for Purchase Program—Acceptable Monetary Investment Funding Sources and Interested Party Contributions requirements. The proposed changes from HUD's October FR Notice were included in an update to HUD's Single Family Housing Policy Handbook, which was published October 31, 2023, and becomes effective on April 29, 2024. After consideration of the public comments received in response to the notice of the proposed changes, FHA has decided not to implement some of the changes proposed in the October FR Notice at this time. HUD will publish a Mortgagee Letter or update the Single Family Housing Policy Handbook to align HUD's policy with this **Federal Register** notice. All other changes previously included in the Handbook will go into effect on April 29, 2024, as planned.

FOR FURTHER INFORMATION CONTACT: Brian Faux, Director, Office of Single Family Program Development, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW, Room 9266, Washington, DC 20410–9000, telephone number 202–402–2378 (this is not a toll-free number); email address *sffeedback@hud.gov*. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or 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.*

SUPPLEMENTARY INFORMATION:

I. Public Comments in Response to HUD's October Federal Register Notice

HUD's regulations at 24 CFR 206.44(b)(4) and 206.44(c)(2) provide the FHA Commissioner authority to permit additional funding sources for a borrower's monetary investment and interested party contributions for HECM for Purchase transactions through notice in the **Federal Register**. HUD relied on these authorities in making the proposed changes described in HUD's October FR Notice published on October 24, 2023, at 88 FR 73040. The changes proposed in that October FR Notice also were prospectively included in an update to HUD's Single Family Housing Policy Handbook, published October 31, 2023, and becoming effective on April 29, 2024.

FHA received two public comments in response to the October FR Notice. One commenter was broadly supportive of the proposed changes to the HECM for Purchase program. The commenter supported HUD's effort to align the HECM for Purchase program with FHA's

forward mortgage programs by permitting the interested party contributions explained in HUD's October FR Notice up to six percent of the sales price. The commenter stated that these changes would help more seniors qualify for and receive the benefits of the HECM for Purchase program, especially in downsizing or otherwise changing the size of their current homes before and during retirement. The commenter concluded that the changes would improve and strengthen seniors' financial status.

The other commenter raised significant concerns about allowing HECM for Purchase borrowers to use lender credits, including premium pricing, to satisfy the monetary investment requirement for a HECM for Purchase. The commenter noted that, because HECMs are negative amortization loans where the loan balance increases over time and interest costs are added to the loan balance each month, accepting a higher interest rate in return for a credit at closing would be very costly for the borrower. The use of premium pricing may result in HECM for Purchase borrowers being steered into more expensive products that do not meet their long-term financial needs.

The commenter further noted that HECM for Purchase borrowers are not likely to understand the true, long-term cost of the higher interest rate nor are they likely to receive a credit at closing that will fully compensate them for paying the higher interest rate because the termination date of a HECM loan is unknown at the time of origination, so the cost calculation can only be an estimate. Additionally, in light of recent enforcement actions by state authorities against mortgage lenders in the forward mortgage market that failed to refund surplus lender credits to borrowers, the commenter also raised concerns that HECM for Purchase borrowers may not receive the full benefit of premium pricing credits.

Finally, the commenter disagreed that FHA should allow mortgagees and third-party originators (TPOs) to contribute to closing costs. The commenter noted that allowing mortgagees and TPOs to contribute toward closing costs would increase the chances of undue influence, fraud, and unaffordable loans for HECM for Purchase borrowers.

II. This Notice

HUD has carefully considered the comments received and has determined that the potential harms to borrowers are significant enough that it would be imprudent to make these changes at this time. Thus, pursuant to the abovementioned authorities, HUD will remove the following changes from HUD's Single Family Housing Policy Handbook 4000.1: (1) permitting premium pricing as an additional funding source used to satisfy a HECM for Purchase borrower's monetary investment; (2) including discount points in the definition of ''interested party contribution''; (3) permitting interested party payment for permanent and temporary interest rate buydowns as an interested party contribution; (4) allowing mortgagees and third parties to make any interested party contributions; and (5) allowing discount points and interest rate buydowns as permissible closing costs for HECM for Purchase transactions. Removing these changes means that the use of premium pricing to help satisfy the borrower's monetary investment and including discount points and permanent and temporary interest rate buydowns as interested party contributions for a HECM for Purchase will not be permissible, that mortgagees and third party originators (TPOs) will be prohibited from making interested party contributions, and that discount points and interest rate buydowns as permissible closing costs will not be allowed after the effective date of HUD's Mortgagee Letter or update to the Single Family Housing Policy Handbook.

Julia R. Gordon,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2024–08819 Filed 4–25–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2024–0063; FXIA16710900000–245–FF09A30000]

Foreign Endangered Species; Receipt of Permit Application

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit application; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on an application to conduct certain activities with a foreign species that is listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activity. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by May 28, 2024.

ADDRESSES: *Obtaining Documents:* The application, application supporting materials, and any comments and other materials that we receive will be available for public inspection at *https://www.regulations.gov* in Docket No. FWS–HQ–IA–2024–0063.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet: https://www.regulations.gov.* Search for and submit comments on Docket No. FWS–HQ–IA–2024–0063.
- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2024–0063; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703–358–2185 or via email at *DMAFR@fws.gov.* 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:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on this application. Before issuing the requested permit, we will take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES.** We will not consider comments sent by email or to an address not in **ADDRESSES.** We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of

your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. 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.

B. May I review comments submitted by others?

You may view and comment on others' public comments at *https://www.regulations.gov* unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who Will See My Comments?

If you submit a comment at *https://www.regulations.gov,* your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, 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. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Application

We invite comments on the following application.

Applicant: San Diego Zoo Wildlife Alliance, dba Zoological Society of San Diego, San Diego, CA; Permit No. PER10054100

The applicant requests a permit to import one male and one female captive-bred giant panda (*Ailuropoda melanoleuca*) from the China Conservation and Research Centre for the Giant Panda, Sichuan, the People's Republic of China, for the purpose of enhancing the propagation or survival of the species. This notification is for a single import.

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue a permit to the applicant listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching *https://www.regulations.gov* for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to regulations.gov and search for ''12345A''.

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Brenda Tapia,

Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2024–09000 Filed 4–25–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500178463]

Notice of Availability for the Central Yukon Proposed Resource Management Plan/Environmental Impact Statement, Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) has prepared a Proposed Resource Management Plan (RMP) and Final Environmental Impact Statement (EIS) for the Central Yukon Planning Area, and by this notice is announcing the start of a 30-day protest period of the Proposed RMP.

DATES: This notice announces the beginning of a 30-day protest period to the BLM on the Proposed RMP. Protests must be postmarked or electronically submitted on the BLM's ePlanning site within 30 days of the date that the Environmental Protection Agency (EPA) publishes its Notice of Availability (NOA) in the **Federal Register**. The EPA usually publishes its NOAs on Fridays.

ADDRESSES: The Proposed RMP/Final EIS is available on the BLM's ePlanning project website at *https://eplanning.blm.gov/eplanning-ui/project/35315/510.* Documents pertinent to this proposal may be examined online at *https://eplanning.blm.gov/eplanning-ui/project/35315/570* and at the BLM Alaska State Office, BLM Alaska Public Information Center, 222 West 7th Avenue (1st Floor), Anchorage, Alaska, 99513; or at the Fairbanks District Office, 222 University Avenue, Fairbanks, Alaska 99709.

Instructions for filing a protest with the BLM for the Central Yukon Proposed RMP/Final EIS can be found at: *https://www.blm.gov/programs/planning-and-nepa/public-participation/filing-a-plan-protest* and in the Code of Federal Regulations (CFR) at 43 CFR 1610.5–2.

FOR FURTHER INFORMATION CONTACT: Melinda Bolton, BLM Alaska Planning and Environmental Specialist, telephone: (907) 271–3342 or email: *mbolton@blm.gov.* 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 for contacting Ms. Bolton. 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 Central Yukon Proposed RMP/Final EIS is a comprehensive framework for future public land management actions in the Central Yukon region of Alaska. The planning area consists of about 55.7 million acres of land, including approximately 13.3 million acres of public lands managed by the BLM Central Yukon Field Office.

The Central Yukon RMP will guide management of these public lands for the benefit of current and future generations as part of the BLM's

multiple-use mission. This planning effort updates management decisions for public land uses and resources, including subsistence resources, mineral exploration and development, and recreation. When complete, the updated Central Yukon RMP will replace the Utility Corridor RMP (1991), the original Central Yukon RMP (1986), and portions of the Southwest Management Framework Plan (1981), as well as provide RMP-level decisions for unplanned lands west of Fairbanks. The proposed plan provides consolidated direction under one resource management plan to address land and resource use and development on BLM-managed public lands within the planning area.

The Central Yukon Proposed RMP/EIS evaluates six alternatives for managing the planning area. Alternatives B, C1, C2 (preferred alternative from Draft RMP/EIS), and D were developed using input from the public, Tribes, stakeholders, and cooperating agencies. Alternative E is the BLM's Proposed RMP. This alternative was developed after considering public comments on the Draft RMP/EIS and provided in the ANILCA section 810 hearings, internal BLM discussions, government-to-government consultation, and cooperating agency input.

The Proposed RMP is drawn from components of the Alternatives analyzed in the Draft RMP/EIS and, as such, the management provisions are within the range of alternatives presented to the public. Alternative A, the no action alternative, represents existing management described by current land use plans and provides the benchmark against which to compare the other alternatives. Alternative B emphasizes reducing the potential for competition between development uses and subsistence resources by identifying key areas for additional management actions. Alternative C1 emphasizes a blend of resource protection and development at the planning level to maintain the long-term sustainability of resources while providing for multiple resource uses. Alternative C2 emphasizes management to facilitate resource development while applying habitat management and administrative designations to accommodate multiple uses. Alternative D focuses on maximizing BLM-managed public lands for development potential with fewer management restrictions at the planning level. Unlike the action alternatives from the Draft RMP/EIS, the Proposed RMP (Alternative E) recommends retention of Public Land Order (PLO) 5150. The Proposed RMP also does not recommend full revocation of the ANCSA 17(d)(1) PLOs, but does recommend revoking the withdrawals in part to allow for selection by Alaska Native Vietnam-era veterans where the PLOs currently do not allow for it. For most resources, the Proposed RMP is similar to Alternative C (either Alternative C1 or Alternative C2). The Proposed RMP designates twenty-one Areas of Critical Environmental Concern (ACECs) or Research Natural Areas, encompassing approximately 3,601,000 acres. For a detailed comparison of Alternatives, including ACEC acreages proposed for designation, see Table 2–1 and corresponding maps in Appendix A of the Proposed RMP/Final EIS.

Major planning issues addressed include subsistence resources, subsistence access, water resources, fisheries, wildlife, forestry, minerals, mining, recreation, travel management, and ACECs.

Protest of the Proposed RMP: The BLM planning regulations state that any person who participated in the preparation of the RMP and has an interest which will or might be adversely affected by approval of the Proposed RMP may protest its approval to the BLM Director. Protest on the Proposed RMP constitutes the final opportunity for administrative review of the proposed land use planning decisions prior to the BLM adopting an approved RMP. Instructions for filing a protest regarding the Proposed RMP with the BLM Director may be found online at *https://www.blm.gov/programs/planning-and-nepa/public-participation/filing-a-plan-protest* and at 43 CFR 1610.5–2. All protests must be in writing and mailed to the appropriate address, as set forth in the **ADDRESSES** section earlier, or submitted electronically through the BLM ePlanning project website as described previously. Protests submitted electronically by any means other than the ePlanning project website or by fax will be invalid unless a protest is also submitted as a hard copy.

The BLM Director will render a written decision on each protest. The Director's decision shall be the final decision of the Department of the Interior. Responses to valid protest will be compiled and documented in a Protest Resolution Report made available following the protest resolution online at: *https://www.blm.gov/programs/planning-and-nepa/public-participation/protest-resolution-reports.* Upon resolution of protests, the BLM will issue a Record of Decision and Approved RMP.

Before including your phone number, email address, or other personal identifying information in your protest, you should be aware that your entire protest– including your personal identifying information—may be made publicly available at any time. While you can ask us in your protest to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2, 43 CFR 1610.5)

Steven M. Cohn,

State Director, Alaska.

[FR Doc. 2024–08966 Filed 4–25–24; 8:45 am]

BILLING CODE 4331–10–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_AK_FRN_MO4500174927]

Notice of Availability of the Ambler Road Final Supplemental Environmental Impact Statement, Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) announces the availability of a Final Supplemental Environmental Impact Statement (EIS) for the proposed Ambler Road project.

DATES: The BLM will issue a Record of Decision (ROD) for the project no earlier than 30 days from the date the EPA publishes its notice of availability of the Final Supplemental EIS in the **Federal Register**.

ADDRESSES: To access the Final Supplemental EIS please visit: *https://www.blm.gov/AmblerRoadEIS.* To request an electronic or paper copy of the Final Supplemental EIS, please reach out to the BLM Alaska State Office, BLM Alaska Public Information Center, 222 West 7th Avenue (First Floor), Anchorage, Alaska 99513; or the Fairbanks District Office, 222 University Avenue, Fairbanks, Alaska 99709.

Documents pertinent to this proposal may be examined online on the BLM ePlanning website at *https://www.blm.gov/AmblerRoadEIS.*

FOR FURTHER INFORMATION CONTACT: Stacie McIntosh, Ambler Road Supplemental EIS Project Manager, telephone: 907–474–2398; email address: *s05mcint@blm.gov.*

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 for contacting Ms. McIntosh. 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 BLM has prepared the Ambler Road Supplemental EIS in response to an application for an industrial road right-of-way (ROW) in north-central Alaska across Federal public lands and other lands. The area involved lies south of the Brooks Range, north of the Yukon River, west of the Dalton Highway, and east of the Purcell Mountains. The Alaska Industrial Development and Export Authority, a public corporation of the State of Alaska, is the applicant.

The road was initially analyzed in an EIS published in March 2020, and a BLM ROW was approved in a Joint Record of Decision (JROD) issued in July 2020. In May 2022, in two lawsuits challenging the JROD and associated environmental analyses, the U.S. District Court for the District of Alaska (District Court) granted a voluntary remand at the request of the Department of the Interior (DOI) due to, among other things, deficiencies in the BLM's analysis of subsistence impacts under the Alaska National Interest Lands Conservation Act (ANILCA) section 810, and in the consultation with Tribes conducted pursuant to section 106 of the National Historic Preservation Act (NHPA). In the motion for voluntary remand, the DOI committed to address these issues, including the identified legal deficiencies, consider new information about declines in salmon and caribou populations, reconsider the appropriate scope of the area of potential effects for purposes of the NHPA, and supplement the EIS, as appropriate, to more thoroughly assess the impacts and resources identified as areas of concern in the two lawsuits challenging the remanded JROD.

The Final Supplemental EIS analyzes: the No Action Alternative; Alternative A, the applicant's 211 mile-long proposed road alignment beginning at Mile 161 of the Dalton Highway, extending west, and ending at the Ambler River; Alternative B, which starts and ends in the same location as Alternative A but follows a shorter route through Gates of the Arctic National Preserve; and Alternative C, which starts at Mile 59.5 of the Dalton Highway and extends 332 miles northwest, ending at the Ambler River. The BLM has identified the No Action Alternative as its preferred alternative.

Section 810 of ANILCA requires the BLM to evaluate the effects of the alternatives presented in the Supplemental EIS on subsistence uses and needs and to hold public hearings if it finds that any alternative may significantly restrict subsistence uses. The BLM found in the evaluation of subsistence impacts that Alternatives A, B, and C and the cumulative case as analyzed in the Draft Supplemental EIS may significantly restrict subsistence uses in multiple communities. Therefore, the BLM held public hearings on subsistence resources and activities in conjunction with the public meetings on the Draft Supplemental EIS in the vicinity of potentially affected communities. In consideration of public comments received on the Draft Supplemental EIS and at the public hearings, BLM revised the ANILCA Section 810 evaluation, published as Appendix M of the Final Supplemental EIS, but did not change its ''may significantly restrict subsistence uses'' findings for the identified communities.

The input of Alaska Native Tribes and Corporations was of critical importance to this Supplemental EIS. Therefore, during the NEPA process, the BLM consulted with potentially affected federally recognized Tribes on a government-to-government basis and with affected Alaska Native Corporations in accordance with Executive Order 13175, as well as Pub. L. 108–199, Div. H, sec. 161, 118 Stat. 452, as amended by Pub. L. 108–447, Div. H, sec. 518, 118 Stat. 3267, and other Department and Bureau policies.

Authority: 40 CFR 1506.6(b).

Steven M. Cohn,

State Director, Alaska.

[FR Doc. 2024–08965 Filed 4–25–24; 8:45 am]

BILLING CODE 4331–10–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1399]

Certain Fiber-Optic Connectors, Adapters, Jump Cables, Patch Cords, Products Containing the Same, and Components Thereof; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on March 22, 2024, under section 337 of the Tariff Act of 1930, as amended, on behalf of US Conec, Ltd. of Hickory, North Carolina. Supplements to the complaint were filed on April 12, 2024. The complaint alleges violations 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 fiber-optic connectors, adapters, jump cables, patch cords, products containing the same, and components thereof by reason of the infringement of certain claims of U.S. Patent No. 11,733,466 (''the '466 patent''); U.S. Patent No. 11,808,994 (''the '994 patent''); U.S. Patent No. 11,906,794 (''the '794 patent''); U.S. Patent No. 11,880,075 (''the '075 patent''); U.S. Patent No. 11,385,415 (''the '415 patent''); and U.S. Patent No. 10,495,823 (''the '823 patent''). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainant requests that the Commission institute an investigation and, after the investigation, issue a general exclusion order, or in the alternative a limited exclusion order, and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2024).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on April 22, 2024, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1–3, 6, 7, and 14–17 of the '466 patent; claims 1–7 and 11–13 of the '994 patent; claims 1–3, 5, 6, 9, 12, and 16–18 of the '794 patent; claims 1, 5, 8–10, 12, 15, and 17–21 of the '075 patent; claims 1, 3, 5, and 12–14 of the '415 patent; and claims 1–5 and 8–10 of the '823 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''fiber-optic connectors, fiber-optic adapters, fiber-optic interconnects, fiber-optic cables, fiber-optic patch cables, fiber-optic cords, and fiber-optic patch cords, including any of the foregoing sold under the monikers SN, SN–MT, SN EZ-Flip, and MPO Plus'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

US Conec, Ltd., 1138 25th Street SE, Hickory, NC 28602

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Senko Advance Co., Ltd., 510–0833 2–5–23 Nakagawara, Yokkaichi City, Mie Prefecture, Japan

Senko Advanced Components, Inc., 2 Cabot Road, Suite 103, Hudson, MA 01749

Eaton Corp., 30 Pembroke Road, Dublin 4, Ireland D04 Y0C2

Tripp Lite Holdings, Inc., 10000 Woodward Avenue, Woodridge, IL 60517

FS.com Inc., 380 Centerpoint Boulevard, New Castle, DE 19720

Infinite Electronics, Inc., 17792 Fitch, Irvine, CA 92614

L-com, Inc., 50 High Street, West Mill, Suite 30, North Andover, MA 01845

Sumitomo Electric Industries, Ltd., 4–5–33, Kitahama, Chuo-ku, 541–0041, Osaka, Japan

Sumitomo Electric Lightwave Corp., 201 South Rogers Lane, Suite 100, Raleigh, NC 27610

Sumitomo Electric U.S.A., Inc., 21241 S Western Avenue, Suite 120, Torrance, CA 90501

EZconn Corp., 13F, No. 27–8, Zhongzheng E. Rd., Sec. 2, New Taipei City, 25170 Taiwan

Flexoptix GmbH, Muehltalstr. 153, 64297, Darmstadt, Germany

Changzhou Co-Net Electronic Technology Co., Ltd., 3rd Floor, Building 3, No. 92, Renmin East, Road, Yaoguan Town, Economic, Development Zone, 213161 Changzhou, Jiangsu, China

Shenzhen UnitekFiber Solution Ltd., 8F, Datang Shidai Building, No. 2203, Meilong Road, Longhua District, Shenzhen, Guangdong province, China

Hubbell Inc., 40 Waterview Drive, Shelton, CT 06484

Hubbell Premise Wiring, Inc., 40 Waterview Drive, Shelton, CT 06484

Shenzhen IH Optics Co., Ltd., G608–609, Baoanzhigu, Yintian Rd., Xixiang, Baoan Dist., Shenzhen, China 518126

Rayoptic Communication Co., Ltd, Floor 3, Building E, Dahong Science And Technology Park, No. B–10, Baihua Community, Guangming Street, Guangming New District, Shenzhen, China

HuNan Surfiber Technology Co., Ltd., 3rd Floor, Building A8, Desiqin Venture Street, No. 686 Yingxin Road, l Yuhua District, Changsha, Hunan, China

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: April 22, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–08940 Filed 4–25–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On April 22, 2024, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of California in the lawsuit entitled *United States* v. *City of San Diego, San Diego Unified Port District, and San Diego County Regional Airport Authority,* Civil Action No. 3:23–cv–00541–LL–BGS.

The Consent Decree resolves claims against the San Diego Unified Port District and the San Diego County Regional Airport Authority pursuant to section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act for reimbursement of response costs incurred for response actions taken in connection with the release of hazardous substances at the Installation Restoration Site 12, the Boat Channel Sediments Site, at the former Naval Training Center in San Diego, California. The proposed Consent Decree requires a payment by both parties collectively of $2,412,029.89, in exchange for a covenant not to sue and contribution protection. The City of San Deigo is not a party to the Consent Decree.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney

General, Environment and Natural Resources Division, and should refer to *United States* v. *City of San Diego, San Diego Unified Port District, and San Diego County Regional Airport Authority,* D.J. Ref. No. 90–11–3–11826. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Any comments submitted in writing may be filed by the United States in whole or in part on the public court docket without notice to the commenter.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* If you require assistance accessing the Consent Decree you may request assistance by email or by mail to the addresses provided above for submitting comments.

Scott Bauer,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2024–09053 Filed 4–25–24; 8:45 am]

BILLING CODE 4410–15–P

LEGAL SERVICES CORPORATION

Sunshine Act Meetings

TIME AND DATE: The Legal Services Corporation (LSC) Board of Directors will hold a virtual meeting on Thursday, May 2, 2024. The meeting will commence at 4:30 p.m. Eastern Time, continuing until the conclusion of the Board's agenda.

PLACE: The meeting will be held virtually via Zoom.

STATUS: Closed to public observation.

A verbatim written transcript will be made of the closed session of the Board meeting. The transcript of any portions of the closed session falling within the relevant provisions of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(2) and(c)(6) will not be available for public inspection. A copy of the General Counsel's certification that, in his opinion, the closing is authorized by law will be available upon request.

MATTERS TO BE CONSIDERED:

Closed Session

Matters to be discussed include approval of the meeting agenda; Management briefing; discussion on program review; and a proposal to convene in Executive Session without LSC Management present.

CONTACT PERSON FOR MORE INFORMATION: Jessica Wechter, Special Assistant to the President, at (202) 295–1626. Questions may also be sent by electronic mail to *wechterj@lsc.gov.*

Non-Confidential Meeting Materials: Non-confidential meeting materials will be made available in electronic format at least 24 hours in advance of the meeting on the LSC website, at *https://www.lsc.gov/about-lsc/board-meeting-materials.*

(Authority: 5 U.S.C. 552b.)

Dated: April 23, 2024.

Stefanie Davis,

Deputy General Counsel, Legal Services Corporation.

[FR Doc. 2024–09068 Filed 4–24–24; 11:15 am]

BILLING CODE 7050–01–P

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

Cost Accounting Standards Board Meeting Agenda

AGENCY: Cost Accounting Standards Board, Office Federal Procurement Policy, Office of Management and Budget.

ACTION: Notice of agenda for closed Cost Accounting Standards Board meetings.

SUMMARY: The Office of Federal Procurement Policy (OFPP), Cost Accounting Standards Board (CAS Board) is publishing this notice to advise the public of its upcoming meetings. The meetings are closed to the public.

ADDRESSES: New Executive Office Building, 725 17th Street NW, Washington, DC 20503.

FOR FURTHER INFORMATION John L. McClung, Manager, Cost Accounting Standards Board (telephone: 202–881–9758; email: *john.l.mcclung2@omb.eop.gov*).

SUPPLEMENTARY INFORMATION: The CAS Board is issuing this notice to inform the public of the discussion topics for upcoming meetings scheduled for April 29, 2024 and June 27, 2024. The list of agenda items for these meetings is set forth below. While CAS Board meetings are closed to the public, the Board welcomes comments and inquiries, which may be directed to the manager using the contact information provided above.

Agenda for CAS Board Meetings During the Third Quarter, Fiscal Year 2024

1. *Conformance of CAS to Generally Accepted Accounting Principles (GAAP).* 41 U.S.C. 1501(c)(2) requires the CAS Board to review and conform Cost Accounting Standards (CAS), where practicable, to GAAP. In furtherance of section 1501(c)(2), the CAS Board will consider issuance of an advanced notice of proposed rulemaking (ANPRM) to address conformance of CAS 404, *Capitalization of Tangible Assets,* and CAS 411, *Accounting for Acquisition Costs of Material,* to GAAP based on public comments received in response to the Staff Discussion Paper (85 FR 58399, September 2020).

2. *Review of Court and Board Decisions Related to CAS.* 41 U.S.C 1501(c)(3) requires the CAS Board to annually review disputes brought before the Boards of Contract Appeals (BCAs) or federal courts involving its standards and consider whether greater clarity in CAS could avoid such disputes. The Board will discuss decisions by the BCAs and courts involving its standards since the last formal review conducted by the previous Board in 2019.

3. *Pension Harmonization for Extraordinary Events.* The Board will discuss an ANPRM to modify CAS 412 and CAS 413. The ANPRM would be a follow-on to a rulemaking issued in 2011 required by the Pension Protection Act (PPA) of 2006. The purpose of the ANPRM is to reconcile the application of the PPA and the CAS adjustment of pension costs for extraordinary events (*i.e.,* curtailment of pension plan benefits, termination of plans, and the accounting of pension plan assets or liabilities following the sale or closing of a corporate segment).

4. Public input. The Board will reserve time to discuss any suggestions that may be received from the public in response to the February 27, 2024 notice (89 FR 14523) and this notice.

The notice is published pursuant to 41 U.S.C. 1501(d), which requires the CAS Board to publish agendas of its meetings in the **Federal Register**.

Christine J. Harada,

Senior Advisor, Office of Federal Procurement Policy, and Chair, Cost Accounting Standards Board, Performing, by Delegation, the Duties of the Administrator for Federal Procurement Policy.

[FR Doc. 2024–09026 Filed 4–25–24; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board hereby gives notice of the scheduling of a teleconference of the National Science Board/National Science Foundation Commission on Merit Review (MRX) for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Tuesday, April 30, 2024, from 9:00 a.m.–12:00 p.m. EDT.

PLACE: This meeting will be in person and via videoconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: Commission Chair's remarks about the agenda; Discussion of Preliminary Recommendations; Vote to Approve Preliminary Recommendations; Commission Chair's closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

Ann E. Bushmiller,

Senior Counsel to the National Science Board Office.

[FR Doc. 2024–09188 Filed 4–24–24; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's Committee on Awards and Facilities (A&F) hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Tuesday, April 30, 2024, from 1:00–4:00 p.m. Eastern.

PLACE: This meeting will be via videoconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: Committee Chair's opening remarks about the agenda; Action Item: National Solar Observatory Operations and Management Award; Information Item: Planning for Future Major Facilities.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Chris Blair, *cblair@nsf.gov,* 703/292–7000. Meeting information and updates may be found at *www.nsf.gov/nsb.*

Ann E. Bushmiller,

Senior Counsel to the National Science Board.

[FR Doc. 2024–09187 Filed 4–24–24; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–611 and 50–612; NRC–2023–0138]

Kairos Power, LLC; Hermes 2; Draft Environmental Assessment and Draft Finding of No Significant Impact

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft environmental assessment (EA) and draft finding of no significant impact (FONSI) for proposed issuance of construction permits (CP) to Kairos Power, LLC (Kairos). The CPs would authorize the construction of two non-power test reactors termed Hermes 2, adjacent to the Hermes test reactor (Hermes), on a 185-acre site located in Oak Ridge, Tennessee. Kairos was issued a CP for Hermes, Construction Permit No. CPTR–6, on December 14, 2023. The Hermes 2 test reactors would demonstrate additional key elements of the Kairos Power Fluoride Salt-Cooled, High Temperature Reactor technology for possible future commercial deployment. The technology is an advanced nuclear reactor technology that leverages TRI-structural ISOtropic (TRISO) particle fuel in pebble form combined with a low-pressure fluoride salt coolant. The NRC has prepared a draft EA and draft FONSI that consider the environmental impacts associated with issuing the CPs.

DATES: Submit comments by May 28, 2024. Comments received after this date will be considered if it is practicable to do so, but the NRC is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by using any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to *https://regulations.gov* and search for Docket ID NRC–2023–0138. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email:* Comments may be submitted to the NRC electronically using the email address: *Kairos-Hermes2Environmental@nrc.gov.*
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Peyton Doub, telephone: 301–415–6703, email: *Peyton.Doub@nrc.gov* and Mary Richmond, telephone: 301–415–7218, email: *Mary.Richmond@nrc.gov.* Both are staff of the Office of Nuclear Material Safety and Safeguards at the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0138 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://regulations.gov* and search for Docket ID NRC–2023–0138.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern

time (ET), Monday through Friday, except Federal holidays.

• *NRC's Public Project Website:* The draft EA and draft FONSI can be accessed online at the Hermes 2—Kairos project specific web page at *https://www.nrc.gov/reactors/non-power/new-facility-licensing/hermes2-kairos.html.*

B. Submitting Comments

The NRC encourages electronic comment submission through any of the methods outlined in **ADDRESSES** section of this document. Please include Docket ID NRC–2023–0138 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

On July 14, 2023, Kairos submitted, pursuant to part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' an application for CPs for the Hermes 2 test reactor facility (a ''testing facility'' as defined in 10 CFR 50.2), that would consist of two fluoride salt-cooled test reactor units at the East Tennessee Technology Park in Oak Ridge, Tennessee. A notice of receipt and availability of the application was published in the **Federal Register** on August 4, 2023 (88 FR 51876). The Hermes 2 site, adjacent to the Hermes test reactor, is situated in the Heritage Center Industrial Park of the East Tennessee Technology Park that was established by the City of Oak Ridge on land formerly owned by the U.S. Department of Energy (DOE) for the Oak Ridge Gaseous Diffusion Plant (ORGDP). The site was occupied by DOE Buildings K–31 and K–33, both of which were part of the ORGDP.

The NRC staff determined that Kairos submitted the application in accordance with 10 CFR 2.101(a)(5), and a notice of the acceptability of docketing of Kairos's CP application was published in the **Federal Register** on September 15, 2023 (88 FR 63632). The docket numbers established for this application are 50–611 and 50–612 for Units 1 and 2, respectively. A notice of opportunity to request a hearing and petition for leave to intervene (88 FR 81439) was published in the **Federal Register** on November 22, 2023.

Section 104 of the Atomic Energy Act of 1954, as amended, and its implementing regulations authorize the NRC to issue CPs for testing facilities. To issue a CP, the NRC is required to consider the environmental impacts of the proposed action under the National Environmental Policy Act of 1969 (NEPA). The NRC's environmental protection regulations that implement NEPA in 10 CFR part 51 identify actions for which the NRC prepares an environmental impact statement (EIS). CPs for test reactors are an action identified as requiring an EIS.

However, based on a review of the environmental report (ER) submitted as part of the CP application for Hermes 2 and the results of the EIS recently issued for the Hermes test reactor, the NRC staff concluded that it would be prudent to first prepare a draft environmental assessment (EA) to determine whether preparation of an EIS would be necessary or whether a finding of no significant impact (FONSI) could be issued for the Hermes 2 CP based on factors unique to the Hermes 2 CP application. These factors include: (1) the similar design of Hermes 2 and Hermes, (2) the proposed siting of Hermes 2 within a few hundred feet of Hermes, (3) the industrial nature and heavy prior disturbance of the site, (4) the recent thorough NEPA review performed by the staff as published in its final EIS for Hermes, and (5) the staff's final EIS for Hermes covering the same site as Hermes 2 and documenting all impacts as SMALL.

The NRC staff has prepared a draft EA and draft FONSI documenting its environmental review of the Hermes 2 CP application. Based on the environmental review, the NRC staff has made a preliminary determination that the proposed action would not significantly affect the quality of the human environment. Therefore, the NRC staff has made a preliminary determination that it will not prepare an EIS and that a draft FONSI appears warranted.

The staff will consider comments received on the draft EA and draft FONSI over a 30-day public comment period from Federal, State, local, and Tribal officials, and members of the public. After consideration of these public comments, the NRC staff will make a final determination as to whether preparation of an EIS is necessary or whether a FONSI can be issued for the Hermes 2 CP application. However, exemptions from certain regulations in 10 CFR part 51 would be necessary to issue a final EA and final FONSI to support issuance of the Hermes 2 CPs. In accordance with 10 CFR 51.6, the NRC may grant exemptions from the requirements of 10 CFR part 51 if it determines that the exemptions are authorized by law and are otherwise in the public interest.

III. Summary of Draft Environmental Assessment

Description of the Proposed Action and Need

The proposed action is for the NRC to issue CPs to Kairos authorizing construction of the two proposed Hermes 2 reactors. The NRC issuance of CPs would constitute authorization for Kairos to proceed with the construction of the Hermes 2 reactors, two fluoride salt-cooled test reactor units, at the East Tennessee Technology Park in Oak Ridge, Tennessee.

The issuance of a CP is a separate licensing action from the issuance of an operating license (OL). If the NRC issues CPs for Hermes 2 and Kairos were to seek NRC approval to operate Hermes 2, then Kairos would have to submit a separate application for OLs pursuant to the NRC's regulations, and Kairos would have to obtain NRC approval before it could operate the Hermes 2 test reactors. The NRC staff would review any application for an OL for Hermes 2 for new and significant information related to the environmental impacts of operating and decommissioning Hermes 2 that might alter the staff's conclusions made in the EA for the CP application.

The need for Hermes 2 is to demonstrate key elements of the Kairos Power Fluoride Salt-Cooled, High Temperature Reactor technology for possible future commercial deployment. The technology is an advanced nuclear reactor technology that leverages TRI-structural ISOtropic particle fuel in pebble form combined with a low-pressure fluoride salt coolant. Hermes 2 would support Kairos's reactor development program, which relies on learning and risk reduction by narrowing the design space through progressive test cycles. Construction and operation of Hermes 2 also would provide validation and qualification data to support potential future commercial reactors using the Kairos

Power Fluoride Salt-Cooled, High Temperature Reactor technology.

Environmental Impacts of the Proposed Action

In the draft EA, the NRC staff assessed the potential direct and indirect environmental impacts from the proposed action associated with the following relevant resource areas: land use and visual resources; air quality and noise; hydrogeology and water resources; ecological resources; historic and cultural resources; socioeconomics and environmental justice; human health; nonradiological waste management; uranium fuel cycle and radiological waste management; transportation of radioactive material; and postulated accidents. The NRC staff also considered the cumulative impacts from past, present, and reasonably foreseeable future actions when combined with the proposed action.

The NRC staff determined that the environmental impacts of the proposed action would be SMALL for each potentially affected environmental resource, meaning that the environmental effects are not detectable or are so minor that they will neither destabilize nor noticeably alter any important attribute of the resource. In addition, the NRC staff determined that the projected effects of climate change would not alter any of the impact determinations described in the EA. Furthermore, the NRC staff found that there would be no significant negative cumulative impact to any resource area from the proposed action when added to other past, present, and reasonably foreseeable future actions.

Environmental Impacts of the Alternatives to the Proposed Action

The NRC staff identified a range of reasonable alternatives to the proposed action and the environmental impacts of the alternatives as appropriate. The NRC staff determined that there are no alternatives that meet the need for the proposed action and that are environmentally preferrable to the proposed action.

IV. Draft Finding of No Significant Impact

The proposed action before the NRC is whether to issue CPs (one for each unit) to Kairos to authorize construction of the two proposed reactors (units) making up the Hermes 2 project. The NRC has conducted an environmental review of a request for NRC issuance of CPs for the Hermes 2 project and prepared an EA. This draft FONSI incorporates by reference the EA summarized in Section II of this notice and referenced in Section V of this notice. On the basis of the EA, and its determination that the environmental impacts would be SMALL for each potentially affected resource area, the NRC staff has preliminarily determined that the proposed action would not have a significant effect on the quality of the human environment. Accordingly, the NRC staff has made a preliminary determination that preparation of an EIS is not required for the proposed action and that a FONSI is appears warranted.

This finding and the related environmental documents referenced throughout the EA are available for public inspection as discussed in the EA and Section I of this notice. The NRC's staff's determination is tentative. Before making a final determination, the NRC staff also will consider comments received on the draft EA and draft FONSI over a 30-day public comment period from Federal, State, local, and Tribal officials, and members of the public. Once NRC makes a final determination, it will publish the final EA and final FONSI or proceed to prepare an EIS.

V. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document description	ADAMS accession No./**Federal Register** notice (FRN)
Environmental Assessment and Finding of No Significant Impact for the Construction Permits for the Kairos Hermes 2 Test Reactors, Draft Report for Comment, dated April 2024.	ML24103A002.
Letter to NRC from Kairos, Responses to Requests for Confirmatory Information for the Environmental Report, dated March 4, 2024.	ML24065A100 (Package).
Letters to NRC from Kairos, Responses to General Audit Questions, dated October 27, 2023	ML23300A141 (Package) and ML23300A144.
FRN: Kairos Power LLC Hermes 2- Construction Permit Application; Opportunity to Request a Hearing and Petition for Leave to Intervene, dated November 22, 2023.	88 FR 81439.
FRN: Acceptance for docketing of the Kairos Power LLC Hermes 2 Test Reactor Construction Permit, dated September 15, 2023.	88 FR 63632.
FRN: Receipt and Availability. Hermes 2 Receipt of Application, August 4, 2023	88 FR 51876.
Letter to NRC from Kairos, Submittal of the Construction Permit Application for the Hermes 2 Kairos Power Fluoride Salt-Cooled, High Temperature Non-Power Reactor, dated July 14, 2023.	ML23195A121 (Package).
Kairos Power LLC—Construction Permit for Hermes Test Reactor, dated December 14, 2023	ML23338A258.
NUREG–2263, Environmental Impact Statement for the Construction Permit for the Kairos Hermes Test Reactor, Final Report, dated August 2023.	ML23214A269.

Dated: April 22, 2024.

For the Nuclear Regulatory Commission.

Daniel Barnhurst,

Chief, Environmental Project Management Branch 3, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety, and Safeguards.

[FR Doc. 2024–08964 Filed 4–25–24; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100004; File No. SR–CboeBYX–2024–012]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule Related to Physical Port Fees

April 22, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 9, 2024, Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') 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

Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/BYX/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[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 its fee schedule relating to physical connectivity fees.[3]

By way of background, a physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,500 per physical port for a 1 gigabit (''Gb'') circuit and $7,500 per physical port for a 10 Gb circuit. The Exchange proposes to increase the monthly fee for 10 Gb physical ports from $7,500 to $8,500 per port. The Exchange notes the proposed fee change better enables it to continue to maintain and improve its market technology and services and also notes that the proposed fee amount, even as amended, continues to be in line with, or even lower than, amounts assessed by other exchanges for similar connections.[4] The physical ports may also be used to access the Systems for the following affiliate exchanges and only one monthly fee currently (and will continue) to apply per port: the Cboe BZX Exchange, Inc. (options and equities), Cboe EDGX Exchange, Inc. (options and equities platforms), Cboe EDGA Exchange, Inc., and Cboe C2 Exchange, Inc., (''Affiliate Exchanges'').[5]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)[9] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities.

The Exchange believes the proposed fee change is reasonable as it reflects a moderate increase in physical connectivity fees for 10 Gb physical ports. Further, the current 10 Gb physical port fee has remained unchanged since June 2018.[10] Since its last increase over 5 years ago however, there has been notable inflation. Particularly, the dollar has had an average inflation rate of 3.9% per year between 2018 and today, producing a cumulative price increase of approximately 21.1% inflation since the fee for the 10 Gb physical port was last modified.[11] Moreover, the Exchange historically does not increase fees every

[3] The Exchange initially filed the proposed fee changes on July 3, 2023 (SR–CboeBYX–2023–010). On September 1, 2023, the Exchange withdrew that filing and submitted SR–CboeBYX–2023–013. On September 29, 2023, the Securities and Exchange Commission issued a Suspension of and Order Instituting Proceedings to Determine whether to Approve or Disapprove a Proposed Rule Change to Amend its Fees Schedule Related to Physical Port Fees (the ''OIP''). On September 29, 2023, the Exchange filed the proposed fee change (SR–CboeBYX–2023–014). On October 13, 2023, the Exchange withdrew that filing and submitted SR–CboeBYX–2023–015. On December 12, 2023, Exchange filed the proposed fee change (SR–CboeBYX–2023–018). On December 12, 2023, the Exchange withdrew that filing and submitted SR–CboeBYX–2023–019. On February 9, 2024, the Exchange withdrew that filing and submitted SR–CboeBYX–2024–006. On April 9, 2024, the Exchange withdrew that filing and submitted this filing.

[4] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

[5] The Affiliate Exchanges are also submitting contemporaneous identical rule filings.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] 15 U.S.C. 78f(b)(4).

[10] *See* Securities and Exchange Release No. 83441 (June 14, 2018), 83 FR 28684 (June 20, 2018) (SR–CboeBYX–2018–006).

[11] *See https://www.officialdata.org/us/inflation/2010?amount=1.*

year, notwithstanding inflation. Accordingly, the Exchange believes the proposed fee is reasonable as it represents only an approximate 13% increase from the rates adopted five years ago, notwithstanding the cumulative rate of 21.1%. The Exchange is also unaware of any standard that suggests any fee proposal that exceeds a certain yearly or cumulative inflation rate is unreasonable, and in any event, in this instance the increase is well below the cumulative rate. The Exchange also believes its offerings are more affordable as compared to similar offerings at competitor exchanges.[12]

Additionally, the Exchange believes the proposed fee increase is reasonable in light of recent and anticipated connectivity-related upgrades and changes. The Exchange and its affiliated exchanges recently launched a multi-year initiative to improve Cboe Exchange Platform performance and capacity requirements to increase competitiveness, support growth and advance a consistent world class platform. The goal of the project, among other things, is to provide faster and more consistent order handling and matching performance for options, while ensuring quicker processing time and supporting increasing volumes and capacity needs. For example, the Exchange recently performed switch hardware upgrades. Particularly, the Exchange replaced existing customer access switches with newer models, which the Exchange believes resulted in increased determinism. The recent switch upgrades also increased the Exchange's capacity to accommodate more physical ports by nearly 50%. Network bandwidth was also increased nearly two-fold as a result of the upgrades, which among other things, can lead to reduce message queuing. The Exchange also believes these newer models result in less natural variance in the processing of messages. The Exchange notes that it incurred costs associated with purchasing and upgrading to these newer models, of which the Exchange has not otherwise passed through or offset.

As of April 1, 2024, market participants also having the option of connecting to a new data center (*i.e.,* Secaucus NY6 Data Center (''NY6'')), in addition to the current data centers at NY4 and NY5. The Exchange made NY6 available in response to customer requests in connection with their need for additional space and capacity. In order to make this space available, the Exchange expended significant resources to prepare this space, and will also incur ongoing costs with respect to maintaining this offering, including costs related to power, space, fiber, cabinets, panels, labor and maintenance of racks. The Exchange also incurred a large cost with respect to ensuring NY6 would be latency equalized, as it is for NY4 and NY5.

The Exchange also has made various other improvements since the current physical port rates were adopted in 2018. For example, the Exchange has updated its customer portal to provide more transparency with respect to firms' respective connectivity subscriptions, enabling them to better monitor, evaluate and adjust their connections based on their evolving business needs. The Exchange also performs proactive audits on a weekly basis to ensure that all customer cross connects continue to fall within allowable tolerances for Latency Equalized connections. Accordingly, the Exchange expended, and will continue to expend, resources to innovate and modernize technology so that it may benefit its Members and continue to compete among other equities markets. The ability to continue to innovate with technology and offer new products to market participants allows the Exchange to remain competitive in the equities space which currently has 16 equities markets and potential new entrants.

The Exchange also believes the proposed fee is reasonable as it is still in line with, or even lower than, amounts assessed by other exchanges for similar connections.[13] Indeed, the Exchange believes assessing fees that are a lower rate than fees assessed by other exchanges for analogous connectivity (which were similarly adopted via the rule filing process and filed with the Commission) is reasonable. As noted above, the proposed fee is also the same as is concurrently being proposed for its Affiliate Exchanges. Further, Members are able to utilize a single port to connect to any of the Affiliate Exchanges with no additional fee assessed for that same physical port. Particularly, the Exchange believes the proposed monthly per port fee is reasonable, equitable and not unfairly discriminatory as it is assessed only once, even if it connects with another affiliate exchange since only one port is being used and the Exchange does not wish to charge multiple fees for the same port. Indeed, the Exchange notes that several ports are in fact purchased and utilized across one or more of the Exchange's affiliated Exchanges (and charged only once).

The Exchange also believes that the proposed fee change is not unfairly discriminatory because it would be assessed uniformly across all market participants that purchase the physical ports. The Exchange believes increasing the fee for 10 Gb physical ports and charging a higher fee as compared to the 1 Gb physical port is equitable as the 1 Gb physical port is 1/10th the size of the 10 Gb physical port and therefore does not offer access to many of the products and services offered by the Exchange (*e.g.,* ability to receive certain market data products). Thus, the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb physical ports utilize the most bandwidth and therefore consume the most resources from the network. The Exchange also anticipates that firms that utilize 10 Gb ports will benefit the most from the Exchange's investment in offering NY6 as the Exchange anticipates there will be much higher quantities of 10 Gb physical ports connecting from NY6 as compared to 1 Gb ports. Indeed, the Exchange notes that 10 Gb physical ports account for approximately 90% of physical ports across the NY4, NY5, and NY6 data centers, and to date, 80% of new port connections in NY6 are 10 Gb ports. As such, the Exchange believes the proposed fee change for 10 Gb physical ports is reasonably and appropriately allocated.

The Exchange also notes Members and non-Members will continue to choose the method of connectivity based on their specific needs and no broker-dealer is required to become a Member of, let alone connect directly to, the Exchange. There is also no regulatory requirement that any market participant connect to any one particular exchange. Market participants may voluntarily choose to become a

[12] *See e.g., See e.g.,* [sic] The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gbps Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gbps physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gbps LX LCN Circuits (which are analogous to the Exchange's 10 Gbps physical port) are assessed $22,000 per month, per port.

[13] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

member of one or more of a number of different exchanges, of which, the Exchange is but one choice. Additionally, any Exchange member that is dissatisfied with the proposal is free to choose not to be a member of the Exchange and send order flow to another exchange. Moreover, direct connectivity is not a requirement to participate on the Exchange. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other equities exchanges that a market participant may connect to in lieu of the Exchange, and/or trading of any equities product, such as within the Over-the-Counter (OTC) markets which do not require connectivity to the Exchange. Indeed, there are currently 16 registered equities exchanges that trade equities (12 of which are not affiliated with Cboe), some of which have similar or lower connectivity fees.[14] Based on publicly available information, no single equities exchange has more than approximately 16% of the market share.[15] Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers. For example, in 2020 alone, three new exchanges entered the market: Long Term Stock Exchange (LTSE), Members Exchange (MEMX), and Miami International Holdings (MIAX Pearl).

As noted above, there is no regulatory requirement that any market participant connect to any one equities exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one equities exchange whose membership includes every registered broker-dealer. By way of example, while the Exchange has 110 members that trade equities, Cboe EDGX has 124 members that trade equities, Cboe EDGA has103 members and Cboe BZX has 132 members. There is also no firm that is a Member of BYX Equities only. Further, based on publicly available information regarding a sample of the Exchange's competitors, NYSE has 143 members,[16] IEX has 129 members,[17] and MIAX Pearl has 51 members.[18]

Vigorous competition among national securities exchanges provides many alternatives for firms to voluntarily decide whether direct connectivity to the Exchange is appropriate and worthwhile, and as noted above, no broker-dealer is required to become a Member of the Exchange, let alone connect directly to it. In the event that a market participant views the Exchange's proposed fee change as more or less attractive than the competition, that market participant can choose to connect to the Exchange indirectly or may choose not to connect to that exchange and connect instead to one or more of the other 12 non-Cboe affiliated equities markets. Indeed, market participants are free to choose which exchange to use to satisfy their business needs. Moreover, Moreover [sic], if the Exchange were to assess supracompetitve rates, members and non-members alike, may decide not to purchase, or to reduce its use of, the Exchange's direct connectivity. Disincentivizing market participants from purchasing Exchange connectivity would only serve to discourage participation on the Exchange which ultimately does not benefit the Exchange. For example, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity. Notwithstanding the foregoing, the Exchange still believes that the proposed fee increase is reasonable, equitably allocated and not unfairly discriminatory, even for market participants that determine to connect directly to the Exchange for business purposes, as those business reasons should presumably result in revenue capable of covering the proposed fee.

The Exchange lastly notes that it is not required by the Exchange Act, nor any other rule or regulation, to undertake a cost-of-service or rate-making approach with respect to fee proposals. Moreover, Congress's intent in enacting the 1975 Amendments to the Act was to enable competition—rather than government order—to determine prices. The principal purpose of the amendments was to facilitate the creation of a national market system for the trading of securities. Congress intended that this ''national market system evolve through the interplay of *competitive forces* as unnecessary regulatory restrictions are removed.'' [19] Other provisions of the Act confirm that intent. For example, the Act provides that an exchange must design its rules ''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.'' [20] Likewise, the Act grants the Commission authority to amend or repeal ''[t]he rules of [an] exchange [that] impose any burden on competition not necessary or appropriate in furtherance of the purposes of this chapter.'' [21] In short, the promotion of free and open competition was a core congressional objective in creating the national market system.[22] Indeed, the Commission has historically interpreted that mandate to promote competitive forces to determine prices whenever compatible with a national market system. Accordingly, the Exchange believes it has met its burden to demonstrate that its proposed fee change is reasonable and consistent with the immediate filing process chosen by Congress, which created a system whereby market forces determine access fees in the vast majority of cases, subject to oversight only in particular cases of abuse or market failure. Lastly, and importantly, the Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for the proposed fee would be so complicated that it could not be done practically.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed fee change will not impact intramarket competition because it will apply to all similarly situated Members equally (i.e., all market participants that

[14] *Id.*

[15] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (April 4, 2024), available at *https://www.cboe.com/us/equities/_statistics/.*

[16] *See https://www.nyse.com/markets/nyse/membership.*

[17] *See https://www.iexexchange.io/membership.*

[18] *See https://www.miaxglobal.com/sites/default/files/page-files/20230630_MIAX_Pearl_Equities_Exchange_Members_June_2023.pdf.*

[19] *See* H.R. Rep. No. 94–229, at 92 (1975) (Conf. Rep.) (emphasis added).

[20] 15 U.S.C. 78f(b)(5).

[21] 15 U.S.C. 78f(8).

[22] *See* also 15 U.S.C. 78k–l(a)(1)(C)(ii) (purposes of Exchange Act include to promote ''fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets''); Order, 73 FR at 74781 (''The Exchange Act and its legislative history strongly support the Commission's reliance on competition, whenever possible, in meeting its regulatory responsibilities for overseeing the SROs and the national market system.'').

choose to purchase the 10 Gb physical port). Additionally, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can continue to buy the less expensive 1 Gb physical port (which cost is not changing). While pricing may be increased for the larger capacity physical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most.

The Exchange's proposed fee is also still lower than some fees for similar connectivity on other exchanges and therefore may stimulate intermarket competition by attracting additional firms to connect to the Exchange or at least should not deter interested participants from connecting directly to the Exchange. Further, if the changes proposed herein are unattractive to market participants, the Exchange can, and likely will, see a decline in connectivity via 10 Gb physical ports as a result. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect directly to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative venues that they may participate on and direct their order flow, including 12 non-Cboe affiliated equities markets, as well as off-exchange venues, where competitive products are available for trading. 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.'' [23] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[24] Accordingly, the Exchange does not believe its proposed 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

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [25] and paragraph (f) of Rule 19b–4 [26] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

[23] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[24] *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)).

[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBYX–2024–012 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–CboeBYX–2024–012. 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 (*https://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 the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBYX–2024–012 and should be submitted on or before May 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08944 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. IA–6595]

Notice of Intention To Cancel Registrations of Certain Investment Advisers Pursuant to Section 203(H) of the Investment Advisers Act of 1940

April 23, 2024.

Notice is given that the Securities and Exchange Commission (the ''*Commission*'') intends to issue an order, pursuant to section 203(h) of the Investment Advisers Act of 1940 (the ''*Act*''), cancelling the registrations of the investment advisers whose names appear in the attached Appendix, hereinafter referred to as the ''registrants.''

Section 203(h) of the Act provides, in pertinent part, that if the Commission finds that any person registered under section 203, or who has pending an application for registration filed under that section, is no longer in existence, is not engaged in business as an investment adviser, or is prohibited from registering as an investment adviser under section 203A, the Commission shall by order cancel the registration of such person.

Each registrant listed in the attached Appendix either (a) has not filed a Form ADV amendment with the Commission as required by rule 204–1 under the Act [1] and appears to be no longer engaged in business as an investment adviser or (b) has indicated on Form ADV that it is no longer eligible to remain registered with the Commission as an investment adviser but has not filed Form ADV–W to withdraw its registration. Accordingly, the Commission believes that reasonable grounds exist for a finding that these registrants are no longer in existence, are not engaged in business as investment advisers, or are prohibited from registering as investment advisers under section 203A, and that their registrations should be cancelled pursuant to section 203(h) of the Act.

Notice is also given that any interested person may, by May 20, 2024, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the cancellation of the registration of any registrant listed in the attached Appendix, accompanied by a statement as to the nature of such person's interest, the reason for such person's request, and the issues, if any, of fact or law proposed to be controverted, and the writer may request to be notified if the Commission should order a hearing thereon. Any such communication should be emailed to the Commission's Secretary at *Secretarys-Office@sec.gov.*

At any time after May 20, 2024, the Commission may issue an order or orders cancelling the registrations of any or all of the registrants listed in the attached Appendix, upon the basis of the information stated above, unless an order or orders for a hearing on the cancellation shall be issued upon request or upon the Commission's own motion. Persons who requested a hearing, or who requested to be advised as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof. Any registrant whose registration is cancelled under delegated authority may appeal that decision directly to the Commission in accordance with rules 430 and 431 of the Commission's rules of practice (17 CFR 201.430 and 431).

ADDRESSES: The Commission: *Secretarys-Office@sec.gov*.

FOR FURTHER INFORMATION CONTACT: Matthew Cook, Senior Counsel, at 202–551–6825; Division of Investment Management, Chief Counsel's Office, 100 F Street NE, Washington, DC 20549–8549.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.[2]

Sherry R. Haywood,

Assistant Secretary.

Appendix

SEC No.	Full legal name
801–64406	SUNBRIDGE MANAGEMENT INC.
801–108976 ...	TIMESWELL LLC.

[FR Doc. 2024–09034 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

[1] Rule 204–1 under the Act requires any adviser that is required to complete Form ADV to amend the form at least annually and to submit the amendments electronically through the Investment Adviser Registration Depository.

[2] 17 CFR 200.30–5(e)(2).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100009; File No. SR–OCC–2024–001]

Self-Regulatory Organizations; Options Clearing Corporation; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change by the Options Clearing Corporation Concerning Its Process for Adjusting Certain Parameters in Its Proprietary System for Calculating Margin Requirements During Periods When the Products It Clears and the Markets It Serves Experience High Volatility

April 22, 2024.

I. Introduction

On January 10, 2024, the Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–OCC–2024–001 pursuant to Section 19(b) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 [2] thereunder to codify OCC's process for adjusting certain parameters in its proprietary system for calculating margin requirements during periods when the products OCC clears and the markets it serves experience high volatility.[3] The proposed rule change was published for public comment in the **Federal Register** on January 25, 2024.[4] The Commission has received comments regarding the proposed rule change.[5]

On February 23, 2024, pursuant to Section 19(b)(2) of the Exchange Act,[6] the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the proposed rule change.[7] This order institutes proceedings, pursuant to Section 19(b)(2)(B) of the Exchange Act,[8] to determine whether to approve or disapprove the proposed rule change (hereinafter defined as ''Proposed Rule Change'').

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Notice of Filing *infra* note 4, at 89 FR 5062.

[4] Securities Exchange Act Release No. 99393 (Jan. 19, 2024), 89 FR 5062 (Jan. 25, 2024) (File No. SR–OCC–2024–001) (''Notice of Filing'').

[5] Comments on the proposed rule change are available at *https://www.sec.gov/comments/sr-occ-2024-001/srocc2024001.htm.*

[6] 15 U.S.C. 78s(b)(2).

[7] Securities Exchange Act Release No. 99594 (Feb. 23, 2024), 89 FR 14909 (Feb. 29, 2024) (File No. SR–OCC–2024–001).

[8] 15 U.S.C. 78s(b)(2)(B).

II. Summary of the Proposed Rule Change

OCC is a central counterparty (''CCP''), which means that as part of its function as a clearing agency, it interposes itself as the buyer to every seller and the seller to every buyer for financial transactions. As the CCP for the listed options markets and for certain futures in the United States, OCC is exposed to the risk that one or more of its Clearing Members may fail to make a payment or to deliver securities. OCC addresses such risk exposure, in part, by requiring its members to provide collateral, including margin collateral. Margin is the collateral that CCPs collect to cover potential changes in a member's positions over a set period of time. Typically, margin is designed to cover such exposures during normal market conditions, which means that margin collateral should be sufficient to cover exposures at least 99 out of 100 days.

OCC's methodology for calculating margin collateral is called the System for Theoretical Analysis and Numerical Simulations (''STANS''). The STANS Methodology Description is a single document describing OCC's system for calculating daily and intra-day margin requirements for its Clearing Members.[9] The STANS Methodology Description briefly discusses margin methodology parameter controls that OCC uses during periods of high volatility.[10] The STANS Methodology Description does not, however, describe OCC's process for implementing, changing, and terminating the high-volatility parameter controls. As such, OCC is filing the Proposed Rule Change to codify and describe this process. More specifically, OCC proposes to amend its existing Margin Policy to include material details regarding its high-volatility parameter control setting process. Although the Proposed Rule Change would amend OCC's Margin Policy, the proposal does not significantly change OCC's existing high-volatility parameter control setting practices.

Proposed additions to the Margin Policy regarding OCC's high-volatility control setting process include the following: (1) setting and reviewing regular and high-volatility control settings; (2) monitoring the volatility of products being cleared and markets served, and establishing thresholds to escalate the results of such monitoring to senior decisionmakers; and (3) internal governance for implementing and terminating high-volatility control settings.

III. Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Change and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act [11] to determine whether the Proposed Rule Change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the Proposed Rule Change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to comment on the Proposed Rule Change, providing the Commission with arguments to support the Commission's analysis as to whether to approve or disapprove the Proposed Rule Change.

Pursuant to Section 19(b)(2)(B) of the Exchange Act,[12] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the Proposed Rule Change's consistency with Section 17A of the Exchange Act,[13] and the rules thereunder, including the following provisions:

- Section 17A(b)(3)(F) of the Exchange Act,[14] which requires, among other things, that the rules of a clearing agency are designed to promote the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions; and to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible;
- Rule 17Ad–22(e)(2) of the Exchange Act,[15] which requires that a covered clearing agency provide for governance arrangements that, among other things, specify clear and direct lines of responsibility; and
- Rule 17Ad–22(e)(6) of the Exchange Act,[16] which requires that a covered clearing agency establish, implement, maintain, and enforce written policies and procedures reasonably designed to cover, if the covered clearing agency provides central counterparty services, its credit exposures to its participants by establishing a risk-based margin system that, among other things, (1) considers, and produces margin levels commensurate with, the risks and particular attributes of each relevant product, portfolio, and market,[17] and (2) calculates sufficient margin to cover its potential future exposure to participants in the interval between the last margin collection and the close out of positions following a participant default.[18]

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the Proposed Rule Change. In particular, the Commission invites the written views of interested persons concerning whether the Proposed Rule Change is consistent with Section 17A(b)(3)(F),[19] Rule 17Ad–22(e)(2),[20] and Rule 17Ad–22(e)(6) [21] of the Exchange Act, or any other provision of the Exchange Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4(g) under the Exchange Act,[22] any request for an opportunity to make an oral presentation.[23]

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[9] *See* Securities Exchange Act Release No. 91079 (Feb. 8, 2021), 86 FR 9410 (Feb. 12, 2021) (File No. SR–OCC–2020–016) (''STANS Methodology Approval'').

[10] *See* Securities Exchange Act Release No. 90763 (Dec. 21, 2020), 85 FR 85788, 85793 (Dec. 29, 2020) (File No. SR–OCC–2020–016) (''The STANS Methodology Description would also describe the controls that may be placed on the GJR–GARCH parameters after their initial calibration. GARCH volatility forecasting models can be very reactive in certain market environments. As a result, OCC may implement parameter controls for risk factors and classes of risk factors, which are subject to periodic review and approval by the [Model Risk Working Group].'').

[11] 15 U.S.C. 78s(b)(2)(B).

[12] *Id.*

[13] 15 U.S.C. 78q–1.

[14] 15 U.S.C. 78q–1(b)(3)(F).

[15] 17 CFR 240.17Ad–22(e)(2).

[16] 17 CFR 240.17Ad–22(e)(6).

[17] 17 CFR 240.17Ad–22(e)(6)(i).

[18] 17 CFR 240.17Ad–22(e)(6)(iii).

[19] 15 U.S.C. 78q–1(b)(3)(F).

[20] 17 CFR 240.17Ad–22(e)(2).

[21] 17 CFR 240.17Ad–22(e)(6).

[22] 17 CFR 240.19b–4(g).

[23] Section 19(b)(2) of the Exchange Act grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

Interested persons are invited to submit written data, views, and arguments regarding whether the Proposed Rule Change should be approved or disapproved by May 17, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by May 31, 2024.

The Commission asks that commenters address the sufficiency of OCC's statements in support of the Proposed Rule Change, which are set forth in the Notice of Filing,[24] in addition to any other comments they may wish to submit about the Proposed Rule Change.

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–OCC–2024–001 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–OCC–2024–001. 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 (*https://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 OCC and on OCC's website at *https://www.theocc.com/Company-Information/Documents-and-Archives/By-Laws-and-Rules.*

Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to File Number SR–OCC–2024–001 and should be submitted on or before May 17, 2024. Rebuttal comments should be submitted by May 31, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08948 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100001; File No. SR–CboeEDGX–2024–020]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend its Fees Schedule Related to Physical Port Fees

April 22, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 9, 2024, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') 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

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule relating to physical connectivity fees.[3]

By way of background, a physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,500 per physical port for a 1 gigabit (''Gb'') circuit and $7,500 per physical port for a 10 Gb circuit. The Exchange proposes to increase the monthly fee for 10 Gb physical ports from $7,500 to $8,500 per port. The Exchange notes the proposed fee change better enables it to continue to maintain and improve its market technology and services and also notes that the proposed fee amount, even as amended, continues to be in line with, or even lower than, amounts assessed by other exchanges for similar connections.[4] The physical ports may

[24] *See* Notice of Filing, *supra* note 4.

[25] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed fee changes on July 3, 2023 (SR–CboeEDGX–2023–044). On September 1, 2023, the Exchange withdrew that filing and submitted SR–CboeEDGX–2023–057. On September 29, 2023, the Securities and Exchange Commission issued a Suspension of and Order Instituting Proceedings to Determine whether to Approve or Disapprove a Proposed Rule Change to Amend its Fees Schedule Related to Physical Port Fees (the ''OIP''). On September 29, 2023, the Exchange filed the proposed fee change (SR–CboeEDGX–2023–62). On October 13, 2023, the Exchange withdrew that filing and on business date October 16, 2023 submitted SR–CboeEDGX–2023–065. On December 12, the Exchange withdrew that filing and submitted SR–CboeEDGX–2023–079. On December 20, the Exchange withdrew that filing and submitted SR–CboeEDGX–2023–081. On February 12, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGX–2024–013. On April 9, 2024, the Exchange withdrew that filing and submitted this filing.

[4] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the

Continued

also be used to access the Systems for the following affiliate exchanges and only one monthly fee currently (and will continue) to apply per port: the Exchange's options platform (EDGX Options), Cboe BZX Exchange, Inc. (options and equities platforms), Cboe BYX Exchange, Inc., Cboe EDGA Exchange, Inc., and Cboe C2 Exchange, Inc., (''Affiliate Exchanges'').[5]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)[9] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities.

The Exchange believes the proposed fee change is reasonable as it reflects a moderate increase in physical connectivity fees for 10 Gb physical ports. Further, the current 10 Gb physical port fee has remained unchanged since June 2018.[10] Since its last increase over 5 years ago however, there has been notable inflation. Particularly, the dollar has had an average inflation rate of 3.9% per year between 2018 and today, producing a cumulative price increase of approximately 21.1% inflation since the fee for the 10 Gb physical port was last modified.[11] Moreover, the Exchange historically does not increase fees every year, notwithstanding inflation. Accordingly, the Exchange believes the proposed fee is reasonable as it represents only an approximate 13% increase from the rates adopted five years ago, notwithstanding the cumulative rate of 21.1%. The Exchange is also unaware of any standard that suggests any fee proposal that exceeds a certain yearly or cumulative inflation rate is unreasonable, and in any event, in this instance the increase is well below the cumulative rate.

Additionally, the Exchange believes the proposed fee increase is reasonable in light of recent and anticipated connectivity-related upgrades and changes. The Exchange and its affiliated exchanges recently launched a multi-year initiative to improve Cboe Exchange Platform performance and capacity requirements to increase competitiveness, support growth and advance a consistent world class platform. The goal of the project, among other things, is to provide faster and more consistent order handling and matching performance for options, while ensuring quicker processing time and supporting increasing volumes and capacity needs. For example, the Exchange recently performed switch hardware upgrades. Particularly, the Exchange replaced existing customer access switches with newer models, which the Exchange believes resulted in increased determinism. The recent switch upgrades also increased the Exchange's capacity to accommodate more physical ports by nearly 50%. Network bandwidth was also increased nearly two-fold as a result of the upgrades, which among other things, can lead to reduce message queuing. The Exchange also believes these newer models result in less natural variance in the processing of messages. The Exchange notes that it incurred costs associated with purchasing and upgrading to these newer models, of which the Exchange has not otherwise passed through or offset.

As of April 1, 2024, market participants also having the option of connecting to a new data center (*i.e.,* Secaucus NY6 Data Center (''NY6'')), in addition to the current data centers at NY4 and NY5. The Exchange made NY6 available in response to customer requests in connection with their need for additional space and capacity. In order to make this space available, the Exchange expended significant resources to prepare this space, and will also incur ongoing costs with respect to maintaining this offering, including costs related to power, space, fiber, cabinets, panels, labor and maintenance of racks. The Exchange also incurred a large cost with respect to ensuring NY6 would be latency equalized, as it is for NY4 and NY5.

The Exchange also has made various other improvements since the current physical port rates were adopted in 2018. For example, the Exchange has updated its customer portal to provide more transparency with respect to firms' respective connectivity subscriptions, enabling them to better monitor, evaluate and adjust their connections based on their evolving business needs. The Exchange also performs proactive audits on a weekly basis to ensure that all customer cross connects continue to fall within allowable tolerances for Latency Equalized connections. Accordingly, the Exchange expended, and will continue to expend, resources to innovate and modernize technology so that it may benefit its Members and continue to compete among other equities markets. The ability to continue to innovate with technology and offer new products to market participants allows the Exchange to remain competitive in the equities space which currently has 16 equities markets and potential new entrants.

The Exchange also believes the proposed fee is reasonable as it is still in line with, or even lower than, amounts assessed by other exchanges for similar connections.[12] Indeed, the Exchange believes assessing fees that are a lower rate than fees assessed by other exchanges for analogous connectivity

Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port; *see also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

[5] The Affiliate Exchanges are also submitting contemporaneous identical rule filings.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] 15 U.S.C. 78f(b)(4).

[10] *See* Securities and Exchange Release No. 83450 (June 15, 2018), 83 FR 28884 (June 21, 2018) (SR–CboeEDGX–2018–016).

[11] *See https://www.officialdata.org/us/inflation/2010?amount=1.*

[12] *See, e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port; *see also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

(which were similarly adopted via the rule filing process and filed with the Commission) is reasonable. As noted above, the proposed fee is also the same as is concurrently being proposed for its Affiliate Exchanges. Further, Members are able to utilize a single port to connect to any of the Affiliate Exchanges with no additional fee assessed for that same physical port. Particularly, the Exchange believes the proposed monthly per port fee is reasonable, equitable and not unfairly discriminatory as it is assessed only once, even if it connects with another affiliate exchange since only one port is being used and the Exchange does not wish to charge multiple fees for the same port. Indeed, the Exchange notes that several ports are in fact purchased and utilized across one or more of the Exchange's affiliated Exchanges (and charged only once).

The Exchange also believes that the proposed fee change is not unfairly discriminatory because it would be assessed uniformly across all market participants that purchase the physical ports. The Exchange believes increasing the fee for 10 Gb physical ports and charging a higher fee as compared to the 1 Gb physical port is equitable as the 1 Gb physical port is 1/10th the size of the 10 Gb physical port and therefore does not offer access to many of the products and services offered by the Exchange (*e.g.,* ability to receive certain market data products). Thus, the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb physical ports utilize the most bandwidth and therefore consume the most resources from the network. The Exchange also anticipates that firms that utilize 10 Gb ports will benefit the most from the Exchange's investment in offering NY6 as the Exchange anticipates there will be much higher quantities of 10 Gb physical ports connecting from NY6 as compared to 1 Gb ports. Indeed, the Exchange notes that 10 Gb physical ports account for approximately 90% of physical ports across the NY4, NY5, and NY6 data centers, and to date, 80% of new port connections in NY6 are 10 Gb ports. As such, the Exchange believes the proposed fee change for 10 Gb physical ports is reasonably and appropriately allocated.

The Exchange also notes Members and non-Members will continue to choose the method of connectivity based on their specific needs and no broker-dealer is required to become a Member of, let alone connect directly to, the Exchange. There is also no regulatory requirement that any market participant connect to any one particular exchange. Market participants may voluntarily choose to become a member of one or more of a number of different exchanges, of which, the Exchange is but one choice. Additionally, any Exchange member that is dissatisfied with the proposal is free to choose not to be a member of the Exchange and send order flow to another exchange. Moreover, direct connectivity is not a requirement to participate on the Exchange. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other equities exchanges that a market participant may connect to in lieu of the Exchange and/or trading of any equities product, such as within the Over-the-Counter (OTC) markets which do not require connectivity to the Exchange. Indeed, there are currently 16 registered equities exchanges that trade equities (12 of which are not affiliated with Cboe), some of which have similar or lower connectivity fees.[13] Based on publicly available information, no single equities exchange has more than approximately 16% of the market share.[14] Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers. For example, in 2020 alone, three new exchanges entered the market: Long Term Stock Exchange (LTSE), Members Exchange (MEMX), and Miami International Holdings (MIAX Pearl).

As noted above, there is no regulatory requirement that any market participant connect to any one equities exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one equities exchange whose membership includes every registered broker-dealer. By way of example, while the Exchange has 124 members that trade equities, Cboe BZX has 132 members that trade equities, Cboe EDGA has103 members and Cboe BYX has 110 members. There is also no firm that is a Member of EDGX Equities only. Further, based on publicly available information regarding a sample of the Exchange's competitors, NYSE has 143 members,[15] IEX has 129 members,[16] and MIAX Pearl has 51 members.[17]

Vigorous competition among national securities exchanges provides many alternatives for firms to voluntarily decide whether direct connectivity to the Exchange is appropriate and worthwhile, and as noted above, no broker-dealer is required to become a Member of the Exchange, let alone connect directly to it. In the event that a market participant views the Exchange's proposed fee change as more or less attractive than the competition, that market participant can choose to connect to the Exchange indirectly or may choose not to connect to that exchange and connect instead to one or more of the other 12 non-Cboe affiliated equities markets. Moreover, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity. Notwithstanding the foregoing, the Exchange still believes that the proposed fee increase is reasonable, equitably allocated and not unfairly discriminatory, even for market participants that determine to connect directly to the Exchange for business purposes, as those business reasons should presumably result in revenue capable of covering the proposed fee.

The Exchange lastly notes that it is not required by the Exchange Act, nor any other rule or regulation, to undertake a cost-of-service or rate-making approach with respect to fee proposals. Moreover, Congress's intent in enacting the 1975 Amendments to the Act was to enable competition—rather than government order—to determine prices. The principal purpose of the amendments was to facilitate the creation of a national market system for the trading of securities. Congress intended that this ''national market system evolve through the interplay of *competitive forces* as unnecessary regulatory restrictions are removed.'' [18] Other provisions of the Act confirm that intent. For example, the Act provides that an exchange must design its rules

[13] *Id.*

[14] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (April 4,2024), available at *https://www.cboe.com/us/equities/_statistics/.*

[15] *See https://www.nyse.com/markets/nyse/membership.*

[16] *See https://www.iexexchange.io/membership.*

[17] *See https://www.miaxglobal.com/sites/default/files/page-files/20230630_MIAX_Pearl_Equities_Exchange_Members_June_2023.pdf.*

[18] *See* H.R. Rep. No. 94–229, at 92 (1975) (Conf. Rep.) (emphasis added)

''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.'' [19] Likewise, the Act grants the Commission authority to amend or repeal ''[t]he rules of [an] exchange [that] impose any burden on competition not necessary or appropriate in furtherance of the purposes of this chapter.'' [20] In short, the promotion of free and open competition was a core congressional objective in creating the national market system.[21] Indeed, the Commission has historically interpreted that mandate to promote competitive forces to determine prices whenever compatible with a national market system. Accordingly, the Exchange believes it has met its burden to demonstrate that its proposed fee change is reasonable and consistent with the immediate filing process chosen by Congress, which created a system whereby market forces determine access fees in the vast majority of cases, subject to oversight only in particular cases of abuse or market failure. Lastly, and importantly, the Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for the proposed fee would be so complicated that it could not be done practically.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed fee change will not impact intramarket competition because it will apply to all similarly situated Members equally (i.e., all market participants that choose to purchase the 10 Gb physical port). Additionally, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can continue to buy the less expensive 1 Gb physical port (which cost is not changing). While pricing may be increased for the larger capacity physical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most.

The Exchange's proposed fee is also still lower than some fees for similar connectivity on other exchanges and therefore may stimulate intermarket competition by attracting additional firms to connect to the Exchange or at least should not deter interested participants from connecting directly to the Exchange. Further, if the changes proposed herein are unattractive to market participants, the Exchange can, and likely will, see a decline in connectivity via 10 Gb physical ports as a result. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect directly to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative venues that they may participate on and direct their order flow, including 12 non-Cboe affiliated equities markets, as well as off-exchange venues, where competitive products are available for trading. 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.'' [22] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[23] Accordingly, the Exchange does not believe its proposed 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

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [24] and paragraph (f) of Rule 19b–4 [25] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–CboeEDGX–2024–020 on the subject line.

[19] 15 U.S.C. 78f(b)(5).

[20] 15 U.S.C. 78f(8).

[21] *See also* 15 U.S.C. 78k–l(a)(1)(C)(ii) (purposes of Exchange Act include to promote ''fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets''); Order, 73 FR at 74781 (''The Exchange Act and its legislative history strongly support the Commission's reliance on competition, whenever possible, in meeting its regulatory responsibilities for overseeing the SROs and the national market system.'').

[22] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[23] *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)).

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f).

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–CboeEDGX–2024–020. 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 (*https://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 the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGX–2024–020 and should be submitted on or before May 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08941 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100006; File No. SR–FINRA–2024–004]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend FINRA Rule 6730 (Transaction Reporting) To Reduce the 15-Minute TRACE Reporting Timeframe to One Minute

April 22, 2024.

I. Introduction

On January 11, 2024, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend FINRA Rule 6730 to reduce the 15-minute reporting timeframe for transactions reported to FINRA's Trade Reporting and Compliance Engine (''TRACE'') system to one minute, with exceptions for FINRA member firms with de minimis reporting activity and for manual trades. The proposed rule change was published for comment in the **Federal Register** on January 25, 2024.[3] The Commission received comments in response to the proposal.[4] On February 29, 2024, the Commission extended until April 24, 2024, the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] This order institutes proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act[6] to determine whether to approve or disapprove the proposed rule change.

II. Summary of the Proposed Rule Change

As described in more detail in the Notice, FINRA rules currently specify the applicable outer-limit reporting timeframe for different types of TRACE-Eligible Securities.[7] Most transactions in corporate bonds, agency debt securities,[8] asset-backed securities (''ABS''),[9] and agency pass-through mortgage-backed securities (''MBS'') traded to-be-announced (''TBA'') for good delivery (''GD'')[10] must be reported within 15 minutes.[11] The 15-

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4

[3] *See* Securities Exchange Act Release No. 99404 (January 19, 2024), 89 FR 5034 (January 25, 2024) (''Notice'').

[4] Comments received on the proposed rule change are available at: *https://www.sec.gov/comments/sr-finra-2024-004/srfinra2024004.htm.*

[5] *See* Securities Exchange Act Release No. 99640 (February 29, 2024), 89 FR 16042 (March 6, 2024).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] ''TRACE-Eligible Security'' means a debt security that is United States (''U.S.'') dollar-denominated and is: (1) issued by a U.S. or foreign private issuer, and, if a ''restricted security'' as defined in Rule 144(a)(3) under the Securities Act of 1933 (''Securities Act''), sold pursuant to Securities Act Rule 144A; (2) issued or guaranteed by an Agency as defined in Rule 6710(k) or a Government-Sponsored Enterprise as defined in Rule 6710(n); (3) a U.S. Treasury Security as defined in Rule 6710(p); or (4) a Foreign Sovereign Debt Security as defined in Rule 6710(kk). ''TRACE-Eligible Security'' does not include a debt security that is a Money Market Instrument as defined in Rule 6710(o). *See* Rule 6710(a).

[8] ''Agency Debt Security'' means a debt security (i) issued or guaranteed by an Agency as defined in Rule 6710(k); (ii) issued or guaranteed by a Government-Sponsored Enterprise as defined in Rule 6710(n); or (iii) issued by a trust or other entity that was established or sponsored by a Government-Sponsored Enterprise for the purpose of issuing debt securities, where such enterprise provides collateral to the trust or other entity or retains a material net economic interest in the reference tranches associated with the securities issued by the trust or other entity. The term excludes a U.S. Treasury Security as defined in Rule 6710(p) and a Securitized Product as defined in Rule 6710(m), where an Agency or a Government-Sponsored Enterprise is the Securitizer as defined in Rule 6710(s) (or similar person), or the guarantor of the Securitized Product. *See* Rule 6710(l).

[9] ''Asset-Backed Security'' means a type of Securitized Product where the Asset-Backed Security is collateralized by any type of financial asset, such as a consumer or student loan, a lease, or a secured or unsecured receivable, and excludes: (i) a Securitized Product that is backed by residential or commercial mortgage loans, mortgage-backed securities, or other financial assets derivative of mortgage-backed securities; (ii) an SBA-Backed ABS as defined in Rule 6710(bb) traded To Be Announced as defined in Rule 6710(u) or in a Specified Pool Transaction as defined in Rule 6710(x); and (iii) a collateralized debt obligation. *See* Rule 6710(cc).

[10] ''Agency Pass-Through Mortgage-Backed Security'' means a type of Securitized Product issued in conformity with a program of an Agency as defined in Rule 6710(k) or a Government-Sponsored Enterprise (''GSE'') as defined in Rule 6710(n), for which the timely payment of principal and interest is guaranteed by the Agency or GSE, representing ownership interest in a pool (or pools) of mortgage loans structured to ''pass through'' the principal and interest payments to the holders of the security on a pro rata basis. *See* Rule 6710(v). ''To Be Announced'' means a transaction in an Agency Pass-Through Mortgage-Backed Security or an SBA-Backed ABS as defined in Rule 6710(bb) where the parties agree that the seller will deliver to the buyer a pool or pool(s) of a specified face amount and meeting certain other criteria but the specific pool or pool(s) to be delivered at settlement is not specified at the Time of Execution, and includes TBA transactions ''for good delivery'' and TBA transactions ''not for good delivery'' (''NGD''). *See* Rule 6710(u).

[11] *See* Rule 6730(a). However, a ''List or Fixed Offering Price Transaction,'' as defined in Rule 6710(q), and a ''Takedown Transaction,'' as defined in Rule 6710(r) are required to be reported to

Continued

minute reporting timeframe has been in place for corporate bonds since 2005 [12] and was implemented later for agency debt (2010),[13] ABS (2015),[14] and MBS TBA GD (2013).[15] In 2015, the Commission approved FINRA rule amendments generally requiring firms to report transactions in these TRACE-Eligible Securities as soon as practicable but no later than 15 minutes from the time of execution,[16] and FINRA publicly disseminates information on these transactions immediately upon receipt. According to FINRA, 82.9 percent of trades in the TRACE-Eligible Securities that are currently subject to the 15-minute outer-limit reporting timeframe are reported within one minute of execution.[17]

According to FINRA, since the implementation of TRACE, fixed income markets have changed dramatically, including a significant increase in the use of electronic trading platforms or other electronic communication protocols to facilitate the execution of transactions. In light of these advances and consistent with FINRA's goals of increasing transparency and improving access to timely transaction data, FINRA is proposing updates to modernize the reporting timeframes and provide timelier transparency.

A. One-Minute Reporting

FINRA is proposing amendments to Rule 6730 to reduce the reporting timeframe for securities currently subject to the 15-minute reporting outer limit to one minute, with exceptions for FINRA member firms with de minimis reporting activity and for manual trades. FINRA would continue to make information on the transactions publicly available immediately upon receipt of the trade reports.

Under existing Rule 6730(a)(1), transactions in corporate bonds, agency debt, ABS, and MBS TBA GD generally must be reported as soon as practicable, but no later than within 15 minutes of execution.[18] Specifically, transactions executed on a business day at or after 12:00:00 a.m. ET through 7:59:59 a.m. ET must be reported the same day no later than 15 minutes after the TRACE system opens. Transactions executed on a business day at or after 8:00:00 a.m. ET through 6:29:59 p.m. ET must be reported no later than within 15 minutes of the Time of Execution,[19] except for transactions executed on a business day less than 15 minutes before 6:30:00 p.m. ET, which must be reported no later than 15 minutes after the TRACE system opens the next day (and, if reported on T+1, designated ''as/of'' with the date of execution). Finally, transactions executed on a business day at or after 6:30:00 p.m. ET through 11:59:59 p.m. ET, or trades executed on a Saturday, a Sunday, a federal or religious holiday, or other day on which the TRACE system is not open at any time during that day, must be reported on the next business day no later than 15 minutes after the TRACE system opens (and must be designated ''as/of'' and include the date of execution).

Amended Rule 6730(a)(1) would provide that transactions must be reported as soon as practicable, but no later than within one minute of the Time of Execution. Amended Rule 6730(a)(1)(B) would require that a transaction executed on a business day at or after 8:00:00 a.m. ET through 6:29:59 p.m. ET must be reported as soon as practicable, but no later than one minute from the Time of Execution, except that, a transaction executed on a business day less than one minute before 6:30:00 p.m. ET, must be reported no later than 15 minutes after the TRACE system opens the next business day (T+1) (and, if reported on T+1, designated ''as/of'' with the date of execution). Any trades executed on a business day prior to the open of the TRACE system, on a business day at or after 6:30:00 p.m. ET through 11:59:59 p.m. ET, or on a Saturday, a Sunday, a federal or religious holiday or other day on which the TRACE system is not open at any time during that day would continue to be reportable as soon as practicable on the next business day (T+1), but no later than within 15 minutes after the TRACE system opens (and must be designated ''as/of,'' as appropriate, and include the date of execution).

B. Exceptions From One-Minute Reporting

FINRA is proposing two exceptions from the one-minute reporting timeframe for: (1) FINRA member firms with ''limited trading activity'' in the TRACE-Eligible Securities that are subject to one-minute reporting; and (2) manual trades.[20]

1. Exception for FINRA Members With ''Limited Trading Activity''

New Supplementary Material .08 would provide an exception to the one-minute reporting timeframe for FINRA members with ''limited trading activity.'' A FINRA member with ''limited trading activity'' would be defined as one that, during one of the prior two calendar years, reported to TRACE fewer than 4,000 transactions in the TRACE-Eligible Securities that are subject to paragraphs (a)(1)(A) through (a)(1)(D) of Rule 6730 (*i.e.,* corporate bonds, agency debt, ABS and MBS TBA GD), including any manual trades. Supplementary Material .08(b) would require FINRA members relying on the exception to confirm annually their qualification for the exception.[21] As outlined in Supplementary Material .08(c), qualifying FINRA members would be required to report these trades as soon as practicable, but no later than within 15 minutes of the Time of Execution.[22]

FINRA members exceeding the 4,000-trade threshold for each of two consecutive calendar years would need to comply with the one-minute reporting requirements of paragraphs

TRACE by the next business day (T+1). *See* Rule 6730(a)(2).

[12] *See* Securities Exchange Act Release No. 49845 (June 14, 2004), 69 FR 35088 (June 23, 2004) (Order Approving File No. SR–NASD–2004–057); *see also* Notice to Members 04–51 (July 2004).

[13] *See* Securities Exchange Act Release No. 60726 (September 28, 2009), 74 FR 50991 (October 2, 2009) (Order Approving File No. SR–FINRA–2009–010); *see also* Regulatory Notice 09–57 (September 2009).

[14] *See* Securities Exchange Act Release No. 71607 (February 24, 2014), 79 FR 11481 (February 28, 2014) (Order Approving File No. SR–FINRA–2013–046); *see also* Regulatory Notice 14–34 (August 2014).

[15] *See* Securities Exchange Act Release No. 66829 (April 18, 2012), 77 FR 24748 (April 25, 2012) (Order Approving File No. SR–FINRA–2012–020); *see also* Regulatory Notice 12–26 (May 2012).

[16] *See* Securities Exchange Act Release No. 75782 (August 28, 2015), 80 FR 53375 (September 3, 2015) (Order Approving File No. SR–FINRA 2015–025).

[17] *See* Notice at Table 1.

[18] *See supra* notes 12–16.

[19] Under Rule 6710(d), the ''Time of Execution'' generally means the time when the parties to a transaction agree to all of the terms of the transaction that are sufficient to calculate the dollar price of the trade. For transactions involving TRACE-Eligible Securities that are trading ''when issued'' on a yield basis, the ''Time of Execution'' is when the yield for the transaction has been agreed to by the parties to the transaction.

[20] FINRA is also proposing a conforming amendment to Supplementary Material .03 to refer to Rule 6730 generally rather than ''paragraph (a)'' to reflect that members reporting pursuant to one of the exceptions in new Supplementary Material .08 and .09 are still required to report their trades ''as soon as practicable.''

[21] Evidence of this confirmation should be retained as part of the member's books and records. However, members eligible for the exception would not need to take other affirmative steps to have their trade reports processed pursuant to the exception's 15-minute reporting timeframe, such as submitting a certification of eligibility to FINRA or adding a modifier or indicator to their trade reports.

[22] However, a trade executed outside of TRACE system hours, less than 15 minutes before 6:30 p.m. ET, or on a Saturday, Sunday, federal or religious holiday, or other day on which the TRACE system is not open at any time during that day, would need to be reported as soon as practicable, but no later than within 15 minutes after the TRACE system opens the next business day (T+1).

(a)(1)(A) through (a)(1)(D) of amended Rule 6730 beginning 90 days after the firm no longer meets the criteria for the exception (*i.e.,* beginning 90 days after January 1 of the next calendar year). If a FINRA member's reporting activity subsequently dropped below the 4,000-trade threshold, the member would again be eligible for the exception.[23]

2. Manual Trades Exception

New Supplementary Material .09 would provide an exception for manual trades that are not electronic from end to end. Where a trade qualifies for the manual trades exception, a 15-minute outer limit would apply for the first year following implementation; a 10-minute outer limit would apply for the second year; and a five-minute outer limit would apply thereafter.

The manual trades exception would apply to ''transactions that are manually executed'' or where a ''[FINRA] member must manually enter any of the trade details or information necessary for reporting the trade through the TRAQS website or into a system that facilitates trade reporting to TRACE.'' [24] A trade that requires manual intervention at any point to complete the trade execution or reporting process would qualify. FINRA provided the following non-exhaustive list of situations in which trades would be considered to have a manual component:

- where a FINRA member executes a trade [25] by manual or hybrid means, such as by telephone, email, or through a chat/messaging function,[26] and subsequently must manually enter into a system that facilitates trade reporting all or some of the information required to book the trade and report it to TRACE;
- where allocations to individual accounts must be manually input in connection with a trade by a dually-registered broker-dealer/investment adviser;
- where an electronic trade is subject to manual review for risk management or regulatory compliance purposes and, as part of or following the review, the trade must be manually approved, amended, or released before the trade is reported to TRACE (*e.g.,* a firm's risk management procedures require a secondary approver for trades over a certain threshold; a firm's best execution procedures require manually checking another market to confirm that a better price is not available to the customer);
- where a FINRA member trades a bond for the first time and additional manual steps are necessary to set the bond up in the firm's systems to book and report the trade (*e.g.,* entering the CUSIP number and associated bond data into the firm's system); and
- where a FINRA member agrees to trade a basket of securities at a single price and manual action is required to calculate the price of component securities in the basket or to book and report the trade in component securities to TRACE.

According to FINRA, the above examples are illustrative of the types of circumstances in which, due to the manual nature of components of the trade execution or reporting process, reporting a transaction within one minute of the Time of Execution may be unfeasible, even where a FINRA member makes reasonable efforts to report the trade as soon as practicable (as required). FINRA also would assess FINRA members' trade reporting in connection with manual trades to determine whether the five-minute trade reporting timeframe (to become applicable after two years) is appropriate, and would be prepared to adjust, as necessary.

FINRA would review use of the manual trades exception for abuse. FINRA members would not, in any case, be allowed to purposely delay the execution or reporting of a transaction by handling any aspect of a trade manually or introducing manual steps following the Time of Execution. Additionally, considering the overarching obligation to report trades as soon as practicable, FINRA members would be encouraged to consider the types of transactions in which they regularly engage and whether they can reasonably reduce the time between a trade's Time of Execution and its reporting, and more generally must make a good faith effort to report their trades as soon as practicable.

Under amended Rule 6730(d)(4), any FINRA member that executes or reports a trade manually would be required to append a manual trade indicator to the trade report. The indicator must be included in any manual trade, regardless of whether the FINRA member reports outside of the one-minute timeframe in reliance on the manual trades exception. Application of the indicator would give FINRA greater insight into manual trading and the use of the exception. The indicator would not be included in publicly disseminated TRACE data.

Finally, FINRA is proposing to amend Rule 6730(f) to provide that a pattern or practice of late reporting may be considered conduct inconsistent with high standards of commercial honor and just and equitable principles of trade, in violation of Rule 2010, absent ''reasonable justification'' (in addition to the rule's existing reference to ''exceptional circumstances'').[27] Recurring issues in the systems of a FINRA member firm or its vendor would not be considered a reasonable justification or exceptional circumstance that excuses a pattern or practice of late trade reporting.[28]

III. Summary of Comments

The Commission received comments on the proposed rule change.[29] Commenters generally address the one-minute reporting timeframe, the exceptions to the timeframe (both in general and specifically discussing the manual trades and de minimis exceptions), the gradual five-minute decreases in the manual trades exception, consistent application of reporting requirements, the proposed implementation period, and the proposed rule's consistency with the Exchange Act.

Several commenters support the proposal to shorten the 15-minute TRACE reporting timeframe to one minute and its aim of increasing transparency in fixed income markets.[30]

[23] For example, a member that reported 3,000 trades in the relevant TRACE-Eligible Securities to TRACE in 2022 and then 4,150 trades in 2023 would continue to be eligible for the exception in 2024; however, if the member then reported 4,100 trades in 2024, the member would be required to comply with the one-minute reporting requirements starting 90 days after January 1, 2025 (with January 1 being day one of 90). If the member proceeded to report 3,500 trades in 2025, the member would once again be eligible for the exception from one-minute reporting for 2026 under the two-year lookback. FINRA believes the two-year lookback period for eligibility for the exception will accommodate fluctuations in trading activity that may be due to unusual market-wide events or unique client demands.

[24] *See* Supplementary Material .09(a).

[25] As noted above, for purposes of Rule 6730, the reporting timeframe is measured from the Time of Execution as defined by Rule 6710(d), which generally refers to the time that the parties have agreed to all of the terms of the transaction sufficient to calculate the dollar price of the trade (or yield, in the case of when-issued securities priced to a spread).

[26] FINRA reminds members of their obligation to retain these electronic communications as part of their books and records, consistent with FINRA and Commission recordkeeping requirements. *See, e.g.,* Notice to Members 03–33 (July 2003).

[27] *See, e.g.,* Rule 6623 describing ''exceptional circumstances'' as instances of system failure by a member or service bureau, or unusual market conditions, such as extreme volatility in a security, or in the market as a whole.

[28] *See, e.g.,* FINRA Trade Reporting Frequently Asked Questions, Q206.21, available at *https://www.finra.org/filing-reporting/market-transparency-reporting/trade-reporting-faq.*

[29] *See supra* note 4.

[30] *See, e.g.,* Letter to Vanessa Countryman, Secretary, Commission, from Tyler Gellasch, President and CEO, Healthy Markets Association (February 15, 2024) (''HMA Letter'') at 7; Letter to

Continued

Some commenters support increasing price transparency in general but caution restraint and the need for broad exceptions, citing the potential for reduced liquidity and execution quality.[31] Some commenters oppose one minute reporting, questioning the feasibility and cost of compliance due to technical limitations and the prevalence of manual processes.[32]

Commenters express varied views on the proposed exceptions to one minute reporting. Some commenters state the exceptions are essential to the success of the rule.[33] These commenters cite the burdens of compliance with one-minute reporting on broker-dealers which rely on manual processes.[34] Others state that the exceptions are too narrow [35] or too broad.[36] One commenter that states the exceptions are too narrow also states that anything less than 15-minute reporting is infeasible and cites the concern that compliance costs associated with faster reporting could price small broker-dealers out of fixed income markets.[37] Two commenters that state the exceptions are too broad suggest FINRA withdraw the proposal and instead require market participants to report trades as soon as practicable but no later than five minutes after execution.[38] Another commenter that states the exceptions are too broad also states that the exceptions ''create significant risk to the efficacy and legal durability of the entire rule.'' [39] Finally, one commenter encourages FINRA to phase out both exceptions completely over time, which it states would incentivize firms to modernize their execution processes.[40]

Several commenters specifically address the de minimis exception. Some commenters state support for the de minimis exception.[41] One of these commenters states the de minimis exception is appropriately tailored to protect minority, veteran, and women owned business enterprises and small dealers from incurring significant costs.[42] The commenter also states the proposed two-year look back period will prevent surprise application of the rule and allow newly impacted broker-dealers time to comply.[43] Some commenters state opposition to the de minimis exception.[44] One of these commenters supports the logic behind the de minimis exception but states the proposed 4,000-trade report threshold is too low and insufficiently justified.[45] This commenter also requests FINRA expand the threshold or at minimum provide more analysis to support its proposed limit.[46] Another commenter that opposes the de minimis exception states FINRA did not sufficiently justify the need for the exception, nor its decisions to set the exception's threshold at 4,000 annual trades and the lookback period for applicability of the threshold at two years.[47] This commenter suggests the de minimis exception be abandoned or more narrowly tailored.[48]

Several commenters offer specific views about the manual trades exception. Some commenters characterize the manual trades exception as essential to ensuring compliance with the rule.[49] Some commenters state it would be more operationally feasible to flag trades subject to one-minute reporting, rather than flagging all manual trades.[50] One commenter states that the exception should be expanded to include certain fully electronic transactions that cannot feasibly be reported within one minute, such as large post-trade allocations, batch-processed trades, and trades involving multiple systems in trade workflow.[51] This commenter states that post-trade allocations are especially difficult to report within one minute for broker-dealers also registered as investment advisers.[52] Another commenter states support for FINRA's proposal to apply the exception to a scenario where a firm has not previously traded a bond.[53] This commenter also notes a similar proposal by the Municipal Securities Rulemaking Board (''MSRB'') that would apply to transactions in municipal securities and states that FINRA and MSRB should harmonize the scope of the manual trades exceptions.[54] Finally, the commenter describes certain scenarios that could be experienced by a reporting firm, questioning whether the manual trades exception would apply, and suggesting a dialogue with industry about such scenarios.[55]

Several comments address the gradual phase-in of five-minute reporting written into the proposed rule for manual trades.[56] One commenter requests FINRA propose for notice and comment each time it seeks to reduce the timeframe.[57] The commenter also states FINRA must consider that the proposed rule will be implemented

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Vanessa Countryman, Secretary, Commission, from Stephen John Berger, Managing Director, Global Head of Government and Regulatory Policy, Citadel (February 15, 2024) (''Citadel Letter'') at 1; Letter to Vanessa Countryman, Secretary, Commission, from Joanna Mallers, Executive Director, FIA Principal Traders Group (February 15, 2024) (''FIA PTG Letter'') at 1; Letter to Vanessa Countryman, Secretary, Commission, from Gerard O'Reilly, Co-Chief Executive Officer and Co-Chief Investment Officer, Dimensional Fund Advisors LP and David A. Plecha, Global Head of Fixed Income, Dimensional Fund Advisors LP (February 15, 2024) (''Dimensional Letter'') at 1.

[31] *See, e.g.,* Letter to Vanessa Countryman, Secretary, Commission, from Sarah A. Bessin, Deputy General Counsel, Investment Company Institute and Kevin Ercoline, Assistant General Counsel, Investment Company Institute (February 15, 2024) (''ICI Letter'') at 2; Letter to Vanessa Countryman, Secretary, Commission, from Michael Decker, Senior Vice President, Bond Dealers of America (February 15, 2024) (''BDA Letter'') at 1; Letter to Secretary, Commission, from Howard Meyerson, Managing Director, Financial Information Forum (February 15, 2024) (''FIF Letter I'') at 2.

[32] *See, e.g.,* Letter to Vanessa Countryman, Secretary, Commission, from Kenneth E. Bentsen, Jr., President and CEO, Securities Industry and Financial Markets Association (February 15, 2024) (''SIFMA Letter'') at 2; Letter to Vanessa Countryman, Secretary, Commission, from Christopher A. Iacovella, President & Chief Executive Officer, American Securities Association (February 16, 2024) (''ASA Letter'') at 2; Letter to Vanessa Countryman, Secretary, Commission, from Melissa P. Hoots, CEO/CCO, Falcon Square Capital (February 15, 2024) (''Falcon Letter'') at 1–2; BDA Letter at 2.

[33] *See, e.g.,* BDA Letter at 1; FIF Letter I at 2; SIFMA Letter at 3–4.

[34] *See* BDA Letter at 1; FIF Letter I at 2; SIFMA Letter at 3–4.

[35] *See, e.g.,* ASA Letter at 1–2; Falcon Letter at 1.

[36] *See, e.g.,* Dimensional Letter at 2; HMA Letter at 13; Citadel Letter at 2–3; FIA PTG Letter at 1–2.

[37] *See* ASA Letter at 2; *see also* Falcon Letter at 4 (''[O]ur fear is that the Filing will, over time, eliminate smaller fixed-income brokers like Falcon Square and harm the small and medium-size institutional clients that we serve due to an inability to realistically further reduce the time it takes to conduct these manual trade processes.'').

[38] *See* Citadel at 4; FIA PTG at 4.

[39] HMA Letter at 2.

[40] *See* Dimensional Letter at 2.

[41] *See, e.g.,* SIFMA Letter at 9; BDA Letter at 2.

[42] *See* SIFMA Letter at 9.

[43] *See id.*

[44] *See, e.g.,* Falcon Letter at 2–4; HMA Letter at 9–11, 13.

[45] *See* Falcon Letter at 2–3.

[46] *See id.*

[47] *See* HMA Letter at 11.

[48] *See id.* at 9.

[49] *See* BDA Letter at 1; FIF Letter I at 2; SIFMA Letter at 6.

[50] *See* BDA Letter at 3; SIFMA Letter at 9.

[51] *See* SIFMA Letter at 7–9.

[52] *See id.* at 7; *see also* BDA Letter at 3–4; FIF Letter I at 3 (''FIF members request that FINRA and the MSRB provide an additional exception for the scenario where an entity dually-registered as a broker-dealer and investment adviser . . . is required to report a large number of allocations for a block trade that the dual registrant executes, allocates and reports automatically.'').

[53] *See* FIF Letter I at 4.

[54] *See id.* at 3.

[55] *See* Letter to Secretary, Commission, from Howard Meyerson, Managing Director, Financial Information Forum (February 26, 2024) at 2–4; FIF Letter I at 3–4.

[56] *See, e.g.,* ICI Letter at 3–4; Falcon Letter at 4; SIFMA Letter at 6; BDA Letter at 2–3.

[57] *See* ICI Letter at 3; *see also* Falcon Letter at 4 (stating that FINRA must produce supporting data before proposing a mandatory phase-in period for the manual trades exception); SIFMA Letter at 6 (stating that FINRA should conduct an impact assessment before reducing the reporting window for manual trades to five minutes).

alongside other regulatory initiatives.[58] Another commenter states support for the phase-in approach, but asks FINRA to maintain close communication with industry during the phase-in period and to remain sensitive to operational roadblocks that market participants could confront.[59]

Several commenters state the manual trades exception is too broad.[60] Two of these commenters question the lack of estimates in the proposal of the number of transactions expected to qualify for the manual trades exception.[61] These commenters raise the concern that a large proportion of the total number of trades currently reported outside of one minute could fall within the proposed rule's manual trades exception, undermining the goal of increasing post-trade transparency.[62] These commenters also raise concerns that firms could build manual steps into the trade execution process as a means of qualifying for the longer manual trades reporting window.[63]

Several commenters raise concerns related to consistent application of reporting requirements. One commenter describes the potential negative consequences of applying different levels of post-trade transparency depending on a trade's mode of execution.[64] Another commenter raises concern about different reporting requirements under the proposal depending on a trade's time of execution.[65] The commenter states that under the current rule, trades executed when TRACE is closed must be reported within 15 minutes of TRACE being open, mirroring the deadline for reporting of trades executed when TRACE is open.[66] But, the commenter continues, under the proposal, trades executed outside of the hours when TRACE is open will still be subject to the deadline to report within 15 minutes of TRACE being open while trades executed when TRACE is open will be subject to the new one minute requirement.[67] The commenter urges consistent reporting times in this scenario.[68]

Some comments address the proposed implementation period. Two commenters request an implementation period of two years from the time of adoption due to the high cost of compliance.[69] Another commenter states the cost of implementing the proposal is anticipated to be especially high for smaller firms and suggests an implementation period of at least 18 months from the date of FINRA and MSRB publishing updated technical specifications and guidance.[70] The commenter also requests that FINRA provide an expanded free testing period of 90 days instead of the standard free testing period of 30 days.[71]

Several commenters question the proposed rule's consistency with the Exchange Act. Two commenters state that FINRA failed to meet its burden to demonstrate consistency with the Exchange Act, particularly by failing to estimate the number of transactions captured by the manual trades exception.[72] These commenters also state that the differing reporting windows for manual and electronic trades violate the Exchange Act by discriminating based on the mode of execution and unduly burdening competition.[73]

IV. Proceedings To Determine Whether To Approve or Disapprove the FINRA Proposal and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2) of the Exchange Act[74] to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposal. Institution of proceedings does not indicate, however, that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Exchange Act,[75] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with: (1) Section 15A(b)(6) of the Exchange Act, which requires, among other things, that FINRA rules promote just and equitable principles of trade, foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, remove impediments to and perfect the mechanism of a free and open market, and, in general, protect investors and the public interest,[76] and (2) Section 15A(b)(9) of the Exchange Act, which requires that FINRA rules not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.[77] The Commission asks that commenters address the sufficiency of FINRA's statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the scope and implementation of the proposed exceptions to the one-minute reporting timeframe.

V. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change is consistent with the Exchange Act and the rules and regulations thereunder.

Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of data, views, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Exchange Act,[78] any request for an opportunity to make an oral presentation.[79]

[58] *See* ICI Letter at 3–4.

[59] *See* BDA at 3.

[60] *See, e.g.,* HMA Letter at 11–12; Citadel Letter at 2–3; FIA PTG Letter at 2–4.

[61] *See* Citadel Letter at 2–3; FIA PTG Letter at 2.

[62] *See* Citadel Letter at 2–3; FIA PTG Letter at 2.

[63] *See* Citadel Letter at 3; FIA PTG at 3; *see also* HMA Letter at 12 (''[T]he Proposal . . . does not assuage our concerns that firms may intentionally add a 'manual' component to their post-execution processes so as to avoid timely reporting (and dissemination) of their trading activity.'').

[64] *See* Citadel Letter at 1–3.

[65] *See* HMA Letter at 8.

[66] *See id.*

[67] *See id.*

[68] *See* HMA Letter at 9.

[69] *See* SIFMA Letter at 10; BDA Letter at 4.

[70] *See* FIF Letter I at 5.

[71] *See id.* at 6–7.

[72] *See* Citadel Letter at 3; FIA PTG Letter at 3; *see also* Falcon Letter at 1 (stating that FINRA did not adequately justify the exceptions to the rule).

[73] *See* Citadel Letter at 3; FIA PTG Letter at 3–4.

[74] 15 U.S.C. 78s(b)(2).

[75] 15 U.S.C. 78s(b)(2)(B).

[76] 15 U.S.C. 78*o*–3(b)(6).

[77] 15 U.S.C. 78*o*–3(b)(9).

[78] 17 CFR 240.19b–4.

[79] Section 19(b)(2) of the Exchange Act, as amended by the Securities Acts Amendments of 1975, Public Law 94–29 (Jun. 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for

Continued

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by May 17, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by May 31, 2024.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–FINRA–2024–004 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–FINRA–2024–004. 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 (*https://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 the filing also will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–FINRA–2024–004 and should be submitted on or before May 17, 2024. Rebuttal comments should be submitted by May 31, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[80]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08946 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99997; File No. SR–PEARL–2024–21]

Self-Regulatory Organizations; MIAX PEARL LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 404, Series of Option Contracts Open for Trading To Amend the Short Term Option Series Program

April 19, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 18, 2024, MIAX PEARL, LLC (''MIAX Pearl'' 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 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 Short Term Option Series Program.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-equities/pearl-equities/rule-filings,* 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

1. Purpose

The Exchange proposes to amend Interpretations and Policies .02 of Exchange Rule 404, ''Series of Options Contracts Open for Trading.'' The Exchange proposes to expand the Short Term Option Series program to permit the listing and trading of options series with Tuesday and Thursday expirations for options on iShares Russell 2000 ETF (''IWM''), specifically permitting two expiration dates for the proposed Tuesday and Thursday expirations in IWM. These proposed rule changes are based on a similar proposal submitted by Nasdaq ISE, LLC (''ISE'') and approved by the Commission.[3]

Currently, Table 1 in Interpretations and Policies .02 of Exchange Rule 404 specifies each symbol that qualifies as a Short Term Option Daily Expiration.[4] Today, Table 1 permits the listing and trading of Monday Short Term Option Daily Expirations and Wednesday Short Term Option Daily Expirations for IWM. At this time, the Exchange proposes to expand the Short Term Option Series Program to permit the listing and trading of no more than a total of two IWM Short Term Option Daily Expirations beyond the current week for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time.[5]

consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[80] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99946 (April 11, 2024), File No. SR–ISE–2024–06 (Order Approving a Proposed Rule Change to Amend the Short Term Option Program).

[4] The Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire at the close of business open each of the next five Fridays that are business days and are not Fridays in which standard expiration options series, Monthly Options Series, or Quarterly Options Series. Of these series of options, the Exchange may have no more than a total of five Short Term Option Expiration Dates. In addition, the Exchange may open for trading series of options on certain symbols that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Short Term Option Daily Expirations''). See Interpretations and Policies .02 of Exchange Rule 404.

[5] The Exchange would amend the Tuesday and Thursday expirations for IWM in Table 1 in Interpetations and Policies .02 of Exchange Rule 404 from ''0'' to ''2'' to permit Tuesday and Thursday expirations for options on IWM listed

The listing and trading of Tuesday and Thursday Short Term Option Daily Expirations would be subject to Interpretations and Policies .02 of Exchange Rule 404.

Today, Tuesday Short Term Option Daily Expirations in SPDR S&P 500 ETF Trust (''SPY'') and Invesco QQQ Trust (''QQQ'') may open for trading on any Monday or Tuesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Tuesday Short Term Option Expiration Date'').[6] Also, today, Thursday Short Term Option Daily Expirations in SPY and QQQ may open for trading on any Tuesday or Wednesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Wednesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Wednesday Short Term Option Expiration Date'').

In the event that options on IWM expire on a Tuesday or Thursday and that Tuesday or Thursday is a business day in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. With this proposal, the Exchange would be able to open for trading series of options on IWM that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[7]

The interval between strike prices for the proposed Tuesday and Thursday IWM Short Term Option Daily Expirations will be the same as those for Tuesday and Thursday Short Term Option Daily Expirations in SPY and QQQ, applicable to the Short Term Option Series Program.[8] Interpretations and Policies .10 of Exchange Rule 404 provides that, notwithstanding any other provision regarding the interval of strike prices of series of options on Exchange-Traded Fund Shares in Exchange Rule 404, the interval of strike prices on options on IWM will be $1 or greater.[9] Further, Interpretations and Policies .02(e) of Exchange Rule 404 provides that the strike price interval for Short Term Option Series may be $0.50 or greater for option classes that trade in $1 strike price intervals and are in the Short Term Option Series Program. Therefore, the Tuesday and Thursday IWM Short Term Option Daily Expirations will have a $0.50 strike interval minimum. As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Tuesday and Thursday IWM Short Term Option Daily Expiration series will be P.M.-settled.

Pursuant to Exchange Rule 100,[10] with respect to the Short Term Option Series Program, a Tuesday or Thursday expiration series shall expire on the first business day immediately prior to that Tuesday or Thursday, *e.g.,* Monday or Wednesday of that week, respectively, if the Tuesday or Thursday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.[11] The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.[12] This thirty (30) series restriction would apply to Tuesday and Thursday IWM Short Term Option Daily Expiration series as well.

With this proposal, Tuesday and Thursday IWM Expirations would be treated the same as Tuesday and Thursday Expirations in SPY and QQQ. With respect to standard expiration option series, Short Term Option Daily Expirations may expire in the same week in which standard expiration option series on the same class expire. In the case of Monthly Options Series and Quarterly Options Series, no Short Term Option Series may expire on the same day as an expiration of a Monthly Options Series or Quarterly Options Series, respectively, in the same class.[13] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.

The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Tuesday and Thursday IWM Short Term Option Daily Expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Short Term Option Daily Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ and has not experienced any market disruptions nor issues with capacity. Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire

pursuant to the Short Term Option Series. The Exchange notes that Cboe Exchange, Inc. (''Cboe'') began listing Tuesday and Thursday expirations in the Russell 2000 Index Weeklys® (''RUTW'') and Mini-Russell 2000 Index Weeklys® (''MRUT'') on January 8, 2024. *See* Securities Exchange Act Release No. 98621 (September 28, 2023), 88 FR 68896 (October 4, 2024) (SR–CBOE–2023–054) (a Proposed Rule Change To Amend Rule 4.13); Securities Exchange Act Release No. 98957 (November 15, 2023), 88 FR 81130 (November 21, 2023) (SR–CBOE–2023–054) (Order Approving a Proposed Rule Change To Amend Rule 4.13 To Expand the Nonstandard Expirations Program To Include P.M.-Settled Options on Broad-Based Indexes That Expire on Tuesday or Thursday); *See also* Cboe Global Markets, Inc., Cboe To Offer Daily Expiries For Russell 2000 Index Options Suite, Beginning January 8, 2024, available at *https://ir.cboe.com/news/news-details/2023/Cboe-TO-OFFER-DAILY-EXPIRIES-FOR-RUSSELL-2000-INDEX-OPTIONS-SUITE-BEGINNING-JANUARY-8-2024/default.aspx* (last visit February 14, 2024).

[6] *See* Interpretations and Policies .02 of Exchange Rule 404.

[7] Today, IWM may trade on Mondays and Wednesdays in addition to Fridays, as is the case for all options series.

[8] *See* Interpretations and Policies .10 of Exchange Rule 404.

[9] Options on SPY, iShares Core S&P 500 ETF (''IVV''), QQQ, IWM, and the SPDR Dow Jones Industrial Average ETF (''DIA'') are also subject to Interpretations and Policies .10 of Exchange Rule 404.

[10] The term ''Short Term Option Series'' means a series in an option class that is approved for listing and trading on the Exchange in which the series is opened for trading on any Monday, Tuesday, Wednesday, Thursday or Friday that is a business day and that expires on the Monday, Tuesday, Wednesday, Thursday, or Friday of the next business week, or, in the case of a series that is listed on a Friday and expires on a Monday, is listed one business week and one business day prior to that expiration. If a Tuesday, Wednesday, Thursday or Friday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday, Wednesday, Thursday or Friday, respectively. For a series listed pursuant to this section for Monday, expiration, if a Monday is not a business day, the series shall expire on that first business day immediately following that Monday. *See* Exchange Rule 100.

[11] *See* Interpretations and Policies .02(c) and (d) of Exchange Rule 404.

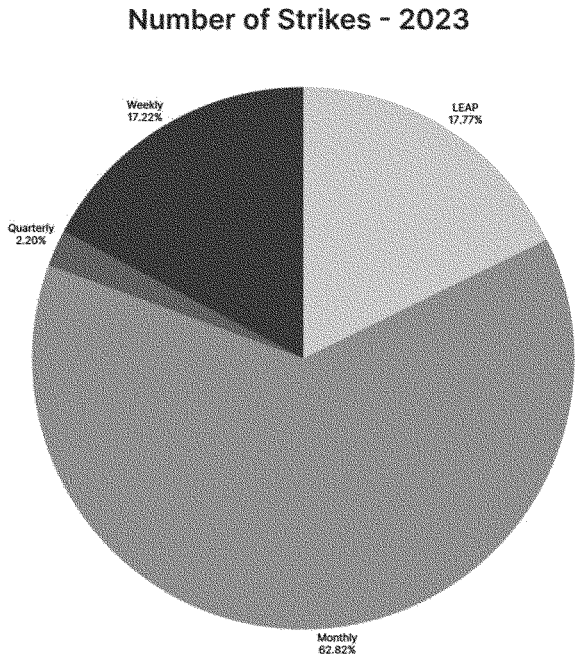
[12] *See* Interpretations and Policies .02 of Exchange Rule 404.

[13] *See* Interpretations and Policies .02(b) of Exchange Rule 404.

Tuesday and Thursday for SPY and QQQ.

Impact of Proposal

The Exchange notes that listings in the Short Term Option Series Program comprise a significant part of the standard listing in options markets. The below diagram taken from the Nasdaq ISE proposal demonstrates the percentage of weekly listings as compared to monthly, quarterly, and Long-Term Option Series in 2023 in the options industry.[14] The Exchange notes that during this time period all options exchanges mitigated weekly strike intervals.



Similar to SPY and QQQ, the Exchange would limit the number of Short Term Option Daily Expirations for IWM to two expirations for Tuesday and Thursday expirations while expanding the Short Term Option Series Program to permit Tuesday and Thursday expirations for IWM. Expanding the Short Term Option Series Program to permit the listing of Tuesday and Thursday expirations in IWM will account for the addition of 6.77% of strikes for IWM.[15] With respect to the impact to the Short Term Option Series Program on IWM overall, the impact would be a 20% increase in strikes.[16] With respect to the impact to the Short Term Options Series Program overall, the impact would be a 0.1% increase in strikes.[17]

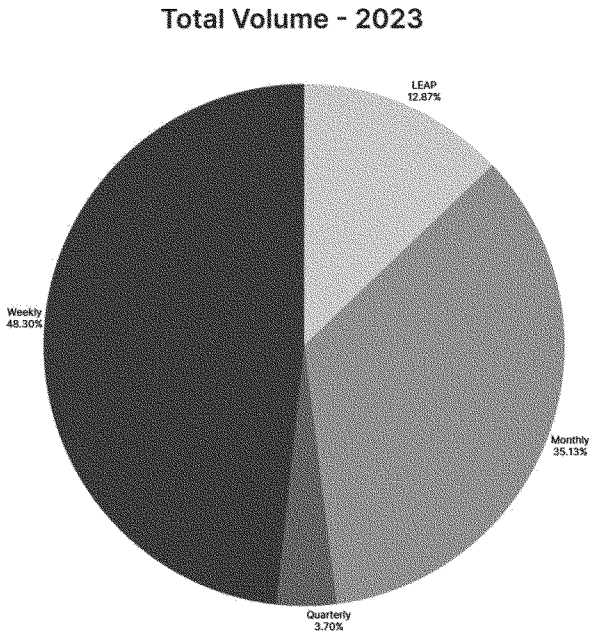
Members will continue to be able to expand hedging tools because all days of the week would be available to permit Members to tailor their investment and hedging needs more effectively in IWM.

[14] *See* Securities Exchange Act Release No. 99604 (February 26, 2024), 89 FR 15235 (March 1, 2024) (SRISE–2024–06) (Notice of Proposed Rule Change to Amend the Short Term Option Series Program). (ISE sourced this information from The Options Clearing Corporation (''OCC''). The information includes time averaged data (the number of strikes by maturity date divided from the number of trading days) for all 17 options markets through December 8, 2023.)

[15] See supra note 14. (ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024.)

[16] *See supra* note 14. (ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024.)

[17] *See supra* note 14. (ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024.)



Weeklies comprise 48.30% of the total volume of options contracts.[18] The Exchange believes that inner weeklies (first two weeks) represent high volume as compared to outer weeklies (the last three weeks) and would be more attractive to market participants.

The introduction of IWM Tuesday and Thursday expirations will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[19] in general, and furthers the objectives of Section 6(b)(5) of the Act,[20] 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.

The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the proposal to permit Tuesday and Thursday Short Term Daily Expirations for options on IWM listed pursuant to the Short Term Option Series Program, subject to the proposed limitation of two nearest expirations, would protect investors and the public interest by providing the investing public and other market participants more flexibility to closely tailor their investment and hedging decisions in IWM options, thus allowing them to better manage their risk exposure.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Tuesday and Thursday IWM Short Term Daily Expirations should simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Tuesday and Thursday IWM Short Term Daily Expirations should create greater trading and hedging opportunities and provide customers the flexibility to tailor their investment objectives more effectively. The Exchange currently lists SPY and QQQ Tuesday and Thursday Short Term Daily Expirations.[21]

With this proposal, Tuesday and Thursday IWM Expirations would be treated similar to existing Tuesday and Thursday SPY and QQQ Expirations and would expire in the same week that standard monthly options expire on Fridays.[22] Further, today, Tuesday and Thursday Short Term Option Daily Expirations do not expire on a business day in which monthly options series or Quarterly Options Series expire.[23] Today, all Short Term Option Daily Expirations expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days in which monthly options series or Quarterly Options Series expire. There are no material differences in the treatment of Tuesday and Thursday SPY and QQQ Short Term Daily Expirations as compared to the proposed Tuesday and Thursday IWM Short Term Daily Expirations.

Finally, the Exchange represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed Tuesday and Thursday IWM Short Term Daily Expirations, in the same way that it monitors trading in the current Short Term Option Series and trading in Tuesday and Thursday SPY and QQQ Expirations. The Exchange also represents that it has the necessary systems capacity to support the new options series. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of Tuesday and

[18] *See supra* note 14. (The chart represents industry volume in terms of overall contracts. Weeklies comprise 48.30% of volume while only comprising 17.22% of the strikes. ISE sourced this information from OCC. The information includes data for all 17 options markets through December 8, 2023.)

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

[21] *See* Interpretations and Policies .02 of Exchange Rule 404.

[22] *See* Interpretations and Policies .02(b) of Exchange Rule 404.

[23] *See* Interpretations and Policies .02 of Exchange Rule 404.

Thursday IWM Short Term Daily Expirations.

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.

Similar to SPY and QQQ Tuesday and Thursday Expirations, the introduction of IWM Tuesday and Thursday Short Term Daily Expirations does not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. The Exchange notes that Cboe began listing Tuesday and Thursday expirations in RUTW and MRUT on January 8, 2024.[24]

The Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents other options exchanges from proposing similar rules to list and trade Short-Term Option Series with Tuesday and Thursday Short Term Daily Expirations. The Exchange notes that having Tuesday and Thursday IWM expirations is not a novel proposal, as SPY and QQQ Tuesday and Thursday Expirations are currently listed on the Exchange.[25]

Further, the Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner under this proposal.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[26] and Rule 19b–4(f)(6) thereunder.[27] 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 from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[28] and subparagraph (f)(6) of Rule 19b–4 thereunder.[29]

A proposed rule change filed under Rule 19b–4(f)(6)[30] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[31] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. According to the Exchange, the proposed rule change is a competitive response to a filing submitted by Nasdaq ISE that was recently approved by the Commission.[32] The Exchange has stated that waiver of the 30-day operative delay would permit the Exchange to implement the proposal at the same time as at least one other exchange, thus enhancing competition among exchanges by allowing Tuesday and Thursday IWM expirations to be traded on multiple exchanges. The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[33]

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–PEARL–2024–21 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–2024–21. 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 (*https://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 the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2024–21 and should be submitted on or before May 17, 2024.

[24] *See supra* note 5.

[25] *See* Interpretations and Policies .02 of Exchange Rule 404.

[26] 15 U.S.C. 78s(b)(3)(A)(iii).

[27] 17 CFR 240.19b–4(f)(6).

[28] 15 U.S.C. 78s(b)(3)(A)(iii).

[29] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) 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.

[30] 17 CFR 240.19b–4(f)(6).

[31] 17 CFR 240.19b–4(f)(6)(iii).

[32] *See supra* note 3.

[33] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100003; File No. SR–MSRB–2024–01]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change Consisting of Proposed Rule Change To Amend MSRB Rule G–14 To Shorten the Timeframe for Reporting Trades in Municipal Securities to the MSRB

April 22, 2024.

I. Introduction

On January 12, 2024, the Municipal Securities Rulemaking Board (''MSRB'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to (1) amend MSRB Rule G–14 (''Rule G–14''), on reports of sales or purchases, to (i) shorten the amount of time within which brokers, dealers, and municipal securities dealers (collectively, ''dealers,'' and each individually, a ''dealer'') must report most transactions to the MSRB; and (ii) require dealers to report certain transactions with a new trade indicator, and make certain clarifying amendments, and (2) make conforming amendments to MSRB Rule G–12, on uniform practice (''Rule G–12''), and the MSRB's Real-Time Transaction Reporting System (''RTRS'') Information Facility (''IF–1'') to reflect the shortened reporting timeframe (collectively, the ''proposed rule change'').[3] The proposed rule change was published for comment in the **Federal Register** on January 26, 2024.[4] The Commission received comments in response to the proposed rule change.[5] This order institutes proceedings under Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposed Rule Change

Rule G–14 on reports of sales or purchases requires dealers to report their transactions to RTRS within 15 minutes of the Time of Trade,[7] absent an exception,[8] in accordance with Rule G–14, the Rule G–14 RTRS Procedures, and the RTRS Users Manual.[9] Since the current 15-minute requirement went into effect in 2005, the fixed income markets have changed dramatically, including a significant increase in the use of electronic trading platforms or other electronic communication protocols to facilitate the execution of transactions. As described in more detail in the Notice, the proposed rule change is intended to bring about greater market transparency through more timely disclosure and dissemination of information to market participants and market-supporting vendors so that the information better reflects current market conditions on a real-time basis, while carefully balancing the considerations raised by commenters throughout the rulemaking process.[10] Additionally, the proposed rule change would also make certain conforming technical changes to Rule G–12(f)(i) and IF–1. The MSRB has stated that it will review the available trade reporting information and data arising from implementation of the changes to trade reporting introduced by the proposed rule change, including but not limited to the two exceptions to the one-minute reporting requirement,[11] to inform any further potential changes by the MSRB, through future rulemaking, to the trade reporting requirements due to increasing marketplace and technology efficiencies, process improvements, continuing or new barriers to accelerated reporting, unanticipated market impacts, or other factors.[12]

A. New Baseline Reporting Requirement: One Minute After the Time of Trade

The proposed amendments to Rule G–14 RTRS Procedures Section (a)(ii) generally would provide that transactions effected with a Time of Trade during the hours of an RTRS Business Day[13] must be reported to an RTRS Portal[14] ''as soon as practicable, but no later than one minute'' (rather than within the current 15-minute standard) after the Time of Trade, subject to several existing reporting exceptions, which would be retained in the amended rule,[15] and two new intra-day reporting exceptions relating to dealers with limited trading activity and trades with a manual component that would be added by the proposed rule change.[16] Except for those trades that would qualify for a reporting exception, all trades currently required to be reported within 15 minutes after the Time of Trade would, under the proposed rule change, be required to be reported no later than one minute after the Time of Trade.

i. New Requirement To Report Trades ''as Soon as Practicable''

Section (a)(ii) of the proposed amendment to Rule G–14 RTRS Procedures adds a new requirement that, absent an exception, trades must be reported as soon as practicable (but no later than one minute after the Time of Trade).[17] This ''as soon as practicable'' requirement would also apply to trades subject to longer trade reporting deadlines under the two new exceptions for dealers with limited trading activity pursuant to Rule G–14 RTRS Procedures Section (a)(ii)(C)(1) and Supplementary Material .01, or trades with a manual component pursuant to Rule G–14 RTRS Procedures Section (a)(ii)(C)(2) and Supplementary Material .02.[18] Although Rule G–14 RTRS Procedures do not currently explicitly prohibit a dealer from waiting until the existing 15-minute deadline to report a trade notwithstanding the fact that the dealer could reasonably have reported such

[34] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 34–99402 (Jan. 19, 2024), 89 FR 5384 (Jan. 26, 2024) (''Notice'').

[4] Notice, 89 FR at 5384.

[5] Comment letters received by the Commission are available on our website at *https://www.sec.gov/comments/sr-msrb-2024-01/srmsrb202401.htm.*

[6] 15 U.S.C. 78s(b)(2)(B).

[7] Rule G–14 RTRS Procedures Section (d)(iii) defines ''Time of Trade'' as the time at which a contract is formed for a sale or purchase of municipal securities at a set quantity and set price.

[8] *See* Notice, 89 FR at 5384 n.5 (describing transactions currently exempt from the reporting requirements under Rule G–14(b)(v)).

[9] The RTRS Users Manual is available at *https://www.msrb.org/RTRS-Users-Manual.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] Rule G–14 RTRS Procedures Section (d)(ii) defines ''RTRS Business Day'' as 7:30 a.m. to 6:30 p.m., Eastern Time, Monday through Friday, unless otherwise announced by the MSRB.

[14] *See* Notice, 89 at 5385 n.13 (discussing the various portals).

[15] *See* Notice, 89 FR at 5385 n.14 (describing the existing exceptions).

[16] The two new intra-day reporting exceptions, consisting of trades by dealers with limited trading activity and trades with a manual component, would be designated as Rule G–14 RTRS Procedures Sections (a)(ii)(C)(1) and (2), respectively. *See* Notice, 89 FR at 5385 n.15.

[17] Notice, 89 FR at 5386.

[18] *Id.*

trade more rapidly, the MSRB notes that under the proposed rule change a dealer could not simply await the deadline to report a trade if it were practicable to report such trade more rapidly.[19]

As provided in more detail in the Notice, proposed Supplementary Material .03 would provide guidance relating to policies and procedures for complying with the ''as soon as practicable'' reporting requirement.[20] The MSRB noted that dealers must not purposely withhold trade reports, for example, by programming their systems to delay reporting until the last permissible minute or by otherwise delaying reports to a time just before the deadline if it would have been practicable to report such trades more rapidly.[21] For trades with a manual component, and consistent with Supplementary Material .03(b) of FINRA Rule 6730, the MSRB recognized that the trade reporting process may not be completed as quickly as, for example, where an automated trade reporting system is used.[22] The MSRB explained that it expected that the regulatory authorities that examine dealers and enforce compliance with this requirement would take into consideration the manual nature of the dealer's trade reporting process in determining whether the dealer's policies and procedures are reasonably designed to report the trade ''as soon as practicable'' after execution.[23]

ii. Time of Trade Discussion

The ''Time of Trade'' is the time at which a contract is formed for a sale or purchase of municipal securities at a set quantity and set price.[24] For transaction reporting purposes, the Time of Trade is the same as the time that a trade is ''executed'' and, generally, is consistent with the ''time of execution'' for recordkeeping purposes.[25]

iii. Valid Contract Discussion

In general, to form a valid contract, there must be at least an offer and acceptance of that offer. As a result, the MSRB noted that dealers should consider the point in time at which an offer to buy or sell municipal securities was met with an acceptance of that offer. This ''meeting of the minds,'' [26] cannot occur before the final material terms, such as the exact security, price and quantity, have been agreed to and such terms are known by the parties to the transaction.[27] The MSRB further explained that dealers should be clear in their communications regarding the final material terms of the trade and how such terms would be conveyed between the parties [28] to ensure that such a valid trade contract has been formed.[29]

iv. Exceptions to the Baseline Reporting Requirement

Proposed amendments to Rule G–14 RTRS Procedures Section (a)(ii) add two new exceptions to the proposed one-minute reporting requirement: (a) New Section (C)(1) provides an exception for a dealer with ''limited trading activity,'' and (b) new Section (C)(2) provides an exception for a dealer reporting a ''trade with a manual component.'' [30]

a. Exception for Dealers With Limited Trading Activity

New Section (a)(ii)(C)(1) would except a dealer with ''limited trading activity'' from the one-minute reporting requirement and would instead be required to report its trades as soon as practicable, but no later than 15 minutes after the Time of Trade for so long as the dealer remains qualified for the limited trading activity exception, as further specified in new Supplementary Material .01.[31] Proposed Section (d)(xi) of Rule G–14 RTRS Procedures would define a dealer with limited trading activity as a dealer that, during at least one of the prior two consecutive calendar years, reported to an RTRS Portal fewer than 1,800 transactions, excluding transactions exempted under Rule G–14(b)(v) and transactions specified in Rule G–14 RTRS Procedures Sections (a)(ii)(A) and (B) (*i.e.,* transactions having an end-of-trade-day reporting exception).[32] A dealer relying on this exception to report trades within the 15-minute timeframe, rather than the new standard one-minute timeframe, would have to confirm that it meets the criteria for a dealer with limited trading activity for each year during which it continues to rely on the exception (*e.g.,* the dealer could confirm its eligibility based on its internal trade records and by checking MSRB compliance tools which would indicate a dealer's transaction volume for a given year).[33] Notwithstanding the foregoing, the MSRB reminded dealers with limited trading activity of the new overarching obligation to report trades as soon as practicable.[34]

b. Exception for Trades With a Manual Component

Rule G–14 RTRS Procedures Section (a)(ii)(C)(2) would except a ''trade with a manual component'' as defined in new Section (d)(xii) of Rule G–14 RTRS Procedures from the one-minute reporting requirement. Dealers with such trades would be required to report such trades as soon as practicable and within the time periods specified in new Supplementary Material .02, unless another exception from the one-minute reporting requirement applies under proposed Rule G–14 RTRS Procedures Sections (a)(ii)(A) and (B) (*i.e.,* transactions having an end-of-trade-day or post-trade-day reporting exception) or (a)(ii)(C)(1) (*i.e.,* transactions by dealers with limited trading activity).[35] Section (d)(xii) of Rule G–14 RTRS Procedures would define a ''trade with a manual component'' as a transaction that is

[19] *Id.*

[20] *Id.* Where a dealer has reasonably designed policies, procedures and systems in place, the dealer generally would not be viewed as violating the ''as soon as practicable'' requirement because of delays in trade reporting due to extrinsic factors that are not reasonably predictable and where the dealer does not intend to delay the reporting of the trade (for example, due to a systems outage).

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *See* current Rule G–14 RTRS Procedures Section (d)(iii).

[25] *See* Notice, 89 FR at 5386 for a discussion on time of execution and note 22 for additional guidance material on the time of execution.

[26] *See generally* FINRA Regulatory Notice 16–30 (Trade Reporting and Compliance Engine (TRACE): FINRA Reminds Firms of their Obligation to Report Accurately the Time of Execution for Transactions in TRACE-eligible Securities) (Aug. 2016); MSRB Notice 2016–19 (MSRB Provides Guidance on MSRB Rule G–14, on Reports of Sales or Purchases of Municipal Securities (Aug. 9, 2019) (the ''2016 RTRS FAQs'') at questions 1 and 2.

[27] *See generally* MSRB Notice 2004–18 (Notice Requesting Comment on Draft Amendments to Rule G–34 to Facilitate Real-Time Transaction Reporting and Explaining Time of Trade for Reporting New Issue Trades) (June 18, 2004); 2016 RTRS FAQs at question 1.

[28] Notice, 89 FR at 5386 n.26.

[29] *See* Notice 89 FR at 5387 (discussing the particulars for when transactions have been executed, confirmed, and reported).

[30] Notice, 89 FR at 5387 (explaining how these exceptions have a narrowly tailored purpose).

[31] The MSRB noted that transactions effected by such a dealer with a Time of Trade outside the hours of an RTRS Business Day would be permitted to be reported no later than 15 minutes after the beginning of the next RTRS Business Day pursuant to Rule G–14 RTRS Procedures Section (a)(iii). The MSRB also noted that, as is the case today, transactions for which an end-of-trade-day or post-trade-day reporting exception is available under redesignated Sections (A) and (B) would continue to have that exception available. Notice, 89 FR at 5387 n.29.

[32] This number of transactions is expected to capture approximately 1.5 percent of the trades in the municipal securities markets in a given calendar year. Notice, 89 FR at 5387 n.30.

[33] *See* Notice, 89 FR at 5387–5388 (using a hypothetical to illustrate variations in dealer eligibility for the limited trading exception).

[34] *See* Notice, 89 FR at 5386 discussing the new requirement to report trades as soon as practicable.

[35] As explained by the MSRB, transactions effected with a Time of Trade outside the hours of an RTRS Business Day would be permitted to be reported no later than 15 minutes after the beginning of the next RTRS Business Day pursuant to Rule G–14 RTRS Procedures Section (a)(iii). Notice, 89 FR at 5387 n.38.

manually executed or where the dealer must manually enter any of the trade details or information necessary for reporting the trade directly into an RTRS Portal (for example, by manually entering trade data into the RTRS Web Portal) or into a system that facilitates trade reporting (for example, by transmitting the information manually entered into a dealer's in-house or third-party system) to an RTRS Portal. As described below and in the Notice, a dealer reporting to the MSRB a trade meeting the definition for a ''trade with a manual component'' would be required to append a new trade indicator so that the MSRB can identify manual trades.[36]

As explained by the MSRB, this ''manual'' exception would apply narrowly, and would normally encompass any human participation, approval or other intervention necessary to complete the initial execution and reporting of trade information after execution, regardless of whether undertaken by electronic means (*e.g.,* keyboard entry), physical signature or other physical action. To qualify as a trade with a manual component, the manual aspect(s) of the trade generally would occur after the relevant Time of Trade (*i.e.,* the time at which a contract is formed for the transaction). As further explained by the MSRB, any manual aspects that precede the time of trade (*e.g.,* phone calls to locate bonds to be sold to a customer before the dealer agrees to sell such bonds to a purchasing customer) would normally not be relevant for purposes of the exception unless they have a direct impact on the activities that must be undertaken post-execution to enter information necessary to report the trade.[37]

The MSRB provided the following non-exhaustive list of situations in which trades would be considered to have a manual component: where a dealer executes a trade by manual or hybrid means, such as voice or negotiated trading by telephone, email, or through a chat/messaging function, and subsequently must manually enter into a system that facilitates trade reporting all or some of the information required to book the trade and report it to RTRS; where a dealer executes a trade (typically a larger-sized trade) that requires additional steps to negotiate and confirm details of the trade with a client and manually enters the trade into risk and reporting systems; where a dually-registered broker-dealer/investment adviser executes a block transaction that requires allocations of portions of the block trade to the individual accounts of the firm's advisory clients that must be manually inputted in connection with a trade; where an electronically or manually executed trade is subject to manual review by a second reviewer for risk management (*e.g.,* transactions above a certain dollar or par amount or other transactions meriting heightened risk review) and, as part of or following the review, the trade must be manually approved, amended or released before the trade is reported to RTRS; where a dealer's trade execution processes may entail further diligence following the Time of Trade involving a manual step (*e.g.,* manually checking another market to confirm that a better price is not available to the customer); [38] where a dealer trades a municipal security, whether for the first time or under other circumstances where the security master information may not already be populated (*e.g.,* information has been removed or archived due to a long lapse in trading the security), and additional manual steps are necessary to set up the security and populate the associated indicative data in the dealer's systems prior to executing and reporting the trade; where a dealer receives a large order or a trade list resulting in a portfolio of trades with potentially numerous unique securities involving rapid execution and frequent communications on multiple transactions with multiple counterparties, and the dealer must then book and report those transactions manually, one by one; [39] where a broker's broker engages in mediated transactions that involve multiple transactions with multiple counterparties; and where a dealer reports a trade manually through the RTRS Web Portal.

The MSRB stated that the appropriateness of treating any step in the trade execution and reporting process as being manual must be assessed in light of the anti-circumvention provision included in the proposed rule change with regard to the delay in execution or insertion of manual tasks for the purpose of meeting this new exception.[40] New Supplementary Material .02(a) would require all trades with a manual component to be reported as soon as practicable and would specify that in no event may a dealer purposely delay the execution of an order, introduce any manual steps following the Time of Trade, or otherwise modify any steps prior to executing or reporting a trade for the purpose of utilizing the exception for manual trades.[41]

New Supplementary Material .03 would require that dealers adopt policies and procedures for complying with the as soon as practicable reporting requirement, including by implementing systems that commence the trade reporting process without delay upon execution and provides for additional guidance for regulatory authorities that enforce and examine dealers for compliance with this requirement to take into consideration the manual nature of the dealer's trade reporting process.[42]

The MSRB also noted that dealers should consider the types of transactions in which they regularly engage and whether they can reasonably reduce the time between a transaction's Time of Trade and its reporting, and more generally should make a good faith effort to report their trades as soon as practicable.[43] The MSRB currently collects and analyzes data regarding dealers' historic reporting of transactions to RTRS under various scenarios and such data will continue to be available to the regulators for analysis under the proposed one-minute

[36] Such new indicator would be required for any trade with a manual component, whether the dealer reports such trade within the new one-minute timeframe or the dealer seeks to take advantage of the longer timeframes permitted for trades with a manual component. Notice, 89 FR at 5388 n.39.

[37] The MSRB provided various scenarios to illustrate application of the manual exception would apply. *See generally* Notice, 89 FR at 5389 n.40 and 5390 n.50.

[38] The MSRB noted that dealers experiencing significant levels of post-Time of Trade price adjustments due to such post-trade best execution processes should consider whether these processes are well suited to the dealer's obligations under MSRB Rule G–18 and whether the dealer is appropriately evaluating when a contract has in fact been formed with its customer. Notice, 89 FR at 5389 n.41.

[39] The MSRB explained that in instances where a dealer trades a basket of securities at a single price for the full basket, rather than individual prices for each security based on its then-current market price, such price likely would be away from the market, requiring inclusion of the ''away from market'' special condition indicator and qualifying for an end-of-trade-day reporting exception under proposed Rule G–14 RTRS Procedures Section (a)(ii)(A)(3). Notice, 89 FR at 5389 n.42.

[40] *See* Notice, 89 FR at 5390 (discussing the prohibition on purposeful insertion of manual steps in trade reporting process).

[41] *Id.*

[42] For trades with a manual component, the MSRB explained that it recognized that the trade reporting process may not be completed as quickly as, for example, where an automated trade reporting system is used. The MSRB further explained that in these cases, the MSRB expects that the regulatory authorities that examine dealers and enforce compliance with this requirement would take into consideration the manual nature of the dealer's trade reporting process in determining whether the dealer's policies and procedures are reasonably designed to report the trade ''as soon as practicable'' after execution. Notice, 89 FR at 5388.

[43] *Id.* at 5389.

standard. Subject to Commission approval of the proposed rule change, the MSRB explained that it would be reviewing the use of the manual exception and would share with the examining authorities any analyses resulting from such reviews.[44]

1. Phase-In Period for Trades With a Manual Component

New Supplementary Material .02(b) would subject trades with a manual component to a phase-in period for timely reporting over three years (''phase-in period''). During the first year of effectiveness of the exception, trades meeting this definition would be required to be reported as soon as practicable, but no later than 15 minutes after the Time of Trade.[45] During the second year, such trades would be required to be reported as soon as practicable, but no later than 10 minutes after the Time of Trade. After the second year and thereafter, such trades would be required to be reported as soon as practicable, but no later than five minutes after the Time of Trade. Dealers should remember that the ''as soon as practicable'' reporting obligation may, depending on the facts and circumstances, require quicker reporting than the applicable outer reporting obligation during and after the phase-in period.

The MSRB explained that it would be reviewing the available trade reporting information and data arising from implementation of the proposed rule, as well as marketplace developments, feedback from market participants, and examination or enforcement findings from the Commission, FINRA and the other appropriate regulatory agencies to inform any further potential changes to the trade reporting requirements.[46]

2. Prohibition on Purposeful Insertion of Manual Steps in Trade Reporting Process

New Supplementary Material .02(a) would specifically prohibit dealers from purposely delaying the execution of an order, introducing any manual steps following the Time of Trade, or otherwise purposefully modifying any steps to execute or report a trade to utilize the exception for manual trades. This requirement would not prohibit reasonable manual steps that are taken for legitimate purposes and would not apply to any steps that are taken prior to the time of trade that do not have the effect of delaying the subsequent reporting of such trade.[47]

3. Manual Trade Indicator

Proposed amendments to Rule G–14 RTRS Procedures Section (b)(iv) would require the report of a trade meeting the MSRB's definition for a ''trade with a manual component,'' as defined in proposed Section (d)(xii) of Rule G–14 RTRS Procedures,[48] to append a new trade indicator[49] to such a trade report. This indicator would be mandatory for every trade that meets the standard to append the indicator,[50] regardless of whether the trade is actually reported within one minute after the Time of Trade, is reported within the applicable timeframe under the manual trade exception or is otherwise subject to another reporting exception.

v. Pattern or Practice of Late Trade Reporting

Current Rule G–14 RTRS Procedures Section (a)(iv) requires that transaction data that is not submitted in a timely and accurate manner must be submitted or corrected as soon as possible—even when a dealer is late in reporting a trade, the dealer remains obligated to report such trade as soon as possible. The proposed amendments further provide that any transaction that is not reported within the applicable time period shall be designated as ''late.''[51] The MSRB stated that a pattern or practice of late reporting without exceptional circumstances or reasonable justification may be considered a violation of Rule G–14. The MSRB further noted that the determination of whether exceptional circumstances or reasonable justifications exist for late trade reporting is dependent on the particular facts and circumstances and whether such circumstances are addressed in the dealer's systems and procedures.[52] The MSRB explained that it expected that the regulatory authorities that examine dealers and enforce compliance with the reporting timeframes established under Rule G–14 RTRS Procedures would focus their examination for and enforcement of the rule's timing requirements on the consistency of timely reporting and the existence of effective controls to limit late reporting to exceptional circumstances or where reasonable justifications exist for a late trade report, rather than on individual late trade report outliers.[53] Notwithstanding such expectation, where facts and circumstances indicate that an individual late report was intentional or otherwise egregious, or could reasonably be viewed as potentially giving rise to an associated fair practice, fair pricing, best execution or other material regulatory concern under MSRB or Commission rules with respect to that or a related transaction, the MSRB noted that the regulatory authorities could reasonably determine to take action with respect to such late trade in the examination or enforcement context.[54]

vi. Compliance Tools

The MSRB explained that it would continue to provide various compliance tools to assist dealers with compliance and for examining authorities to monitor for compliance.[55]

vii. Proposed Technical Amendments

a. Non-Substantive Amendments

Non-substantive amendments to Rule G–14 RTRS Procedures Section (a)(ii) regroup and renumber its current Sections (A) through (C) to new Sections (A)(1) through (A)(3), renumber current Sections (D) and (E) to new Sections (B)(1) and B(2), and correct a cross-reference in Section (b)(iv) to certain of these Sections to be consistent with such renumbering.[56] In addition, a technical amendment to Rule G–14 RTRS Procedures Section (a)(ii) changes the word ''of'' to ''after'' and omits the word ''within'' in the phrase ''within 15 minutes of Time of Trade'' for clarity and consistency of usage throughout the Rule G–14 RTRS Procedures as amended.[57]

[44] *Id.* at 5390.

[45] While the deadline for reporting during this first year would remain the same as the current 15-minute timeframe, such trade reports would also be subject to the new requirement that they be reported as soon as practicable. *See* Notice, 89 FR at 5390 n.48.

[46] Notice, 89 FR at 5390.

[47] Notice, 89 FR at 5890.

[48] *See generally* Notice, 89 FR at 5388–90.

[49] *See* Notice, 89 FR at 5391 n.51 (discussing how the manual trade indicator would be used for regulatory purposes).

[50] Current Rule G–14 RTRS Procedures Section (a)(iv) requires that transaction data that is not submitted in a timely and accurate manner must be submitted or corrected as soon as possible. The manual trade indicator is not intended to be used to reflect the manual nature of any correction to a prior trade report. Notice, 89 FR at 5390 n.50.

[51] *See generally id.* at 5391 n.52 (MSRB explaining that late trade designations are currently, and would continue to be, available to regulators and, through the MSRB compliance tool described below in the Notice under ''Purpose—Proposed Rule Change—Compliance Tools,'' to the dealer submitting the late trade).

[52] *See* Notice, 89 FR at 5391 for non-exhaustive list of factors that would be considered in determining whether a rule violation has occurred.

[53] *Id.*

[54] *Id.*

[55] *Id.* (discussing the various compliance tools).

[56] *Id.* at 5392.

[57] *Id.*

b. Clarifying Amendments—Special Condition Indicators and Trades on an Invalid RTTM Trade Date

Rule G–14 RTRS Procedures Section (b)(iv) currently sets forth information regarding certain existing special condition indicators while also referencing the existence of other special condition indicators in Section 4.3.2 of the Specifications for Real-Time Reporting of Municipal Securities Transactions. The proposed clarifying amendments to Section (b)(iv) of Rule G–14 RTRS Procedures would incorporate into the language thereof reference to all applicable special condition indicators, including the new trade with a manual component indicator and existing special condition indicators previously adopted by the MSRB but that are currently only documented explicitly in the Specifications for Real-Time Reporting of Municipal Securities Transactions.[58] Other than the addition of the new trade with a manual component indicator, the proposed clarifying amendments to this provision would not make any changes to the types or usage of existing special condition indicators.[59] Rule G–14 RTRS Procedures Section (a)(iii) would be amended to reflect that, in addition to trades effected outside the hours of the RTRS Business Day, inter-dealer trades may be executed on certain holidays (other than those recognized as non-RTRS Business Days) that are not valid RTTM trade dates (''invalid RTTM trade date''), and in either case such trades are to be reported no later than within 15 minutes after the beginning of the next RTRS Business Day. Such invalid RTTM trade date transactions are already subject to this same next RTRS Business Day reporting requirement.[60] The proposed clarifying amendment to this provision would not make any changes to the circumstances or timing of reporting of such trades.[61]

c. Proposed Conforming Amendments to Rule G–12 and RTRS Information Facility

Proposed amendments to Rule G–12, on uniform practice, would make conforming changes to Section (f)(i) thereof to require that each transaction effected during the RTRS Business Day shall be submitted for comparison as soon as practicable, but no later than one minute after the Time of Trade unless an exception applies. The proposed rule change would also modify the IF–1 to clarify lateness checking against the applicable reporting deadline(s) provided for in proposed amendments to Rule G–14 RTRS Procedures, as opposed to the current 15-minute requirement.[62]

III. Summary of Comments Received

The Commission received thirteen comment letters on the proposed rule change.[63] Commenters generally supported the MSRB's goal of facilitating equal access to information and market transparency.[64] However, many commenters expressed concern that the MSRB failed to demonstrate how a one-minute reporting requirement would clearly and substantially benefit the municipal securities market.[65] To this end, several commenters raised concern that the one-minute reporting requirement would increase costs of new technology infrastructure which, commenters argued, could impair municipal market liquidity by putting small and mid-size firms out of business.[66] Commenters maintained that the exceptions to the one-minute reporting requirement were requisite to implementing the proposed rule change.[67] Otherwise, commenters asserted that a general one-minute reporting requirement would be unworkable.[68] One commenter, however, strongly encouraged the MSRB to fully phase-out the exceptions.[69] Another commenter noted a similar proposal[70] by the Financial Industry Regulatory Authority, Inc. (''FINRA''), and requested that the MSRB and FINRA harmonize the scope of the manual trade exception.[71]

Commenters offered several views relating to the exceptions. Some commenters noted that the manual trade exception balances shortening reporting requirements while avoiding undue disruptions to the municipal securities market.[72] However, one commenter argued that the MSRB had not provided any data to support a reduction in reporting time for manual trades or any evidence that firms that are currently reporting manually are not already reporting as soon as practicable.[73] This commenter also maintained that the phase-in period could eliminate small firms which are incapable of meeting the phased-in time periods.[74] Another commenter remained troubled by the language of the manual trade exception as it suggested the possibility of leading to further reductions or even the elimination of the manual trade exception.[75] As a potential solution, commenters noted that the MSRB could collect data and conduct impact assessments prior to each phase-in period to ensure continued market integrity.[76] Some commenters stated that the proposed use of the manual trade indicator could not be effectively implemented or monitored for compliance and proposed that trades subject to the one-minute reporting requirement should be flagged

[58] *See generally* Notice, 89 FR at 5392 n.55.

[59] *Id.* at 5392.

[60] *See* Section 4.3.2 of the Specifications for Real-Time Reporting of Municipal Securities Transactions; Exchange Act Release No. 55957 (June 26, 2007), 72 FR 36532 (July 3, 2007), File No. SR–MSRB–2007–01.

[61] Notice, 89 FR at 5392.

[62] *Id.*

[63] *See* letters to Vanessa A. Countryman, Secretary, Commission, from Michael Noto, FINRA Registered Representative dated Jan. 31, 2024 (''Noto''); J. Ben Watkins, Director, Division of Bond Finance, State of Florida dated Feb. 13, 2024 (''State of Florida''); Matthew Kamler, President, Sanderlin Securities LLC dated Feb. 14, 2024 (''Sanderlin Securities''); Gerard O'Rielly, Co-Chief Executive Officer and Co-Chief Investment Officer and David A. Plecha, Global Head of Fixed Income, Dimensional Fund Advisors LP dated Feb. 15, 2024 (''Dimensional Fund Advisors''); Michael Decker, Senior Vice President, Bond Dealers of America dated Feb. 15, 2024 (''BDA''); Sarah A. Bessin, Deputy General Counsel, Investment Company Institute dated Feb. 15, 2024 (''ICI''); Kenneth E. Bentsen, Jr., President and CEO, Securities Industry and Financial Markets Association dated Feb. 15, 2024 (''SIFMA''); Howard Meyerson, Managing Director, Financial Information Forum dated Feb. 15, 2024 (''FIF I''); Gregory Babyak, Global Head of Regulatory Affairs, Bloomberg L.P. dated Feb. 16, 2024 (''Bloomberg''); Melissa P. Hoots, CEO/COO, Falcon Square Capital, LLC dated Feb. 16, 2024 (''Falcon Square Capital''); Matt Dalton, Chief Executive Officer, Belle Haven Investments, LP dated Feb. 16, 2024 (''Belle Haven''); Christopher A. Iacovella, President & Chief Executive Officer, American Securities Association dated Feb. 16, 2024 (''ASA''). Also, after the close of the comment period, one commenter submitted a supplemental letter. *See* letter from Financial Information Forum dated Feb. 26, 2024 (''FIF II''). The Commission's Office of Municipal Securities held a meeting with a representative from the State of Florida on Feb. 13, 2024, and the Commission's Offices of Municipal Securities and Trading and Markets held a meeting with representatives from the BDA. *See* Memoranda from the Office of Municipal Securities regarding 2024 meetings.

[64] *See, e.g.,* letters from SIFMA; BDA; ICI; Dimensional Fund Advisors; Belle Haven.

[65] *See, e.g.,* BDA Letter at 1; Noto Letter; State of Florida Letter at 1–2; Sanderlin Securities Letter at 2–4; SIFMA Letter at 2; ASA Letter at 1 and 5–6; Falcon Square Capital Letter at 1–2; Belle Haven Letter at 3–6; ICI Letter at 2, FN4.

[66] *See, e.g.,* BDA Letter at 3–4; State of Florida Letter at 2; Sanderlin Securities Letter at 1–3; Falcon Square Capital Letter at 2.

[67] *See, e.g.,* BDA Letter at 1; ICI Letter at 3; SIFMA Letter at 2; FIF I Letter at 2.

[68] *See generally* BDA Letter; ICI Letter, SIFMA Letter; FIF I Letter; Belle Haven Letter.

[69] Dimensional Fund Advisors Letter at 2.

[70] *See* Securities Exchange Act Release No. 99404 (Jan. 19, 2024), 89 FR 5034 (Jan. 24, 2024) (''FINRA Notice'').

[71] *See* FIF I Letter at 3.

[72] *See, e.g.,* ICI Letter at 3; SIFMA Letter at 3–4 (noting that the proposed manual trade exception is an attempt to promote continued liquidity of the subject fixed-income markets).

[73] Belle Haven Letter at 7.

[74] *Id.* at 5.

[75] ASA Letter at 2.

[76] *See, e.g.,* SIFMA Letter at 6–7; ICI Letter at 3–4; BDA Letter at 3.

instead.[77] Commenters generally viewed the limited trading activity exception favorably.[78] One commenter, however, argued that the proposed 1,800-trade threshold was far too low and requested that the MSRB either significantly expand the threshold or conduct further analysis to justify the 1,800 threshold.[79]

Some commenters addressed the proposed implementation period. Two commenters requested a two-year implementation and requested that the MSRB and FINRA remain open to the creation of FAQs or the provision of implementation guidance to achieve greater compliance.[80] One commenter requested an eighteen-month implementation period from the date the MSRB and FINRA publish updated technical specifications and guidance.[81]

Commenters also challenged the proposed rule change as circumventing regulatory obligations pursuant to the Exchange Act and requested that the MSRB conduct further analysis before implementing the proposed rule change.[82]

IV. Proceedings To Determine Whether To Approve or Disapprove SR–MSRB–2024–01 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[83] to determine whether the proposed rule change should be approved or disapproved. Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate, however, that the Commission has reached any conclusion with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to comment on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,[84] the Commission is providing notice of the grounds for disapproval under consideration. The Commission believes it is appropriate to institute proceedings at this time in view of the legal and policy issues raised by the proposal. In particular, Section 15B(b)(2) of the Act[85] requires that the MSRB propose and adopt rules to effect the purposes of the Act with respect to transactions in municipal securities effected by brokers, dealers, and municipal securities dealers and advice provided to or on behalf of municipal entities or obligated persons by brokers, dealers, municipal securities dealers, and municipal advisors with respect to municipal financial products, the issuance of municipal securities, and solicitations of municipal entities or obligated persons undertaken by brokers, dealers, municipal securities dealers, and municipal advisors. In addition, Section 15B(b)(2)(C) of the Act[86] requires, among other things, that the MSRB's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons facilitating transactions in municipal securities and municipal financial products, to remove impediments to and perfect the mechanisms of a free and open market in municipal securities and municipal financial products, and, in general, to protect investors, municipal entities, obligated persons, and the public interest. The Commission asks that commenters address the sufficiency of MSRB's statements in support of the proposed rule change, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission is instituting proceedings to allow for additional analysis of, and input from commenters with respect to, the scope and implementation of the proposed exceptions to the one-minute reporting timeframe.

V. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their data, views, and arguments with respect to the issues identified above, as well as any others concerns they may have with the proposed rule change. In particular, the Commission invites the written views of interested persons concerning whether the proposed rule change is inconsistent with the Exchange Act and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval which would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,[87] any request for an opportunity to make an oral presentation.[88]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposed rule change should be approved or disapproved by May 17, 2024. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by May 31, 2024.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MSRB–2024–01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2024–01. 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 (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MSRB. All comments received will be posted without change;

[77] *See, e.g.,* SIFMA Letter at 9; BDA Letter at 3.

[78] *See, e.g.,* SIFMA Letter at 9; BDA Letter at 2; Falcon Square Capital Letter at 3; Belle Haven Letter at 6; FIF I Letter at 2.

[79] Falcon Square Capital Letter at 3.

[80] *See* BDA Letter at 4; SIFMA Letter at 10.

[81] *See* FIF I Letter at 5–7 (commenter also requested a free testing period of 90-days instead of the standard 30-days).

[82] *See, e.g.,* Belle Haven Letter at 2; ASA Letter at 3; Falcon Square Capital Letter at 6.

[83] 15 U.S.C. 78s(b)(2)(B).

[84] *Id.*

[85] 15 U.S.C. 78o4–(b)(2).

[86] 15 U.S.C. 78o–4(b)(2)(C).

[87] 17 CFR 240.19b–4.

[88] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to File Number SR–MSRB–2024–01 and should be submitted on or before May 17, 2024. Rebuttal comments should be submitted May 31, 2024.

For the Commission, pursuant to delegated authority.[89]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08943 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99996; File No. SR–MIAX–2024–23]

Self-Regulatory Organizations; MIAX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 404, Series of Option Contracts Open for Trading To Amend the Short Term Option Series Program

April 19, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 18, 2024, Miami International Securities Exchange, LLC (''MIAX'' 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 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 Short Term Option Series Program.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-options/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.

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 Interpretations and Policies .02 of Exchange Rule 404, ''Series of Options Contracts Open for Trading.'' The Exchange proposes to expand the Short Term Option Series program to permit the listing and trading of options series with Tuesday and Thursday expirations for options on iShares Russell 2000 ETF (''IWM''), specifically permitting two expiration dates for the proposed Tuesday and Thursday expirations in IWM. These proposed rule changes are based on a similar proposal submitted by Nasdaq ISE, LLC (''ISE'') and approved by the Commission.[3] MIAX notes that Exchange Rule 404 as proposed to be amended by this filing, is incorporated by reference into the MIAX Emerald, LLC (''MIAX Emerald'') rulebook, and is thus a MIAX Emerald rule applicable to MIAX Emerald members.

Currently, Table 1 in Interpretations and Policies .02 of Exchange Rule 404 specifies each symbol that qualifies as a Short Term Option Daily Expiration.[4] Today, Table 1 permits the listing and trading of Monday Short Term Option Daily Expirations and Wednesday Short Term Option Daily Expirations for IWM. At this time, the Exchange proposes to expand the Short Term Option Series Program to permit the listing and trading of no more than a total of two IWM Short Term Option Daily Expirations beyond the current week for each of Monday, Tuesday, Wednesday, and Thursday expirations at one time.[5] The listing and trading of Tuesday and Thursday Short Term Option Daily Expirations would be subject to Interpretations and Policies .02 of Exchange Rule 404.

Today, Tuesday Short Term Option Daily Expirations in SPDR S&P 500 ETF Trust (''SPY'') and Invesco QQQ Trust℠ (''QQQ'') may open for trading on any Monday or Tuesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Tuesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Tuesday Short Term Option Expiration Date'').[6] Also, today, Thursday Short Term Option Daily Expirations in SPY and QQQ may open for trading on any Tuesday or Wednesday that is a business day series of options on the symbols provided in Table 1 that expire at the close of business on each of the next two Wednesdays that are business days and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options

[89] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 99946 (April 11, 2024), File No. SR–ISE–2024–06 (Order Approving a Proposed Rule Change to Amend the Short Term Option Program).

[4] The Exchange may open for trading on any Thursday or Friday that is a business day series of options on that class that expire at the close of business on each of the next five Fridays that are business days and are not Fridays in which standard expiration options series, Monthly Options Series, or Quarterly Options Series. Of these series of options, the Exchange may have no more than a total of five Short Term Option Expiration Dates. In addition, the Exchange may open for trading series of options on certain symbols that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire (''Short Term Option Daily Expirations''). See Interpretations and Policies .02 of Exchange Rule 404.

[5] The Exchange would amend the Tuesday and Thursday expirations for IWM in Table 1 in Interpretations and Policies .02 of Exchange Rule 404 from ''0'' to ''2'' to permit Tuesday and Thursday expirations for options on IWM listed pursuant to the Short Term Option Series. The Exchange notes that Cboe Exchange, Inc. (''Cboe'') began listing Tuesday and Thursday expirations in the Russell 2000 Index Weeklys® (''RUTW'') and Mini-Russell 2000 Index Weeklys® (''MRUT'') on January 8, 2024. *See* Securities Exchange Act Release No. 98621 (September 28, 2023), 88 FR 68896 (October 4, 2023) (SR–CBOE–2023–054) (a Proposed Rule Change To Amend Rule 4.13); Securities Exchange Act Release No. 98957 (November 15, 2023), 88 FR 81130 (November 21, 2023) (SR–CBOE–2023–054) (Order Approving a Proposed Rule Change To Amend Rule 4.13 To Expand the Nonstandard Expirations Program To Include P.M.-Settled Options on Broad-Based Indexes That Expire on Tuesday or Thursday); *See also* Cboe Global Markets, Inc., Cboe To Offer Daily Expiries For Russell 2000 Index Options Suite, Beginning January 8, 2024, *available at https://ir.cboe.com/news/news-details/2023/Cboe-T-OOFFER-DAILY-EXPIRIES-FOR-RUSSELL-2000-INDEX-OPTIONS-SUITE-BEGINNING-JANUARY-8-2024/default.aspx* (last visit February 14, 2024).

[6] *See* Interpretations and Policies .02 of Exchange Rule 404.

Series expire (''Wednesday Short Term Option Expiration Date'').

In the event that options on IWM expire on a Tuesday or Thursday and that Tuesday or Thursday is a business day in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. With this proposal, the Exchange would be able to open for trading series of options on IWM that expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.[7]

The interval between strike prices for the proposed Tuesday and Thursday IWM Short Term Option Daily Expirations will be the same as those for Tuesday and Thursday Short Term Option Daily Expirations in SPY and QQQ, applicable to the Short Term Option Series Program.[8] Interpretations and Policies .10 of Exchange Rule 404 provides that, notwithstanding any other provision regarding the interval of strike prices of series of options on Exchange-Traded Fund Shares in Exchange Rule 404, the interval of strike prices on options on IWM will be $1 or greater.[9] Further, Interpretations and Policies .02(e) of Exchange Rule 404 provides that the strike price interval for Short Term Option Series may be $0.50 or greater for option classes that trade in $1 strike price intervals and are in the Short Term Option Series Program. Therefore, the Tuesday and Thursday IWM Short Term Option Daily Expirations will have a $0.50 strike interval minimum. As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Tuesday and Thursday IWM Short Term Option Daily Expiration series will be P.M.-settled.

Pursuant to Exchange Rule 100,[10] with respect to the Short Term Option Series Program, a Tuesday or Thursday expiration series shall expire on the first business day immediately prior to that Tuesday or Thursday, *e.g.,* Monday or Wednesday of that week, respectively, if the Tuesday or Thursday is not a business day.

Currently, for each option class eligible for participation in the Short Term Option Series Program, the Exchange is limited to opening thirty (30) series for each expiration date for the specific class.[11] The thirty (30) series restriction does not include series that are open by other securities exchanges under their respective weekly rules; the Exchange may list these additional series that are listed by other options exchanges.[12] This thirty (30) series restriction would apply to Tuesday and Thursday IWM Short Term Option Daily Expiration series as well.

With this proposal, Tuesday and Thursday IWM Expirations would be treated the same as Tuesday and Thursday Expirations in SPY and QQQ. With respect to standard expiration option series, Short Term Option Daily Expirations may expire in the same week in which standard expiration option series on the same class expire. In the case of Monthly Options Series and Quarterly Options Series, no Short Term Option Series may expire on the same day as an expiration of a Monthly Options Series or Quarterly Options Series, respectively, in the same class.[13] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days beyond the current week and are not business days in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire.

The Exchange does not believe that any market disruptions will be encountered with the introduction of P.M.-settled Tuesday and Thursday IWM Short Term Option Daily Expirations. The Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Tuesday and Thursday Short Term Option Daily Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ and has not experienced any market disruptions nor issues with capacity. Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Tuesday and Thursday for SPY and QQQ.

Impact of Proposal

The Exchange notes that listings in the Short Term Option Series Program comprise a significant part of the standard listing in options markets. The below diagram taken from the Nasdaq ISE proposal demonstrates the percentage of weekly listings as compared to monthly, quarterly, and Long-Term Option Series in 2023 in the options industry.[14] The Exchange notes that during this time period all options exchanges mitigated weekly strike intervals.

[7] Today, IWM may trade on Mondays and Wednesdays in addition to Fridays, as is the case for all options series.

[8] *See* Interpretations and Policies .10 of Exchange Rule 404.

[9] Options on SPY, iShares Core S&P 500 ETF (''IVV''), QQQ, IWM, and the SPDR Dow Jones Industrial Average ETF (''DIA'') are also subject to Interpretations and Policies .10 of Exchange Rule 404.

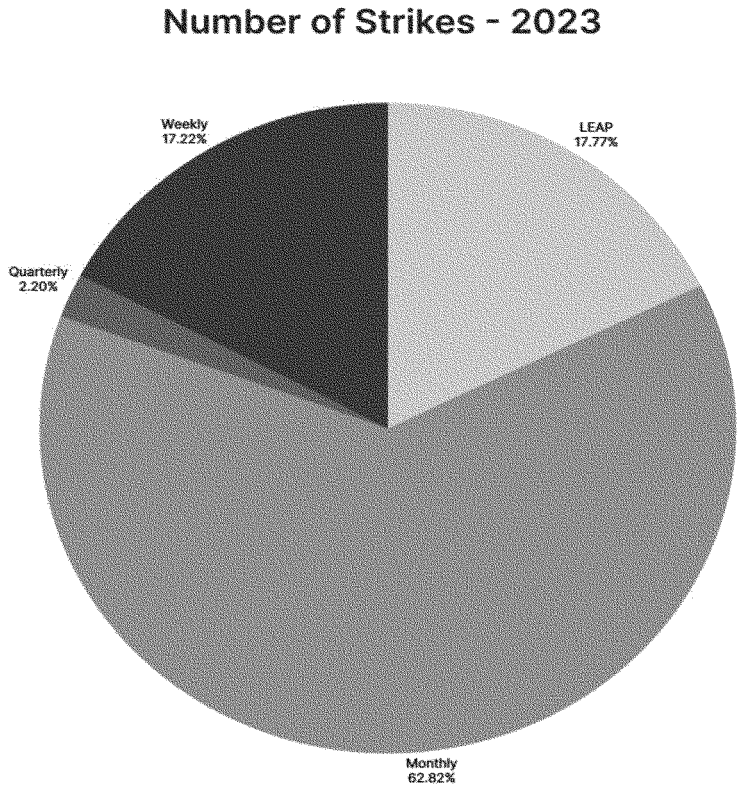
[10] The term ''Short Term Option Series'' means a series in an option class that is approved for listing and trading on the Exchange in which the series is opened for trading on any Monday, Tuesday, Wednesday, Thursday or Friday that is a business day and that expires on the Monday, Tuesday, Wednesday, Thursday, or Friday of the next business week, or, in the case of a series that is listed on a Friday and expires on a Monday, is listed one business week and one business day prior to that expiration. If a Tuesday, Wednesday, Thursday or Friday is not a business day, the series may be opened (or shall expire) on the first business day immediately prior to that Tuesday, Wednesday, Thursday or Friday, respectively. For a series listed pursuant to this section for Monday expiration, if a Monday is not a business day, the series shall expire on the first business day immediately following that Monday. *See* Exchange Rule 100.

[11] *See* Interpretations and Policies .02(c) and (d) of Exchange Rule 404.

[12] *See* Interpretations and Policies .02 of Exchange Rule 404.

[13] *See* Interpretations and Policies .02(b) of Exchange Rule 404.

[14] *See* Securities Exchange Act Release No. 99604 (February 26, 2024), 89 FR 15235 (March 1, 2024) (SR–ISE–2024–06) (Notice of Proposed Rule Change to Amend the Short Term Option Series Program). (ISE sourced this information from The Options Clearing Corporation (''OCC''). The information includes time averaged data (the number of strikes by maturity date divided from the number of trading days) for all 17 options markets through December 8, 2023.)



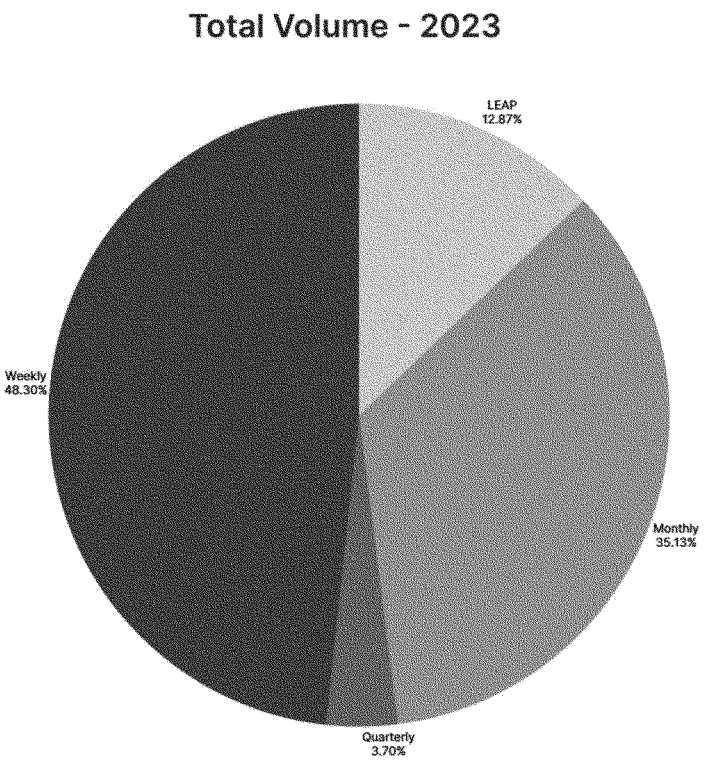
Similar to SPY and QQQ, the Exchange would limit the number of Short Term Option Daily Expirations for IWM to two expirations for Tuesday and Thursday expirations while expanding the Short Term Option Series Program to permit Tuesday and Thursday expirations for IWM. Expanding the Short Term Option Series Program to permit the listing of Tuesday and Thursday expirations in IWM will account for the addition of 6.77% of strikes for IWM.[15] With respect to the impact to the Short Term Option Series Program on IWM overall, the impact would be a 20% increase in strikes.[16] With respect to the impact to the Short Term Options Series Program overall, the impact would be a 0.1% increase in strikes.[17]

Members will continue to be able to expand hedging tools because all days of the week would be available to permit Members to tailor their investment and hedging needs more effectively in IWM.

[15] *See supra* note 14. (ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024.)

[16] *See supra* note 14. (ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024.)

[17] *See supra* note 14. (ISE sourced this information, which are estimates, from LiveVol®. The information includes data for all 17 options markets as of January 3, 2024.)



Weeklies comprise 48.30% of the total volume of options contracts.[18] The Exchange believes that inner weeklies (first two weeks) represent high volume as compared to outer weeklies (the last three weeks) and would be more attractive to market participants.

The introduction of IWM Tuesday and Thursday expirations will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[19] in general, and furthers the objectives of Section 6(b)(5) of the Act,[20] 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.

The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. Further, the proposal to permit Tuesday and Thursday Short Term Daily Expirations for options on IWM listed pursuant to the Short Term Option Series Program, subject to the proposed limitation of two nearest expirations, would protect investors and the public interest by providing the investing public and other market participants more flexibility to closely tailor their investment and hedging decisions in IWM options, thus allowing them to better manage their risk exposure.

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Tuesday and Thursday IWM Short Term Daily Expirations should simply expand the ability of investors to hedge risk against market movements stemming from economic releases or market events that occur throughout the month in the same way that the Short Term Option Series Program has expanded the landscape of hedging. Similarly, the Exchange believes Tuesday and Thursday IWM Short Term Daily Expirations should create greater trading and hedging opportunities and provide customers the flexibility to tailor their investment objectives more effectively. The Exchange currently lists SPY and QQQ Tuesday and Thursday Short Term Daily Expirations.[21]

With this proposal, Tuesday and Thursday IWM Expirations would be treated similar to existing Tuesday and Thursday SPY and QQQ Expirations and would expire in the same week that standard monthly options expire on Fridays.[22] Further, today, Tuesday and Thursday Short Term Option Daily Expirations do not expire on a business day in which monthly options series or Quarterly Options Series expire.[23] Today, all Short Term Option Daily Expirations expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and Thursdays, respectively, that are business days and are not business days in which monthly options series or Quarterly Options Series expire. There are no material differences in the treatment of Tuesday and Thursday SPY and QQQ Short Term Daily Expirations as compared to the proposed Tuesday and Thursday IWM Short Term Daily Expirations.

Finally, the Exchange represents that it has an adequate surveillance program

[18] *See supra* note 14. (The chart represents industry volume in terms of overall contracts. Weeklies comprise 48.30% of volume while only comprising 17.22% of the strikes. ISE sourced this information from OCC. The information includes data for all 17 options markets through December 8, 2023.)

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(5).

[21] *See* Interpretations and Policies .02 of Exchange Rule 404.

[22] *See* Interpretations and Policies .02(b) of Exchange Rule 404.

[23] *See* Interpretations and Policies .02 of Exchange Rule 404.

in place to detect manipulative trading in the proposed Tuesday and Thursday IWM Short Term Daily Expirations, in the same way that it monitors trading in the current Short Term Option Series and trading in Tuesday and Thursday SPY and QQQ Expirations. The Exchange also represents that it has the necessary systems capacity to support the new options series. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of Tuesday and Thursday IWM Short Term Daily Expirations.

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.

Similar to SPY and QQQ Tuesday and Thursday Expirations, the introduction of IWM Tuesday and Thursday Short Term Daily Expirations does not impose an undue burden on competition. The Exchange believes that it will, among other things, expand hedging tools available to market participants and continue the reduction of the premium cost of buying protection. The Exchange believes that IWM Tuesday and Thursday Short Term Daily Expirations will allow market participants to purchase IWM options based on their timing as needed and allow them to tailor their investment and hedging needs more effectively. The Exchange notes that Cboe began listing Tuesday and Thursday expirations in RUTW and MRUT on January 8, 2024.[24]

The Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents other options exchanges from proposing similar rules to list and trade Short-Term Option Series with Tuesday and Thursday Short Term Daily Expirations. The Exchange notes that having Tuesday and Thursday IWM expirations is not a novel proposal, as SPY and QQQ Tuesday and Thursday Expirations are currently listed on the Exchange.[25]

Further, the Exchange does not believe the proposal will impose any burden on intramarket competition, as all market participants will be treated in the same manner under this proposal.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[26] and Rule 19b–4(f)(6) thereunder.[27] 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 from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[28] and subparagraph (f)(6) of Rule 19b–4 thereunder.[29]

A proposed rule change filed under Rule 19b–4(f)(6)[30] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[31] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. According to the Exchange, the proposed rule change is a competitive response to a filing submitted by Nasdaq ISE that was recently approved by the Commission.[32] The Exchange has stated that waiver of the 30-day operative delay would permit the Exchange to implement the proposal at the same time as at least one other exchange, thus enhancing competition among exchanges by allowing Tuesday and Thursday IWM expirations to be traded on multiple exchanges. The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[33]

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MIAX–2024–23 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–2024–23. 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 (*https://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

[24] *See supra* note 5.

[25] *See* Interpretations and Policies .02 of Exchange Rule 404.

[26] 15 U.S.C. 78s(b)(3)(A)(iii).

[27] 17 CFR 240.19b–4(f)(6).

[28] 15 U.S.C. 78s(b)(3)(A)(iii).

[29] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) 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.

[30] 17 CFR 240.19b-4(f)(6).

[31] 17 CFR 240.19b-4(f)(6)(iii).

[32] *See supra* note 3.

[33] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2024–23 and should be submitted on or before May 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08806 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100008; File No. SR–ICC–2024–003]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the ICC Collateral Risk Management Framework

April 22, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4,[2] notice is hereby given that on April 16, 2024, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared primarily by ICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise the Collateral Risk Management Framework (''CRMF''). These revisions do not require any changes to the ICC Clearing Rules[3] (the ''Rules'').[4]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC 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. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes to revise its CRMF. The CRMF describes ICC's collateral assets risk management methodology, including a description of ICC's quantitative risk management approach that accounts for the risk associated with fluctuations of collateral asset prices. ICC believes the proposed revisions will facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. ICC proposes to make such changes effective following Commission approval of the proposed rule change. The proposed revisions are discussed in detail as follows.

The primary purpose of the proposed revisions is to address an internal audit recommendation to remove the 2-day 99.9% Value-at-Risk (''VaR'') risk measure from ICC's ''haircut'' model approach as such measure does not contribute to the determination of the collateral ''haircut'' factors and re-scale certain figures to accompany changes in the axis'.[5] In addition, ICC proposes revisions to the CRMF to correct errors in certain figures contained in the CRMF, typographical errors, and to update the revision history.

Under the current CRMF, the computation of the ''haircut'' factors is achieved by comparing two risk measures: (i) the 5-day 99% Expected Shortfall risk measure and (ii) the 2-day 99.9% VaR risk measure, and then utilizing the more conservative of these two risk measures to determine the ''haircut'' factors that capture potential collateral value losses.[6] In general, the 5-day 99% Expected Shortfall risk measure is a more conservative measurement than the 2-day 99.9% VaR risk measure, given the nature of the calculation (*i.e.,* expected shortfall versus VaR) and the longer measurement period (*i.e.,* 5 days versus 2 days). As a result, the 5-day 99% Expected Shortfall risk measure is the more conservative risk measurement as compared to the 2-day 99.9% VaR risk measure, and it is expected that the 5-day 99% Expected Shortfall risk measure will continue to be the more conservative of these two risk measures. Therefore, the inclusion of the 2-day 99.9% VaR risk measure has not in the past contributed to the determination of collateral ''haircut'' factors, nor is it expected to in the future. As a result, removal of the 2-day 99.9% VaR risk measure will not impact ICC's determination of collateral ''haircut'' factors and the removal of this unnecessary risk measure will simplify the CRMF.

Furthermore, the 2-day 99.9% VaR risk measure is inspired by the general regulatory margin-period-of-risk[7] (''MPOR'') for exchange-traded instruments, while the 5-day 99% Expected Shortfall risk measure is inspired by the MPOR for over-the-counter traded instruments. As ICC clears only over-the-counter swaps with a minimum MPOR of five days and does not clear exchange-traded instruments (with a 2-day MPOR), references to 2-day MPOR in the CRMF are not necessary.

To achieve the foregoing, ICC proposes revisions to the CRMF to remove all references to the 2-day 99.9% VaR risk measure and references

[34] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A copy of the ICC Clearing Rules can be found here: *https://www.ice.com/publicdocs/clear_clear/ICE_Clear_Credit_Rules.pdf.*

[4] Capitalized terms used but not defined herein have the meanings specified in the Rules.

[5] Haircuts are a risk management tool where assets are priced and posted as collateral at a discount, otherwise known as the 'haircut' for the purpose of taking into account their native market risks (*i.e.,* the risk of a decrease in value of the asset posted as collateral) as well as cross-currency risks (*i.e.,* the risk of the change in value of one currency as compared to the value of another currency) when the collateral is to be used to cover an obligation denominated in a different currency.

[6] The 1-day 99% VaR and the 1-day 99% ES risk measures are preserved in current figures 10, 24, 25 and 37. This is because under the statistical model, underpinning the 2-day 99.9% VaR and the 5-day 99% ES risk measures, are calibrated on the 1-day changes as discussed further in Section I, Paragraphs 2 and 3 of the CRMF, which summarizes (that the above-named current figures are still relevant as they preserve the 1-day risk horizon along with the 99% VaR back-testing results since they reflect the same quantile that is ultimately used to estimate collateral haircuts, namely the 99% quantile.

[7] Margin-period-of-risk or 'MPOR' is a maturity factor that is applied to reflect the length of exposure period over which the defaulted portfolio is exposed to changes in value.

the exchange-traded 2-day MPOR, which appear in the following sections of the CRMF: Section I.; Section 1.a. (including removal from Eq. 3); Section I.b. (including removal from Eq.5); Section III.; Section IV.a.; Section IV.b.; and Section IV.c. With the removal of the 2-day 99.9% VaR risk measure from the current two risk measure comparison, it is necessary to change plural nouns to singular nouns throughout the CRMF. In connection with the removal of the 2-day 99.9% VaR risk measure, ICC proposes to delete Figure 11, Figure 12, Figure 26, Figure 27, Figure 28, Figure 29, Figure 38 and Figure 39 from the CRMF as all such figures relate to the 2-day 99.9% VaR risk measure, including 1-day 99.9% VaR which was preserved to calculate 2-day 99.9% VaR.

As a consequence of deleting the figures discussed in the immediately prior paragraph, it is necessary to renumber the remaining figures, and references to the remaining figures, in the CRMF as follows:

- renumber Figure 13 to Figure 11;
- renumber Figure 14 to Figure 12;
- renumber Figure 15 to Figure 13;
- renumber Figure 16 to Figure 14;
- renumber Figure 17 to Figure 15;
- renumber Figure 18 to Figure 16;
- renumber Figure 19 to Figure 17;
- renumber Figure 20 to Figure 18;
- renumber Figure 21 to Figure 19;
- renumber Figure 22 to Figure 20;
- renumber Figure 23 to Figure 21;
- renumber Figure 24 to Figure 22;
- renumber Figure 25 to Figure 23;
- renumber Figure 30 to Figure 24;
- renumber Figure 31 to Figure 25;
- renumber Figure 32 to Figure 26;
- renumber Figure 33 to Figure 27;
- renumber Figure 34 to Figure 28;
- renumber Figure 35 to Figure 29;
- renumber Figure 36 to Figure 30;
- renumber Figure 37 to Figure 31; and
- renumber Figure 40 to Figure 32.

In addition to the foregoing proposed revisions related to the removal of the 2-day 99.9% VaR risk measure and the exchange-traded 2-day MPOR, ICC proposes the following additional revisions to the CRMF to re-scale certain figures and correct typographical errors. Specifically, ICC proposes to re-scale Figure 12, Figure 13, and Figure 26 to adjust the chart from percentage to bps. The change from percentage to bps does not affect the data, but it affects the visualization of the chart because when re-scaling from percentage to bps, the scale will be larger as 1 bps equals 1/100 of a percentage point. The figure numbers below reflect the figure renumbering as described above:

- Updated footnote 1 to the most current link to the ICC Collateral Management presentation on the Intercontinental Exchange, Inc. Website;
- Revised Figure 5: re-scaled Figure 5 to adjust bin sizes [8] (which relate to the thickness of each bar in the histogram) and re-scaled from bps to the correct label of percentage (''%'') on the x-axis; [9]
- Corrected and consistent use of defined term US TIPS;
- Corrected typographical error in label to Figure 8 which was incorrectly labeled Figure 5;
- Corrected and consistent use of defined term BTLS;
- Revised Figure 12: re-scaled Figure 12 from % to bps and added the correct label to x-axis; [10]
- Revised Figure 13: re-scaled Figure 13 from % to bps and added the correct label to x-axis; [11]
- Revised Figure 16: corrected the label in the y-axis from % to bps;
- Revised Figure 17: corrected the label in the y-axis from % to bps;
- Revised Figure 20: corrected the label in the y-axis from % to bps;
- Revised Figure 21: corrected the label in the y-axis from % to bps;
- Revised Figure 26: re-scaled Figure 26 from % to bps and added the correct label to the x-axis; [12]
- Revised Figure 28: corrected the label in the y-axis from % to bps; and
- Revised Figure 30: corrected the label in the y-axis from % to bps.

Lastly, ICC proposes to revise Section VI of the CRMF to update the revision history.

(b) Statutory Basis

ICC believes that the proposed rule change is consistent with the requirements of Section 17A of the Act [13] and the regulations thereunder applicable to it, including the applicable standards under Rule 17Ad–22.[14] In particular, Section 17A(b)(3)(F) of the Act [15] requires that the rule change be consistent with the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts and transactions cleared by ICC, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest.

As discussed herein, the proposed revisions to update the CRMF to remove the 2-day 99.9% VaR risk measure that does not contribute to the estimate of the collateral ''haircut'' factors and removes the unnecessary references to exchange-traded 2-day MPOR. The proposed revisions also correct errors and re-scale certain figures in the CRMF among other typographical errors. The proposed revisions would not amend ICC's methodology and will not impact ICC's determination of collateral ''haircut'' factors. In addition, the removal of the 2-day 99.9% VaR risk measure would simplify the CRMF and would promote effective operation of the collateral assets risk management model by eliminating an unused risk measure. In ICC's view, such changes promote transparency by removing an unused risk measure and only including relevant parameters, computations, equations, definitions, and figures to describe relevant processes, which would also ensure that responsible parties carry out their assigned duties effectively and aid them in doing so. Further, the correction and clarification changes ensure transparency, readability, and clarity by avoiding unnecessary repetition and duplication in the defined terms in the CRMF and correcting drafting errors. ICC believes that having policies and procedures that clearly and accurately document its risk measurements associated with fluctuations of collateral asset prices is an important component to the effectiveness of ICC's risk management system and support ICC's ability to maintain adequate financial resources and collateral management resources. Accordingly, ICC believes that the proposed rule change is consistent with the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of ICC or for which it is responsible, and the protection of investors and the public interest, within

[8] 'Bin size' in risk data refers to the width of intervals used to group similar data points when analyzing risk. The underlying data remains the same regardless of the bin size. A change in bin size, while not including different data, might apportion the data more widely or more narrowly across the chart within newly created intervals. As the distributions change, so could the trend lines across the intervals change.

[9] While the visual illustration of Figure 5 has changed (it is merely illustrative), the underlying data and estimations have remained unchanged.

[10] Figure 12's underlying data and estimates have remained constant with the correction from % to bps, however, the histogram is merely illustrative and the plots have been adjusted to reflect the correct estimations.

[11] Figure 13's underlying data and estimates have remained constant with the correction from % to bps, however, the histogram is merely illustrative and the plots have been adjusted to reflect the correct estimations.

[12] Figure 26's underlying data and estimates have remained constant with the correction from % to bps, however, the histogram is merely illustrative and the plots have been adjusted to reflect the correct estimations.

[13] 15 U.S.C. 78q–1.

[14] 17 CFR 240.17Ad–22.

[15] 15 U.S.C. 78q–1(b)(3)(F).

the meaning of Section 17A(b)(3)(F) of the Act.[16]

Rule 17Ad–22(e)(4)(ii) [17] requires ICC to establish, implement, maintain, and enforce written policies and procedures reasonably designed to effectively identify, measure, monitor, and manage its credit exposures to participants and those arising from its payment, clearing, and settlement processes, including by maintaining additional financial resources at the minimum to enable it to cover a wide range of foreseeable stress scenarios that include, but are not limited to, the default of the two participant families that would potentially cause the largest aggregate credit exposure for ICC in extreme but plausible market conditions. The proposed revisions enhance ICC's ability to manage its financial resources by providing further clarity and transparency on its collateral assets risk management approach through the updated risk measures in the CRMF, which will promote the effective and accurate function of the collateral assets risk management model. The proposed rule change would also enhance the implementation of various processes and procedures associated with the collateral assets risk management methodology to ensure that responsible parties effectively carry out their associated duties, including by providing relevant parameters, computations, equations, definitions, and figures. As such, the proposed amendments would support ICC's ability to maintain its financial resources and withstand the pressures of defaults, consistent with the requirements of Rule 17Ad–22(e)(4)(ii).[18]

Rule 17Ad–22(e)(5) [19] requires ICC to establish, implement, maintain, and enforce written policies and procedures reasonably designed to limit the assets it accepts as collateral to those with low credit, liquidity, and market risks, and set and enforce appropriately conservative haircuts and concentration limits if the covered clearing agency requires collateral to manage its or its participants' credit exposure; and require a review of the sufficiency of its collateral haircuts and concentration limits to be performed not less than annually. ICC would continue to limit the assets that ICC accepts as collateral to those with low credit, liquidity, and market risks under the proposed rule change. Collateral haircut factor estimations are executed daily, and the ICC Risk Department reviews the results and determines any updates, at least monthly. Haircut factors can be updated more frequently at the discretion of the CRO or designee. Furthermore, the CRMF continues to provide a clear framework for ICC to set and enforce appropriately conservative haircuts for acceptable collateral assets. The proposed revisions will improve clarity of the process of calculating the conservative collateral haircut factors that are executed daily. As such, the amendments would satisfy the requirements of Rule 17Ad–22(e)(5).[20]

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition. The proposed changes to remove the 2-day 99.9% VaR risk measure and exchange-traded 2-day MPOR language do not amend ICC's methodology and would result in no change to market participants. ICC does not believe these amendments would affect the costs of clearing or the ability of market participants to access clearing. Therefore, ICC does not believe the proposed rule change imposes any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–ICC–2024–003 on the subject line.

Paper Comments

Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to file number SR–ICC–2024–003. 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 (*https://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 filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.ice.com/clear-credit/regulation.*

Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–ICC–2024–003 and should be submitted on or before May 17, 2024.

[16] Id.

[17] 17 CFR 240.17Ad–22(e)(4)(ii).

[18] Id.

[19] 17 CFR 240.17Ad–22(e)(5).

[20] Id.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08947 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–647, OMB Control No. 3235–0697]

Proposed Collection; Comment Request; Extension: Form SD

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form SD (17 CFR 249b–400) is required by section 13(p) (15 U.S.C. 78m(p)) of the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'') and Rule 13p–1 thereunder (17 CFR 240.13p–1) and is filed by issuers to provide disclosures regarding the source and chain of custody of certain minerals used in their products. Section 13(q) was added by Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (''Dodd-Frank Act''). We estimate that, when used by filers to comply with section 13(p), Form SD takes approximately 480.61265 hours per response to prepare and is filed by approximately 1,009 issuers. We estimate that 75% of the 480.61265 hours per response (360.46 hours) is prepared by the issuer internally for a total annual burden of 363,704 hours (360.46 hours per response × 1009 responses).

Form SD is also used by filers to comply with section 13(q) of the Exchange Act (15 U.S.C. 78m(q)) and Rule 13q–1 thereunder (17 CFR 240.13q–1). Section 13(q) was added by section 1504 of the Dodd-Frank Act. Form SD is used by resource extraction issuers to disclose information relating to certain payments made by the issuer, a subsidiary of the issuer, or an entity under the control of the issuer, to a foreign government or the Federal Government for the purpose of the commercial development of oil, natural gas, or minerals. We estimate that, when used by filers to comply with section 13(q), Form SD takes approximately 296.9202 hours per response to prepare and is filed by approximately 414 issuers. We estimate that 75% of the 296.9202 hours per response (222.69 hours) is prepared by the issuer internally for a total annual burden of 192,194 hours (222.69 hours per response × 414 issuers responses).

For purposes of the Paperwork Reduction Act (''PRA''), we estimate that Form SD take approximately 427.1701 hours per response to comply with collection information requirements of sections 13(p) and 13(q) under the Exchange Act and is filed by 1,423 issuers. We estimate that 75% of the 427.1701 of hours per response (320.3775 hours) is prepared by the issuer internally for a total annual burden of 455,897 hours (320.3775 hours per response × 1,423 issuers). The estimated burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

Written comments are invited on: (a) whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden imposed by the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication by June 25, 2024.

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 control number.

Please direct your written comment to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549 or send an email to: *PRA_Mailbox@sec.gov.*

Dated: April 23, 2024.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–09035 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100010; File No. SR–CBOE–2024–019]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule

April 22, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 10, 2024, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fees Schedule.[3] Specifically, the Exchange proposes to amend the Regular Trading Hours (''RTH'') XSP Lead Market-Makers (''LMMs'') Incentive Program (the ''Program'').

By way of background, the Exchange offers several LMM Incentive Programs which provide a rebate to Trading Permit Holders (''TPHs'') with LMM appointments to the respective incentive program that meet certain quoting standards in the applicable series in a month.[4] The Exchange notes that meeting or exceeding the quoting standards in each of the LMM incentive program products to receive the applicable rebate is optional for an LMM appointed to a program. Particularly, an LMM appointed to an incentive program is eligible to receive the corresponding rebate if it satisfies the applicable quoting standards, which the Exchange believes encourages appointed LMMs to provide liquidity in the applicable class and trading session (*i.e.,* RTH or Global Trading Hours). The Exchange may consider other exceptions to the programs' quoting standards based on demonstrated legal or regulatory requirements or other mitigating circumstances. In calculating whether an LMM appointed to an incentive program meets the applicable program's quoting standards each month, the Exchange excludes from the calculation in that month the business day in which the LMM missed meeting or exceeding the quoting standards in the highest number of the applicable series.

The Exchange proposes to amend the current Program. Currently, the Program provides that if an LMM appointed to the Program provides continuous electronic quotes during RTH that meet or exceed the proposed heightened quoting standards (below) in at least 95% of the series 93% of the time in a given month, the LMM will receive (i) a payment for that month in the amount of $40,000 (or pro-rated amount if an appointment begins after the first trading day of the month or ends prior to the last trading day of the month) and (ii) a rebate of $0.27 per XSP contract that is executed in RTH in Market-Maker capacity and adds liquidity electronically contra to non-customer capacity.

The Exchange now proposes to amend the time requirement for the Program. Specifically, the Exchange proposes to update the time requirement to require an appointed LMM to provide continuous electronic quotes during RTH that meet or exceed the heightened quoting standards in at least 95% of the XSP series 90% of the time in a given month in order to receive the rebate, thereby decreasing the time requirement by 3%.

Further, the Exchange proposes to amend the heightened quoting requirements offered by the Program. The current heightened quoting requirements are as follows in the table below:

WIDTH

Moneyness *	Expiring option	1 day	2 days to 5 days	6 days to 14 days	15 days to 35 days
VIX Value at Prior Close ≤30:					
[>3% ITM)	$0.20	$0.25	$0.25	$0.50	$1.00
[3% ITM to 2% ITM)	0.10	0.15	0.15	0.25	0.75
[2% ITM to 0.25% ITM)	0.04	0.05	0.05	0.06	0.10
[0.25% ITM to ATM)	0.02	0.03	0.04	0.05	0.08
[ATM to 1% OTM)	0.02	0.02	0.02	0.03	0.06
[>1% OTM]	0.02	0.02	0.02	0.02	0.04
VIX Value at Prior Close >30:					
[>3% ITM)	0.25	0.30	0.30	0.55	1.05
[3% ITM to 2% ITM)	0.15	0.20	0.20	0.30	0.80
[2% ITM to 0.25% ITM)	0.05	0.06	0.06	0.07	0.11
[0.25% ITM to ATM)	0.03	0.04	0.05	0.06	0.09
[ATM to 1% OTM)	0.03	0.03	0.03	0.04	0.07
[>1% OTM]	0.03	0.03	0.03	0.03	0.05

* Moneyness is calculated as 1 − strike/index for calls, strike/index − 1 for puts. Negative numbers are Out of the Money (''OTM'') and positive values are In the Money (''ITM''). A Moneyness value of zero for either calls or puts is considered At the Money (''ATM''). For example, if the index is at 400, the 396 call = 1 − 396/400 = 0.01 = 1% ITM, whereas the 396 put = 396/400 − 1 = −0.01 = 1% OTM.

Moneyness	Size (0 to 35 days to expiry)
[>3% ITM)	5
[3% ITM to 2% ITM)	10
[2% ITM to 0.25% ITM)	15
[0.25% ITM to ATM)	20
[ATM to 1% OTM)	20
[>1% OTM]	20

The Exchange proposes to restructure the Program and adopt a new set of heightened quoting standards. The heightened quoting standards proposed for XSP options are as follows in the table below:

[3] The Exchange initially filed the proposed fee changes on April 1, 2024 (SR–CBOE–2024–016). On April 2, 2024, the Exchange withdrew that filing and submitted SR–CBOE–2024–018. On April 10, 2024, the Exchange withdrew that filing and submitted this proposal.

[4] *See* Exchange Rule 3.55(a). In advance of the LMM Incentive Program effective date, the Exchange will send a notice to solicit applications from interested TPHs for the LMM role and will, from among those applications, select the program LMMs. Factors to be considered by the Exchange in selecting LMMs include adequacy of capital, experience in trading options, presence in the trading crowd, adherence to Exchange rules and ability to meet the obligations specified in Rule 5.55.

WIDTH

Moneyness	Expiring option	1 day	2 days to 5 days	6 days to 14 days	15 days to 35 days
VIX Value at Prior Close ≤30:					
[>3% ITM)	$0.20	$0.25	$0.30	$0.40	$0.75
[3% ITM to 2% ITM)	0.10	0.13	0.20	0.25	0.50
[2% ITM to 0.25% ITM)	0.08	0.10	0.13	0.16	0.25
[0.25% ITM to ATM)	0.05	0.06	0.08	0.10	0.15
[ATM to 1% OTM)	0.03	0.04	0.05	0.06	0.10
[>1% OTM]	0.02	0.03	0.04	0.05	0.06
VIX Value at Prior Close >30:					
[>3% ITM)	0.30	0.40	0.50	0.60	1.00
[3% ITM to 2% ITM)	0.15	0.20	0.25	0.30	0.75
[2% ITM to 0.25% ITM)	0.12	0.15	0.19	0.23	0.40
[0.25% ITM to ATM)	0.08	0.09	0.12	0.15	0.20
[ATM to 1% OTM)	0.05	0.06	0.07	0.09	0.10
[>1% OTM]	0.03	0.04	0.05	0.06	0.07

Moneyness	Size (0 to 35 days to expiry)
[>3% ITM)	5
[3% ITM to 2% ITM)	5
[2% ITM to 0.25% ITM)	10
[0.25% ITM to ATM)	20
[ATM to 1% OTM)	20
[>1% OTM]	20

The amended time requirement and proposed heightened quoting standards are designed to incentivize LMMs appointed to the Program to provide significant liquidity in XSP options during the RTH session, which, in turn, would provide greater trading opportunities, added market transparency and enhanced price discovery for all market participants in XSP.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[5] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[6] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) of the Act,[8] which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

The Exchange believes it is reasonable to decrease the time requirement for the Program, as the change is reasonably designed to slightly ease the difficulty in meeting the heightened quoting standards offered under the Program (for which an appointed LMM receives the respective rebates), which, in turn, provides increased incentive for LMMs appointed to the program to provide significant liquidity in XSP options. Such liquidity benefits all market participants by providing more trading opportunities, tighter spreads, and added market transparency and price discovery, and signals to other market participants to direct their order flow to the market, thereby contributing to robust levels of liquidity.

Additionally, the Exchange believes that it is reasonable to amend the Program's heightened quoting standards, as the proposed new quoting requirements are overall reasonably designed to continue to encourage LMMs appointed to the Program to provide significant liquidity in XSP options, which benefits investors overall by providing more trading opportunities, tighter spreads, and overall enhanced market quality to the benefit of all market participants.

The Exchange believes that the proposed changes to width and quote sizes for the Program's heightened quoting requirements eases the heightened quoting standards in a manner that makes it easier for appointed LMMs to achieve such requirements and will incentivize an increase in quoting activity in XSP options. Particularly, by increasing certain quote widths and decreasing certain quote sizes, the Exchange believes the proposed changes will encourage appointed LMMs to post more aggressive quotes in XSP options, in order to meet the heightened quoting standards, as amended, and receive the rebates offered under the incentive program, resulting in tighter spreads and increased liquidity to the benefits of investors. The Exchange also believes that the proposed width and quote sizes are reasonable because they remain generally aligned with the current heightened standards in each program, as the proposed width and quote sizes are only marginally changed in order to incentivize an increase in quoting activity.

The Exchange believes that the proposed changes to the Program are equitable and not unfairly discriminatory. Specifically, the changes to the Program will apply equally to any and all TPHs with LMM

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] *Id.*

[8] 15 U.S.C. 78f(b)(4).

appointments to the Program that seek to meet the Programs' quoting standards in order to receive the rebates offered. The Exchange additionally notes that, if an LMM appointed to the Program does not satisfy the corresponding heightened quoting standard for any given month, then it simply will not receive the rebate offered by the Program for that month.

Regarding the Program generally, the Exchange believes it is reasonable, equitable and not unfairly discriminatory to continue to offer financial incentives to LMMs appointed to the Program, because it benefits all market participants trading in XSP options during RTH. The incentive program encourages the appointed LMMs to satisfy the applicable quoting standards, which may increase liquidity and provide more trading opportunities and tighter spreads. Indeed, the Exchange notes that these LMMs serve a crucial role in providing quotes and the opportunity for market participants to trade XSP options, which can lead to increased volume, providing robust markets. The Exchange ultimately offers the Program, as amended, to sufficiently incentivize LMMs appointed to the Program to provide key liquidity and active markets in the XSP options during RTH and believes that the incentive program, as amended, will continue to encourage increased quoting to add liquidity in XSP options, thereby protecting investors and the public interest. The Exchange also notes that an LMM appointed to an incentive program may undertake added costs each month to satisfy that heightened quoting standards (*e.g.,* having to purchase additional logical connectivity).

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. First, the Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed changes to the Program will apply to all appointed LMMs in a uniform manner. To the extent LMMs appointed to the incentive program receive a benefit that other market participants do not, as stated, these LMMs in their role as Market-Makers on the Exchange have different obligations and are held to different standards. For example, Market-Makers play a crucial role in providing active and liquid markets in their appointed products, thereby providing a robust market which benefits all market participants. Such Market-Makers also have obligations and regulatory requirements that other participants do not have. The Exchange also notes that an LMM appointed to an incentive program may undertake added costs each month to satisfy that heightened quoting standards (*e.g.,* having to purchase additional logical connectivity). The Exchange also notes that the incentive programs are designed to attract additional order flow to the Exchange, wherein greater liquidity benefits all market participants by providing more trading opportunities, tighter spreads, and added market transparency and price discovery, and signals to other market participants to direct their order flow to those markets, thereby contributing to robust levels of liquidity. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [9]

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act as the Program applies only to transactions in a product exclusively listed on the Exchange. As noted above, the incentive program is designed to attract additional order flow to the Exchange, wherein greater liquidity benefits all market participants by providing more trading opportunities, tighter spreads, and added market transparency and price discovery, and signals to other market participants to direct their order flow to those markets, thereby contributing to robust levels of liquidity. The Exchange notes that it operates in a highly competitive market. TPHs have numerous alternative venues that they may participate on and direct their order flow, including 16 other options exchanges, as well as off-exchange venues, where competitive products are available for trading. Based on publicly available information, no single options exchange has more than 15% of the market share.[10] Therefore, no exchange possesses significant pricing power in the execution of option order flow. Indeed, participants can readily choose to send their orders to other exchanges, and, additionally off-exchange venues, if they deem fee levels at those other venues to be more favorable. 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.'' [11] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[12] 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

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [13] and paragraph (f) of Rule 19b–4 [14] thereunder. At any time within 60 days of the filing of the proposed rule

[9] *See* Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

[10] *See* Cboe Global Markets U.S. Options Market Volume Summary, Month-to-Date (March 26, 2024), available at *https://markets.cboe.com/us/options/market_statistics/*.

[11] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[12] *See* 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)).

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f).

change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CBOE–2024–019 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CBOE–2024–019. 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 (*https://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 the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CBOE–2024–019 and should be submitted on or before May 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08949 Filed 4–25–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100005; File No. SR–CboeBZX–2024–027]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule Related to Physical Port Fees

April 22, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 9, 2024, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') 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

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/BZX/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule relating to physical connectivity fees.[3]

By way of background, a physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,500 per physical port for a 1 gigabit (''Gb'') circuit and $7,500 per physical port for a 10 Gb circuit. The Exchange proposes to increase the monthly fee for 10 Gb physical ports from $7,500 to $8,500 per port. The Exchange notes the proposed fee change better enables it to continue to maintain and improve its market technology and services and also notes that the proposed fee amount, even as amended, continues to be in line with, or even lower than, amounts assessed by other exchanges for similar connections.[4] The physical ports may

[15] 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 fee changes on July 3, 2023 (SR–CboeBZX–2023–046). On September 1, 2023, the Exchange withdrew that filing and submitted SR–CboeBZX–2023–067. On September 29, 2023, the Securities and Exchange Commission issued a Suspension of and Order Instituting Proceedings to Determine whether to Approve or Disapprove a Proposed Rule Change to Amend its Fees Schedule Related to Physical Port Fees (the ''OIP''). On October 2, 2023, the Exchange filed the proposed fee change (SR–CboeBZX–2023–080). On October 13, 2023, the Exchange withdrew that filing and on business date October 16, 2023 submitted SR–CboeBZX–2023–084. On December 12, 2023, the Exchange withdrew that filing and submitted SR–CboeBZX–2023–103. On February 9, 2024, the Exchange withdrew that filing and submitted SR–CboeBZX–2024–016. On April 9, 2024, the Exchange withdrew that filing and submitted this filing.

[4] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10

Continued

also be used to access the Systems for the following affiliate exchanges and only one monthly fee currently (and will continue) to apply per port: the Exchange's options platform (BZX Options), Cboe EDGX Exchange, Inc. (options and equities platforms), Cboe BYX Exchange, Inc., Cboe EDGA Exchange, Inc., and Cboe C2 Exchange, Inc., (''Affiliate Exchanges'').[5]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)[9] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities.

The Exchange believes the proposed fee change is reasonable as it reflects a moderate increase in physical connectivity fees for 10 Gb physical ports. Further, the current 10 Gb physical port fee has remained unchanged since June 2018.[10] Since its last increase over 5 years ago however, there has been notable inflation. Particularly, the dollar has had an average inflation rate of 3.9% per year between 2018 and today, producing a cumulative price increase of approximately 21.1% inflation since the fee for the 10 Gb physical port was last modified.[11] Moreover, the Exchange historically does not increase fees every year, notwithstanding inflation. Accordingly, the Exchange believes the proposed fee is reasonable as it represents only an approximate 13% increase from the rates adopted five years ago, notwithstanding the cumulative rate of 21.1%. The Exchange is also unaware of any standard that suggests any fee proposal that exceeds a certain yearly or cumulative inflation rate is unreasonable, and in any event, in this instance the increase is well below the cumulative rate.

Additionally, the Exchange believes the proposed fee increase is reasonable in light of recent and anticipated connectivity-related upgrades and changes. The Exchange and its affiliated exchanges recently launched a multi-year initiative to improve Cboe Exchange Platform performance and capacity requirements to increase competitiveness, support growth and advance a consistent world class platform. The goal of the project, among other things, is to provide faster and more consistent order handling and matching performance for options, while ensuring quicker processing time and supporting increasing volumes and capacity needs. For example, the Exchange recently performed switch hardware upgrades. Particularly, the Exchange replaced existing customer access switches with newer models, which the Exchange believes resulted in increased determinism. The recent switch upgrades also increased the Exchange's capacity to accommodate more physical ports by nearly 50%. Network bandwidth was also increased nearly two-fold as a result of the upgrades, which among other things, can lead to reduce message queuing. The Exchange also believes these newer models result in less natural variance in the processing of messages. The Exchange notes that it incurred costs associated with purchasing and upgrading to these newer models, of which the Exchange has not otherwise passed through or offset.

As of April 1, 2024, market participants also having the option of connecting to a new data center (*i.e.,* Secaucus NY6 Data Center (''NY6'')), in addition to the current data centers at NY4 and NY5. The Exchange made NY6 available in response to customer requests in connection with their need for additional space and capacity. In order to make this space available, the Exchange expended significant resources to prepare this space, and will also incur ongoing costs with respect to maintaining this offering, including costs related to power, space, fiber, cabinets, panels, labor and maintenance of racks. The Exchange also incurred a large cost with respect to ensuring NY6 would be latency equalized, as it is for NY4 and NY5.

The Exchange also has made various other improvements since the current physical port rates were adopted in 2018. For example, the Exchange has updated its customer portal to provide more transparency with respect to firms' respective connectivity subscriptions, enabling them to better monitor, evaluate and adjust their connections based on their evolving business needs. The Exchange also performs proactive audits on a weekly basis to ensure that all customer cross connects continue to fall within allowable tolerances for Latency Equalized connections. Accordingly, the Exchange expended, and will continue to expend, resources to innovate and modernize technology so that it may benefit its Members and continue to compete among other equities markets. The ability to continue to innovate with technology and offer new products to market participants allows the Exchange to remain competitive in the equities space which currently has 16 equities markets and potential new entrants. The Exchange also believes the proposed fee is reasonable as it is still in line with, or even lower than, amounts assessed by other exchanges for similar connections.[12] Indeed, the Exchange believes assessing fees that are a lower rate than fees assessed by other exchanges for analogous connectivity (which were similarly adopted via the rule filing process and filed with the Commission) is reasonable. As noted above, the proposed fee is also the same as is concurrently being proposed for its Affiliate Exchanges. Further, Members are able to utilize a single port to connect to any of the Affiliate

Gb physical port) are assessed $22,000 per month, per port.

[5] The Affiliate Exchanges are also submitting contemporaneous identical rule filings.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] 15 U.S.C. 78f(b)(4).

[10] *See* Securities and Exchange Release No. 83442 (June 14, 2018), 83 FR 28675 (June 20, 2018) (SR–CboeBZX–2018–037).

[11] *See https://www.officialdata.org/us/inflation/2010?amount=1.*

[12] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

Exchanges with no additional fee assessed for that same physical port. Particularly, the Exchange believes the proposed monthly per port fee is reasonable, equitable and not unfairly discriminatory as it is assessed only once, even if it connects with another affiliate exchange since only one port is being used and the Exchange does not wish to charge multiple fees for the same port. Indeed, the Exchange notes that several ports are in fact purchased and utilized across one or more of the Exchange's affiliated Exchanges (and charged only once).

The Exchange also believes that the proposed fee change is not unfairly discriminatory because it would be assessed uniformly across all market participants that purchase the physical ports. The Exchange believes increasing the fee for 10 Gb physical ports and charging a higher fee as compared to the 1 Gb physical port is equitable as the 1 Gb physical port is 1/10th the size of the 10 Gb physical port and therefore does not offer access to many of the products and services offered by the Exchange (*e.g.,* ability to receive certain market data products). Thus, the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb physical ports utilize the most bandwidth and therefore consume the most resources from the network. The Exchange also anticipates that firms that utilize 10 Gb ports will benefit the most from the Exchange's investment in offering NY6 as the Exchange anticipates there will be much higher quantities of 10 Gb physical ports connecting from NY6 as compared to 1 Gb ports. Indeed, the Exchange notes that 10 Gb physical ports account for approximately 90% of physical ports across the NY4, NY5, and NY6 data centers, and to date, 80% of new port connections in NY6 are 10 Gb ports. As such, the Exchange believes the proposed fee change for 10 Gb physical ports is reasonably and appropriately allocated.

The Exchange also notes Members and non-Members will continue to choose the method of connectivity based on their specific needs and no broker-dealer is required to become a Member of, let alone connect directly to, the Exchange. There is also no regulatory requirement that any market participant connect to any one particular exchange. Market participants may voluntarily choose to become a member of one or more of a number of different exchanges, of which, the Exchange is but one choice. Additionally, any Exchange member that is dissatisfied with the proposal is free to choose not to be a member of the Exchange and send order flow to another exchange. Moreover, direct connectivity is not a requirement to participate on the Exchange. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other equities exchanges that a market participant may connect to in lieu of the Exchange and/or trading of any equities product, such as within the Over-the-Counter (OTC) markets which do not require connectivity to the Exchange. Indeed, there are currently 16 registered equities exchanges that trade equities (12 of which are not affiliated with Cboe), some of which have similar or lower connectivity fees.[13] Based on publicly available information, no single equities exchange has more than approximately 16% of the market share.[14] Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers. For example, in 2020 alone, three new exchanges entered the market: Long Term Stock Exchange (LTSE), Members Exchange (MEMX), and Miami International Holdings (MIAX Pearl).

As noted above, there is no regulatory requirement that any market participant connect to any one equities exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one equities exchange whose membership includes every registered broker-dealer. By way of example, while the Exchange has 132 members that trade equities, Cboe EDGX has 124 members that trade equities, Cboe EDGA has103 members and Cboe BYX has 110 members. There is also no firm that is a Member of BZX Equities only. Further, based on publicly available information regarding a sample of the Exchange's competitors, NYSE has 143 members,[15] IEX has 129 members,[16] and MIAX Pearl has 51 members.[17]

Vigorous competition among national securities exchanges provides many alternatives for firms to voluntarily decide whether direct connectivity to the Exchange is appropriate and worthwhile, and as noted above, no broker-dealer is required to become a Member of the Exchange, let alone connect directly to it. In the event that a market participant views the Exchange's proposed fee change as more or less attractive than the competition, that market participant can choose to connect to the Exchange indirectly or may choose not to connect to that exchange and connect instead to one or more of the other 12 non-Cboe affiliated equities markets. Indeed, market participants are free to choose which exchange to use to satisfy their business needs. Moreover, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity. Notwithstanding the foregoing, the Exchange still believes that the proposed fee increase is reasonable, equitably allocated and not unfairly discriminatory, even for market participants that determine to connect directly to the Exchange for business purposes, as those business reasons should presumably result in revenue capable of covering the proposed fee.

The Exchange lastly notes that it is not required by the Exchange Act, nor any other rule or regulation, to undertake a cost-of-service or rate-making approach with respect to fee proposals. Moreover, Congress's intent in enacting the 1975 Amendments to the Act was to enable competition—rather than government order—to determine prices. The principal purpose of the amendments was to facilitate the creation of a national market system for the trading of securities. Congress intended that this ''national market system evolve through the interplay of *competitive forces* as unnecessary regulatory restrictions are removed.'' [18] Other provisions of the Act confirm that intent. For example, the Act provides that an exchange must design its rules ''to remove impediments to and perfect

[13] *Id.*

[14] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (April 4, 2024), available at *https://www.cboe.com/us/equities/_statistics/.*

[15] *See https://www.nyse.com/markets/nyse/membership,.*

[16] *See https://www.iexexchange.io/membership.*

[17] *See https://www.miaxglobal.com/sites/default/files/page-files/20230630_MIAX_Pearl_Equities_Exchange_Members_June_2023.pdf.*

[18] *See* H.R. Rep. No. 94–229, at 92 (1975) (Conf. Rep.) (emphasis added)

the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.'' [19] Likewise, the Act grants the Commission authority to amend or repeal ''[t]he rules of [an] exchange [that] impose any burden on competition not necessary or appropriate in furtherance of the purposes of this chapter.'' [20] In short, the promotion of free and open competition was a core congressional objective in creating the national market system.[21] Indeed, the Commission has historically interpreted that mandate to promote competitive forces to determine prices whenever compatible with a national market system. Accordingly, the Exchange believes it has met its burden to demonstrate that its proposed fee change is reasonable and consistent with the immediate filing process chosen by Congress, which created a system whereby market forces determine access fees in the vast majority of cases, subject to oversight only in particular cases of abuse or market failure. Lastly, and importantly, the Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for the proposed fee would be so complicated that it could not be done practically.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed fee change will not impact intramarket competition because it will apply to all similarly situated Members equally (i.e., all market participants that choose to purchase the 10 Gb physical port). Additionally, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can continue to buy the less expensive 1 Gb physical port (which cost is not changing). While pricing may be increased for the larger capacity physical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most.

The Exchange's proposed fee is also still lower than some fees for similar connectivity on other exchanges and therefore may stimulate intermarket competition by attracting additional firms to connect to the Exchange or at least should not deter interested participants from connecting directly to the Exchange. Further, if the changes proposed herein are unattractive to market participants, the Exchange can, and likely will, see a decline in connectivity via 10 Gb physical ports as a result. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect directly to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative venues that they may participate on and direct their order flow, including 12 non-Cboe affiliated equities markets, as well as off-exchange venues, where competitive products are available for trading. 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.'' [22] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[23] Accordingly, the Exchange does not believe its proposed 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

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [24] and paragraph (f) of Rule 19b–4 [25] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2024–027 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[19] 15 U.S.C. 78f(b)(5).

[20] 15 U.S.C. 78f(8).

[21] *See* also 15 U.S.C. 78k–l(a)(1)(C)(ii) (purposes of Exchange Act include to promote ''fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets''); Order, 73 FR at 74781 (''The Exchange Act and its legislative history strongly support the Commission's reliance on competition, whenever possible, in meeting its regulatory responsibilities for overseeing the SROs and the national market system.'').

[22] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[23] *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)).

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2024–027. 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 (*https://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 the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2024–027 and should be submitted on or before May 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08945 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–99998; File No. SR–MEMX–2024–14]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Fee Schedule Regarding Options Market Data Products

April 19, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 15, 2024, MEMX LLC (''MEMX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend the Market Data section of its fee schedule applicable to its equity options platform (''MEMX Options'') to adopt fees for certain of its market data products, which are currently offered free of charge, pursuant to MEMX Rules 15.1(a) and (c). The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal immediately. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[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 Market Data section of the Exchange's fee schedule applicable to MEMX Options (''MEMX Options Fee Schedule'') to adopt fees for certain of its options market data products which are currently offered free of charge, namely MEMOIR Options Depth and MEMOIR Options Top (collectively, the ''Options Data Feeds''). As set forth below, the Exchange believes that the proposed fees are fair and reasonable and has based its proposal on the fact that competitive forces exist with respect to Options Data Feeds, the fact that Options Data Feeds are optional data products for which there are substitutes, a comparison to competitor pricing, and a detailed cost analysis. The Exchange is proposing to implement the proposed fees on April 15, 2024. The Exchange previously filed this proposal on March 28, 2024 (SR–MEMX–2024–11) (the ''Initial Proposal''). The Exchange has withdrawn the Initial Proposal and replaced the proposal with the current filing (SR–MEMX–2024–14).

Before setting forth the additional details regarding the proposal as well as the cost analysis conducted by the Exchange, immediately below is a description of the proposed fees.

Proposed Market Data Pricing

MEMX Options offers two separate data feeds to subscribers—MEMOIR Options Depth and MEMOIR Options Top. The Exchange notes that there is no requirement that any subscribing entity (''Firm'') subscribe to a particular Options Data Feed or any Options Data Feed whatsoever, but instead, a Firm may choose to maintain subscriptions to those Options Data Feeds they deem appropriate based on their business model. The proposed fee will not apply differently based upon the size or type of Firm, but rather based upon the subscriptions a Firm has to Options Data Feeds. The proposed pricing for each of the Options Data Feeds is set forth below.

MEMOIR Options Depth

The MEMOIR Options Depth feed is a MEMX-only market data feed that contains depth of book quotations and execution information based on options orders entered in the System.[3] For the

[3] *See* MEMX Rule 21.15(b)(1).

receipt of access to the MEMOIR Options Depth feed, the Exchange proposes to charge $1,500 per month. This proposed access fee would be charged to any data recipient that receives a data feed of the MEMOIR Options Depth feed for purposes of internal distribution (*i.e.,* an ''Internal Distributor''), for external redistribution (*i.e.* an ''External Distributor''), or both. The Exchange proposes to define an Internal Distributor as ''a Distributor that receives an Exchange Data product and then distributes that data to one or more data recipients within the Distributor's own organization,'' [4] and an External Distributor as ''a Distributor that receives an Exchange Data product and then distributes that data to a third party or one or more data recipients outside the Distributor's own organization.'' [5] The proposed access fee will be charged only once per month per Firm regardless of whether the Firm uses the MEMOIR Options Depth feed for internal distribution, external distribution, or both.[6]

MEMOIR Options Top

The MEMOIR Options Top feed is a MEMX-only market data feed that contains top of book quotations and executions based on options orders entered into the System.[7] For the receipt of access to the MEMOIR Options Top feed, the Exchange proposes to charge $750 per month. This proposed access fee would be charged to any data recipient that receives a data feed of the MEMOIR Options Top feed for purposes of internal distribution (*i.e.,* an Internal Distributor), external redistribution (*i.e.* an External Distributor), or both. The proposed access fee for internal and external distribution will be charged only once per month per Firm regardless of whether the Firm uses the MEMOIR Options Top feed for internal distribution, external distribution, or both.

Billing Process

The Exchange proposes to bill for the Options Data Feeds in the same manner as it does for the market data products it provides for its equities Exchange, (the ''Equities Data Feeds''), and to make this clear on the Fee Schedule. Specifically, the Fee Schedule would state that ''[f]ees for Market Data products are assessed based on each active product at the close of business on the first day of each month,'' and that ''[i]f a product is cancelled by a subscriber's submission of a written request or via the MEMX User Portal prior to such fee being assessed, then the subscriber will not be obligated to pay the applicable product fee. MEMX does not return pro rated fees if a product is not used for an entire month.'' The Exchange believes that this billing methodology has been efficient with respect to the Equities Data Feeds and is well understood by market participants.

Additional Discussion—Background

The Exchange launched MEMX Options on September 27, 2023. As a new entrant in the equity options trading space, MEMX has not yet charged fees for options market data provided by the Exchange. The objective of this approach was to eliminate any fee-based barriers for Members to join the Exchange, which the Exchange believes has been helpful in its ability to attract order flow as a new options exchange. Further, the Exchange did not initially charge for options market data because MEMX believes that any exchange should first deliver meaningful value to Members and other market participants before charging fees for its products and services.

The Exchange also did not begin charging for the Equities Data Feeds until 2022, nearly two years after it launched as a national securities exchange in 2020. In connection with the adoption of fees for the Equities Data Feeds, the Exchange conducted an extensive cost analysis (the ''2022 Cost Analysis''),[8] and the Exchange's proposal herein to adopt fees for Options Data Feeds stems from the same cost analysis, which it has reviewed and updated for 2024 (the ''2024 Cost Analysis''). As discussed more fully below, the Exchange recently calculated its annual aggregate costs for providing market data for both its equities and options trading platforms (*i.e.* the ''Exchange Data Feeds'') at approximately $3.6 million.[9] In order to establish fees that are designed to recover the aggregate costs of providing the Exchange Data Feeds with a reasonable profit margin, the Exchange is proposing to modify its Fee Schedule, as described above. In addition to the 2024 Cost Analysis, described below, the Exchange believes that its proposed approach to market data fees is reasonable based on a comparison to competitors.

Additional Discussion—Comparison With Other Exchanges

The proposed fee structure for the Options Data Feeds is not novel but is instead comparable to the fee structure currently in place for the options exchanges operated by MIAX, in particular, MIAX Pearl Options (''MIAX Pearl''),[10] and the options exchanges operated by Nasdaq, in particular, Nasdaq BX Options (''BX Options'').[11] The Exchange is proposing fees for its Options Data Feeds that are similar in structure to MIAX Pearl and BX Options and rates that are equal to, or lower than, than the rates data recipients pay for comparable data feeds from those exchanges, in a more simplified fashion.[12] The Exchange notes that other competitors maintain fees applicable to options market data that are considerably higher than those proposed by the Exchange, including Cboe BZX Options (''BZX Options''), NYSE Arca Options and NYSE American Options.[13] However, the

[4] *See* Market Data Definitions under the proposed MEMX Options Fee Schedule. The Exchange also proposes to adopt a definition for ''Distributor'', which would mean any entity that receives an Exchange Data product directly from the Exchange or indirectly through another entity and then distributes internally or externally to a third party.

[5] *See* Market Data Definitions under the proposed MEMX Options Fee Schedule.

[6] The proposed definitions of Internal Distributor and External Distributor are the same definitions used in the Exchange's Equities Fee Schedule.

[7] *See* MEMX Rule 21.15(b)(2).

[8] *See* Securities Exchange Act Release No. 97130 (March 13, 2023), 88 FR 16491 (March 17, 2023) (SR–MEMX–2023–04).

[9] As described more fully below, the Exchange's Cost Analysis combines costs and revenues for Equities and Options in order to not double count any allocations, among other reasons.

[10] See MIAX Pearl Options Fee Schedule, available at: *https://www.miaxglobal.com/markets/us-options/pearl-options/fees* (the ''MIAX Pearl Fee Schedule'').

[11] See the Nasdaq BX Options Fee Schedule, available at: *https://listingcenter.nasdaq.com/rulebook/bx/rules/bx-options-7.*

[12] As noted below, based on its review of MIAX Pearl's Fee Schedule, the Exchange believes that MIAX Pearl charges separate fees for Internal and External Distribution of its options data feeds, and while its External Distribution fees are identical to the Exchange's proposed flat fee for all uses for both comparable products, its Internal Distribution Fees are slightly lower than what the Exchange is proposing for access to the Exchange's Options Data Feeds. Nevertheless, given that the Exchange allows both Internal and External Distribution for a single fee for a single data feed, the Exchange believes its proposed fees remain comparable and competitive with MIAX Pearl.

[13] Fees for BZX Options Depth, which is the comparable product to MEMOIR Options Depth, are $3,000 for internal distribution and $2,000 for external distribution compared to the Exchange's proposed fee of $1,500 for all uses. In addition, BZX Options charges professional user fees of $30 per month and non-professional user fees of $1.00 per month for each entity to which it distributes the feed (alternatively, it offers distributors an option to purchase a monthly Enterprise Fee of $3,500 to distribute to an unlimited number of users), which the Exchange is not proposing to charge. Fees for BZX Options Top, which is the comparable product to MEMOIR Options Top, are $3,000 for internal distribution, $2,000 for external distribution, with Professional User Fees of $5 per month, Non-Professional Fees of $0.10 per month per user, or an Enterprise Fee ranging anywhere from $20,000 to $60,000 per month depending on the number of

Exchange has focused its comparison on MIAX Pearl and BX Options because their similar market data products are offered at prices lower than several other incumbent exchanges, which is a similar approach to that proposed by the Exchange.[14]

The fees for the MIAX Pearl Liquidity Feed—which like the MEMOIR Options Depth feed, includes top of book, depth of book, trades, and administrative messages—consist of an internal distributor access fee of $1,250 per month and an external distributor access fee of $1,500 per month. As such, the Exchange's proposed rate for all uses of $1,500 per month is equal to what MIAX Pearl charges for external distribution, and $250 higher than what it charges for internal distribution only.[15]

The fees for the MIAX Pearl Top of Market Feed—which is the comparable product to MEMOIR Options Top, consist of an internal distributor access fee of $500 per month and an external distributor access fee of $750. Again, the Exchange's proposed rate for all uses of $750 per month is identical to what MIAX Pearl charges for external distribution, and $250 higher than what it charges for internal distribution.

While the Exchange's proposed fee is slightly higher than what MIAX Pearl charges for internal distribution of its similar products, the Exchange believes that the simplicity of a single fee is preferable, specifically by reducing audit risk and simplifying reporting, both for the Exchange and its customers. Further, to the extent MIAX Pearl assesses both fees for both uses, it would cost more overall to receive and provide both internal and external distribution of MIAX Pearl's comparable options data feeds than it does to receive and provide both internal and external distribution of the Exchange's Options Data Feeds.

As an additional cost comparison, the fees for both Nasdaq BX Options Depth of Market Feed (''BX Depth'') and Top of Market Feed (''BX Top'') are $1,500 per month for internal distribution and $2,000 for external distribution, with an added $2,500 fee for a non-Display Enterprise License.[16] While one distributor fee allows access to both BX Top and BX Depth, (for example, $1,500 per month would allow a BX Options customer internal distribution of both BX Top and BX Depth) if a BX Options Customer wanted the same access provided under the Exchange's proposed fees, (*i.e.* for all uses) it would need to pay an additional $2,000 for external distribution and $2,500 per month for a non-display enterprise license fee. In addition, BX Options charges monthly per subscriber fees for professional or non-professional use[17] which the Exchange will not charge for its similar market data products.

Additional Discussion—Cost Analysis

In general, the Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs. Accordingly, in proposing to charge fees for Options Data Feeds, the Exchange has sought to be especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related service, and also carefully and transparently assessing the impact on Members—both generally and in relation to other Members, *i.e.,* to assure the fee will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange does not believe it needs to otherwise address questions about market competition in the context of this filing because the proposed fees are so clearly consistent with the Act based on its 2024 Cost Analysis. The Exchange also believes that this level of diligence and transparency is called for by the requirements of Section 19(b)(1) under the Act,[18] and Rule 19b–4 thereunder,[19] with respect to the types of information self-regulatory organizations (''SROs'') should provide when filing fee changes, and Section 6(b) of the Act,[20] which requires, among other things, that exchange fees be reasonable and equitably allocated,[21] not designed to permit unfair discrimination,[22] and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[23] This rule change proposal addresses those requirements, and the analysis and data in this section are designed to clearly and comprehensively show how they are met.[24]

As noted above, MEMX has conducted and recently updated a study of its aggregate costs to produce the Exchange Data Feeds—the 2024 Cost Analysis. The 2024 Cost Analysis required a detailed analysis of MEMX's aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services and trading permits, regulatory services, physical connectivity, and application sessions (which provide order entry, cancellation and modification functionality, risk functionality, ability to receive drop copies, and other functionality). MEMX separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.,* personnel), and certain general and administrative expenses (''cost drivers''). Next, MEMX adopted an allocation methodology with various principles to guide how much of a particular cost should be allocated to

users to which the distributer plans to distribute the feed. Again, the Exchange is not proposing any additional User Fees for MEMOIR Options Top, but rather, a flat fee of $750 for all uses. *See* the BZX Options Fee Schedule, available at: *https://www.cboe.com/us/options/membership/fee_schedule/bzx/.* Fees for NYSE Arca Options Deep and NYSE American Options Deep, which are the comparable products to MEMOIR Options Depth, are $3,000 for access (internal use) and $2,000 for redistribution (external distribution), and $5,000 for non-display use, compared to the Exchange's proposed fee of $1,500 for all uses. NYSE Arca Options and NYSE American Options also charge professional user fees of $50 per User, and Non-Professional User Fees of $1.00 per user, capped at $5,000 per month. Again, the Exchange does not require any counting of users and has instead proposed a flat fee of $1,500 for all uses. Fees for the NYSE Arca Options Top and NYSE American Options Top, which are the comparable products to MEMOIR Options Top are the same as above ($3,000 for internal, $2,000 for external and $5,000 for non-display, with the additional Professional and Non-Professional User Fees), compared to the Exchange's proposed fee of $750 for all uses. *See* NYSE Proprietary Market Data Pricing Guide, available at: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Market_Data_Pricing.pdf.*

[14] *See supra* notes 10–11.

[15] *See* MIAX Pearl Options Fee Schedule, *supra* note 10.

[16] *See* Nasdaq BX Options Fee Schedule, *supra* note 11.

[17] *Id.*

[18] 15 U.S.C. 78s(b)(1).

[19] 17 CFR 240.19b-4.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(4).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78f(b)(8).

[24] In 2019, Commission staff published guidance suggesting the types of information that SROs may use to demonstrate that their fee filings comply with the standards of the Exchange Act (''Fee Guidance''). While MEMX understands that the Fee Guidance does not create new legal obligations on SROs, the Fee Guidance is consistent with MEMX's view about the type and level of transparency that exchanges should meet to demonstrate compliance with their existing obligations when they seek to charge new fees. *See* Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019) available at *https://www.sec.gov/tm/staff-guidancesro-rule-filings-fees* [sic].

each core service. For instance, fixed costs that are not driven by client activity (*e.g.,* message rates), such as data center costs, were allocated more heavily to the provision of physical connectivity (80%), with smaller allocations to logical ports (11%), and the remainder to the provision of transaction execution, regulatory services, and market data services (9%). The allocation methodology was decided through conversations with senior management familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an estimated allocation of each cost driver to each core service, resulting in the cost allocations described below.

By allocating segmented costs to each core service, MEMX was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has four primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange generally must cover its expenses from these four primary sources of revenue.

Through the Exchange's extensive 2024 Cost Analysis, the Exchange analyzed every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of the Exchange Data Feeds, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of the Exchange Data Feeds, and thus bears a relationship that is, ''in nature and closeness,'' directly related to the Exchange Data Feeds. Based on its analysis, MEMX calculated its aggregate annual costs for providing the Exchange Data Feeds, at $3,683,375. This results in an estimated monthly cost for providing Exchange Data Feeds of $306,948. The Exchange notes that it utilized the same principles to generate the Cost Analysis in 2022 applicable to the Equities Data Feeds only, and at that time, the estimated annual aggregate cost to provide the Equities Data fees was $3,014,348. The differences between such estimated costs and the overall analysis are primarily based on: (1) the addition of MEMX Options, (ii) increased, and in some cases decreased, costs projected by the Exchange, (iii) and changes made to reallocate certain costs into categories that more closely align the Exchange's audited financial statements, as further described below.

Costs Related to Offering Exchange Data Feeds

The following chart details the individual line-item (annual) costs considered by MEMX to be related to offering the Exchange Data Feeds to its Members and other customers as well as the percentage of the Exchange's overall costs that such costs represent for such area (*e.g.,* as set forth below, the Exchange allocated approximately 8% of its overall Human Resources cost to offering Exchange Data Feeds).

COSTS DRIVER	COSTS	% of ALL
Human Resources	$ 2,606,282	8%
Data Center	$ 69,340	2%
Technology (Hardware, Software Licenses, etc.)	$ 287,141	7%
Depreciation	$ 397,471	5%
Allocated Shared Expenses	$ 323,141	4%
TOTAL	**$3,683,375**	**5.8%**

Human Resources

In allocating personnel (Human Resources) costs, in order to not double count any allocations, the Exchange first excluded any employee time allocated towards options regulation in order to recoup costs via the Options Regulatory Fee (''ORF'').[25] Of the remaining employee time left over, MEMX then calculated an allocation of employee time for employees whose functions include directly providing services necessary to offer the Exchange Data Feeds, including performance thereof, as well as personnel with ancillary functions related to establishing and providing such services (such as information security and finance personnel). The Exchange notes that it has fewer than 100 employees and each department leader has direct knowledge of the time spent by each employee with respect to the various tasks necessary to operate the Exchange. The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing the Exchange Data Feeds, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of their time such employees devote to tasks related to providing the Exchange Data Feeds. The Exchange notes that senior level executives were allocated Human Resources costs to the extent the Exchange believed they are involved in overseeing tasks related to providing the Exchange Data Feeds. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

In 2022, 6.9% of the Exchange's Human Resources costs were allocated towards the provision of the Equities Data Feeds, which is slightly lower than the 8% allocation in the 2024 Cost Analysis. The Exchange notes this increase is due to additional hiring necessary to support the launch of MEMX Options and the Options Data Feeds.

Data Center

Data Center costs includes an allocation of the costs the Exchange incurs to provide the Exchange Data Feeds in the third-party data centers where the Exchange maintains its equipment as well as related costs (the Exchange does not own the Primary Data Center or the Secondary Data Center, but instead, leases space in data centers operated by third parties). As the Data Center costs are primarily for space, power, and cooling of servers, the Exchange allocated approximately 2% of the Data Center costs for the Exchange Data Feeds. This is a lower allocation than the 2022 Cost Analysis due to the fact that a greater portion of the Exchange's Data Center costs are now being allocated to the provision of Connectivity, as can be seen in the Exchange's recent proposal to adopt

[25] *See* Securities Exchange Act Release No. 99259 (January 2, 2024), 89 FR 965 (January 8, 2024) (SR–MEMX–2023–38).

Options Connectivity Fees (the ''Options Connectivity Filing'').[26]

Technology

The Technology category includes the Exchange's network infrastructure, other hardware, software, and software licenses used to operate and monitor physical assets necessary to provide the Exchange Data Feeds. Of note, certain of these costs were included in separate Network Infrastructure and Hardware and Software Licenses categories in the 2022 Cost Analysis; however, in order to align more closely with the Exchange's audited financial statements, these costs were combined into the broader Technology category. The Exchange allocated approximately 7% of its Technology costs to the Exchange Data Feeds in 2024.

Depreciation

The vast majority of the software the Exchange uses with respect to its operations, including the software used to generate and disseminate the Exchange Data Feeds has been developed in-house and the cost of such development is depreciated over time. Accordingly, the Exchange included Depreciation costs related to depreciated software used to generate and disseminate the Exchange Data Feeds. The Exchange also included in the Depreciation costs certain budgeted improvements that the Exchange intends to capitalize and depreciate with respect to the Exchange Data Feeds in the near-term, as well as the servers used at the Exchange's primary and back-up data centers specifically used for the Exchange Data Feeds. As with the other allocated costs in the Exchange's updated Cost Analysis, the Depreciation cost was therefore narrowly tailored to depreciation related to the Exchange Data Feeds. In the 2022 Cost Analysis, the Exchange allocated approximately 18% of its Depreciation costs towards the provision of the Equities Data Feeds, which is higher than the 5% allocated herein. This decrease is due to the overall reallocation of Depreciation to other revenue streams.

Allocated Shared Expenses

Finally, a limited portion of general shared expenses were allocated to the Exchange Data Feeds. The costs included in general shared expenses allocated to the Exchange Data Feeds include office space and office expenses (*e.g.,* occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications costs. The cost of paying individuals to serve on the Exchange's Board of Directors or any committee was not allocated to providing Exchange Data Feeds. The Exchange allocated 4% of its Allocated Shared Expenses to the Exchange Data Feeds in 2024, which is slightly higher than the 1.8% allocated in 2022. This is due to the general increase in the costs included in this category overall, resulting in a higher allocation.

Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core service and did not double-count any expenses. Instead, as described above, the Exchange identified and allocated applicable cost drivers across its core services and used the same approach to analyzing costs to form the basis of the Options Connectivity Filing [27] and this filing proposing fees for the Options Data Feeds. Thus, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not double-counted across the core services or their associated revenue streams.

The Exchange anticipates that the projected 2024 revenue for Options Data Feeds ($34,675), in addition to what the Exchange anticipates it will collect for the Equities Data Feeds ($305,305), will generate approximately $339,980 monthly ($4,079,762 annually). The Exchange's method of revenue projection is in part based on its experience in charging for Equities Data Feeds (*i.e.* the Exchange anticipates that certain Firms may discontinue current subscriptions immediately upon the Exchange charging for Options Data Feeds, or sometime thereafter, as was the case when it began charging for Equities Data Feeds). The proposed fees for Exchange Data Feeds are designed to permit the Exchange to cover the costs allocated to providing Exchange Data Feeds with a profit margin that the Exchange believes is modest (approximately 9.7%),[28] which the Exchange believes is fair and reasonable after taking into account the costs related to creating, generating, and disseminating the Exchange Data Feeds and the fact that the Exchange will need to fund future expenditures (increased costs, improvements, etc.).

The Exchange like other exchanges is, after all, a for-profit business. Accordingly, while the Exchange believes in transparency around costs and potential margins, as well as periodic review of revenues and applicable costs (as discussed below), the Exchange does not believe that these estimates should form the sole basis of whether or not a proposed fee is reasonable or can be adopted. Instead, the Exchange believes that the information should be used solely to confirm that an Exchange is not earning supra-competitive profits, and the Exchange believes its Cost Analysis and related projections demonstrate this fact.

As a general matter, the Exchange believes that its costs will remain relatively similar in future years. It is possible however that such costs will either decrease or increase. To the extent the Exchange sees growth in use of Exchange Data Feeds it will receive additional revenue to offset future cost increases. However, if use of Exchange Data Feeds is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs with a reasonable profit margin.[29] Similarly, the Exchange expects that it would propose to decrease fees in the event that revenue materially exceeds current projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (*e.g.,* to monitor for costs increasing/decreasing or subscribers increasing/decreasing, etc. in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and expects that it would propose to increase fees in the event that revenues fail to cover its costs and a reasonable margin, or decrease fees in the event that revenue or the profit margin materially exceeds current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange

[26] *See* Securities Exchange Act Release No. 99635 (February 29, 2024), 89 FR 16049 (March 6, 2024) (SR–MEMX–2024–06).

[27] *See* supra note 26.

[28] The Exchange calculated this profit margin by dividing the annual projected profit of $396,387 by the annual projected revenue of $4,079,762 and multiplying by 100.

[29] The Exchange notes that it does not believe that a 9.7% profit margin is necessarily competitive, and instead that this is likely significantly below the mark-up many businesses place on their products and services.

believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b) [30] of the Act in general, and furthers the objectives of Section 6(b)(4) [31] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. Additionally, the Exchange believes that the proposed fees are consistent with the objectives of Section 6(b)(5) [32] of the Act in that they are designed 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 a free and open market and national market system, and, in general, to protect investors and the public interest, and, particularly, are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange notes prior to addressing the specific reasons the Exchange believes the proposed fees and fee structure are reasonable, equitably allocated and not unreasonably discriminatory, that the proposed definitions and fee structure described above are consistent with the definitions and fee structure used by most U.S. options exchanges, MIAX Pearl and BX Options in particular. As such, the Exchange believes it is adopting a model that is easily understood by Members and non-Members, most of which also subscribe to market data products from other exchanges. For this reason, the Exchange believes that the proposed definitions and fee structure described above are consistent with the Act generally, and Section 6(b)(5) [33] of the Act in particular.

One of the primary objectives of MEMX is to provide competition and to reduce fixed costs imposed upon the industry. Consistent with this objective, the Exchange believes that this proposal reflects a simple, competitive, reasonable, and equitable pricing structure, with fees that are discounted when compared to comparable data products and services offered by competitors.[34]

Reasonableness

Overall. With regard to reasonableness, the Exchange understands that the Commission has traditionally taken a market-based approach to examine whether the SRO making the fee proposal was subject to significant competitive forces in setting the terms of the proposal. The Exchange understands that in general the analysis considers whether the SRO has demonstrated in its filing that (i) there are reasonable substitutes for the product or service; (ii) ''platform'' competition constrains the ability to set the fee; and/or (iii) revenue and cost analysis shows the fee would not result in the SRO taking supracompetitive profits. If the SRO demonstrates that the fee is subject to significant competitive forces, the Exchange understands that in general the analysis will next consider whether there is any substantial countervailing basis to suggest the fee's terms fail to meet one or more standards under the Exchange Act. The Exchange further understands that if the filing fails to demonstrate that the fee is constrained by competitive forces, the SRO must provide a substantial basis, other than competition, to show that it is consistent with the Exchange Act, which may include production of relevant revenue and cost data pertaining to the product or service.

The Exchange has not determined its proposed overall market data fees based on assumptions about market competition, instead relying upon a cost-plus model to determine a reasonable fee structure that is informed by the Exchange's understanding of different uses of the products by different types of participants. In this context, the Exchange believes the proposed fees overall are fair and reasonable as a form of cost recovery plus the possibility of a reasonable return for the Exchange's aggregate costs of offering the Exchange Data Feeds. The Exchange believes the proposed fees are reasonable because they are designed to generate annual revenue to recoup some or all of Exchange's annual costs of providing market data in both Equities and Options with a reasonable profit margin. The Exchange also believes that performing the Cost Analysis by combining costs and revenues for Equities and Options is reasonable because in this manner the Exchange is able to ensure that it does not double count any allocations. The Exchange believes that this holistic approach is reasonable due to the fact that many of the costs associated with providing the Options Data Feeds are the same as those associated with providing the Equities Data Feeds, and the Exchange believes that separately analyzing them could potentially result in double-counting. As discussed in the Purpose section, the Exchange estimates that the fees proposed herein related to Options Data Feeds, coupled with the fees it already charges for Equities Data Feeds, will result in annual revenue of approximately $4 million, representing a profit margin of approximately 9.7% for the provision of market data on its platforms. Accordingly, the Exchange believes that this fee methodology is reasonable because it allows the Exchange to recoup some or all of its expenses for providing market data products (with any additional revenue representing no more than what the Exchange believes to be a reasonable rate of return). The Exchange also believes that the proposed fees are reasonable because they are generally less than the fees charged by competing options exchanges for comparable market data products, notwithstanding that the competing exchanges may have different system architectures that may result in different cost structures for the provision of market data.

The Exchange believes the proposed fees for the Options Data Feeds are reasonable when compared to fees for comparable products, such as the MIAX Pearl Top of Market Feed, the MIAX Pearl Liquidity Feed, and the BX Options Top and Depth Feeds, compared to which the Exchange's proposed fees are equivalent or lower, as well as other comparable data feeds priced significantly higher than the Exchange's proposed fees for the Exchange Data Feeds.[35] Additionally, the Exchange's single flat fee for each of its Options Data Feeds, regardless of use type, offers a more simplistic approach to market data pricing. Specifically with respect to the MEMOIR Options Depth feed, the Exchange believes that the proposed fee for such feed is reasonable because it represents not only the value of the data available from the MEMOIR Options Top feed, which has a lower proposed fee, but also the value of receiving the depth-of-book data on an order-by-order basis. The Exchange believes it is reasonable to have pricing based, in part, upon the amount of information contained in each data feed and the value of that information to market participants. The MEMOIR Options Top feed, as described above,

[30] 15 U.S.C. 78f.

[31] 15 U.S.C. 78f(b)(4).

[32] 15 U.S.C. 78f(b)(5).

[33] 15 U.S.C. 78f(b)(5).

[34] *See supra* note 13.

[35] *Id.*

can be utilized to trade on the Exchange but contains less information than that is available on the MEMOIR Options Depth feed. Thus, the Exchange believes it reasonable for the products to be priced as proposed, with MEMOIR Options Depth having a higher price than MEMOIR Options Top.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Options Data Feeds are reasonable.

Equitable Allocation

Overall. The Exchange believes that its proposed fees are reasonable, fair, and equitable, and not unfairly discriminatory because they are designed to align fees with services provided. The Exchange believes that the proposed fees are equitably allocated because they will apply uniformly to all data recipients that choose to subscribe to the Options Data Feeds. Any Firm that chooses to subscribe to one or both of the Options Data Feeds is subject to the same Fee Schedule, regardless of what type of business they operate, and the decision to subscribe to one or both of the Options Data Feeds is based on objective differences in usage of Options Data Feeds among different Firms, which are still ultimately in the control of any particular Firm. The Exchange believes the proposed pricing between Options Data Feeds is equitably allocated because it is based, in part, upon the amount of information contained in each data feed and the value of that information to market participants. The MEMOIR Options Top feed, as described above, can be utilized to trade on the Exchange but contains less information than that is available on the MEMOIR Options Depth feed. Thus, the Exchange believes it is an equitable allocation of fees for the products to be priced as proposed, with MEMOIR Options Top having the lower price of the two Options Data Feeds.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange Data Feeds are equitably allocated.

The Proposed Fees Are Not Unfairly Discriminatory

The Exchange believes the proposed fees for the Options Data Feeds are not unfairly discriminatory because any differences in the application of the fees are based on meaningful distinctions between the feeds themselves.

Overall. The Exchange believes that the proposed fees are not unfairly discriminatory because they would apply to all data recipients that choose to subscribe to the same Options Data Feed(s). Any Firm that chooses to subscribe to the Options Data Feeds is subject to the same Fee Schedule, regardless of what type of business they operate. Because the proposed fee for MEMOIR Options Depth is higher, Firms seeking lower cost options may instead choose to receive data through the MEMOIR Options Top feed for a lower cost. Alternatively, Firms can choose to receive data solely from the Options Price Reporting Authority (''OPRA'') for a lower cost. The Exchange notes that Firms can also choose to subscribe to a combination of data feeds for redundancy purposes or to use different feeds for different purposes. In sum, each Firm has the ability to choose the best business solution for itself. The Exchange does not believe it is unfairly discriminatory to base pricing upon the amount of information contained in each data feed, which may have additional value to a market participant. As described above, the MEMOIR Options Top feed can be utilized to trade on the Exchange but contains less information than that is available on the MEMOIR Options Depth feed. Thus, the Exchange believes it is not unfairly discriminatory for the products to be priced as proposed, with MEMOIR Options Top having a lower price than MEMOIR Options Depth.

For all of the foregoing reasons, the Exchange believes that the proposed fees for the Exchange Data Feeds are not unfairly discriminatory.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[36] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed fees for Options Data Feeds place certain market participants at a relative disadvantage to other market participants because, as noted above, the proposed fees are associated with usage of Options Data Feeds by each market participant based on the type of business they operate, and the decision to subscribe to one or both Options Data Feeds is based on objective differences in usage of Options Data Feeds among different Firms, which are still ultimately in the control of any particular Firm, and such fees do not impose a barrier to entry to smaller participants. Accordingly, the proposed fees for Options Data Feeds do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed fees reflects the types of Options Data Feeds consumed by various market participants.

Inter-Market Competition

The Exchange does not believe the proposed fees place an undue burden on competition on other SROs that is not necessary or appropriate. In particular, market participants are not forced to subscribe to any of the Options Data Feeds, as described above. Additionally, other exchanges have similar market data fees in place for their participants, but with comparable and in many cases higher rates for options market data feeds.[37] The proposed fees are based on actual costs and are designed to enable the Exchange to recoup its applicable costs with the possibility of a reasonable profit on its investment as described in the Purpose and Statutory Basis sections. Competing options exchanges are free to adopt comparable fee structures subject to the SEC rule filing process.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[38] and Rule 19b–4(f)(2)[39] 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 change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing,

[36] 15 U.S.C. 78f(b)(8).

[37] *See supra* note 13.

[38] 15 U.S.C. 78s(b)(3)(A)(ii).

[39] 17 CFR 240.19b–4(f)(2).

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MEMX–2024–14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MEMX–2024–14. 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 (*https://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 the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MEMX–2024–14 and should be submitted on or before May 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[40]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08808 Filed 4–25–24; 8:45 am]

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[40] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100002; File No. SR–CboeEDGA–2024–013]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule Related to Physical Port Fees

April 22, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 9, 2024, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') 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

Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[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 its fee schedule relating to physical connectivity fees.[3]

By way of background, a physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,500 per physical port for a 1 gigabit (''Gb'') circuit and $7,500 per physical port for a 10 Gb circuit. The Exchange proposes to increase the monthly fee for 10 Gb physical ports from $7,500 to $8,500 per port. The Exchange notes the proposed fee change better enables it to continue to maintain and improve its market technology and services and also notes that the proposed fee amount, even as amended, continues to be in line with, or even lower than, amounts assessed by other exchanges for similar connections.[4] The physical ports may also be used to access the Systems for the following affiliate exchanges and only one monthly fee currently (and will continue) to apply per port: the Cboe BZX Exchange, Inc. (options and equities), Cboe EDGX Exchange, Inc. (options and equities platforms), Cboe BYX Exchange, Inc., and Cboe C2 Exchange, Inc., (''Affiliate Exchanges'').[5]

[3] The Exchange initially filed the proposed fee changes on July 3, 2023 (SR–CboeEDGA–2023–011). On September 1, 2023, the Exchange withdrew that filing and submitted SR–CboeEDGA–2023–015. On September 29, 2023, the Securities and Exchange Commission issued a Suspension of and Order Instituting Proceedings to Determine whether to Approve or Disapprove a Proposed Rule Change to Amend its Fees Schedule Related to Physical Port Fees (the ''OIP''). On September 29, 2023, the Exchange filed the proposed fee change (SR–CboeEDGA–2023–016). On October 13, 2023, the Exchange withdrew that filing and submitted SR–CboeEDGA–2023–017. On December 12 2023, the Exchange withdrew that filing and submitted SR–CboeEDGA–2023–022. On February 9, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGA–2024–006. On April 9, 2024, the Exchange withdrew that filing and submitted this filing.

[4] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

[5] The Affiliate Exchanges are also submitting contemporaneous identical rule filings.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[7] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)[9] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities.

The Exchange believes the proposed fee change is reasonable as it reflects a moderate increase in physical connectivity fees for 10 Gb physical ports. Further, the current 10 Gb physical port fee has remained unchanged since June 2018.[10] Since its last increase over 5 years ago however, there has been notable inflation. Particularly, the dollar has had an average inflation rate of 3.9% per year between 2018 and today, producing a cumulative price increase of approximately 21.1% inflation since the fee for the 10 Gb physical port was last modified.[11] Moreover, the Exchange historically does not increase fees every year, notwithstanding inflation. Accordingly, the Exchange believes the proposed fee is reasonable as it represents only an approximate 13% increase from the rates adopted five years ago, notwithstanding the cumulative rate of 21.1%. The Exchange is also unaware of any standard that suggests any fee proposal that exceeds a certain yearly or cumulative inflation rate is unreasonable, and in any event, in this instance the increase is well below the cumulative rate.

Additionally, the Exchange believes the proposed fee increase is reasonable in light of recent and anticipated connectivity-related upgrades and changes. The Exchange and its affiliated exchanges recently launched a multi-year initiative to improve Cboe Exchange Platform performance and capacity requirements to increase competitiveness, support growth and advance a consistent world class platform. The goal of the project, among other things, is to provide faster and more consistent order handling and matching performance for options, while ensuring quicker processing time and supporting increasing volumes and capacity needs. For example, the Exchange recently performed switch hardware upgrades. Particularly, the Exchange replaced existing customer access switches with newer models, which the Exchange believes resulted in increased determinism. The recent switch upgrades also increased the Exchange's capacity to accommodate more physical ports by nearly 50%. Network bandwidth was also increased nearly two-fold as a result of the upgrades, which among other things, can lead to reduce message queuing. The Exchange also believes these newer models result in less natural variance in the processing of messages. The Exchange notes that it incurred costs associated with purchasing and upgrading to these newer models, of which the Exchange has not otherwise passed through or offset.

As of April 1, 2024, market participants also having the option of connecting to a new data center (*i.e.,* Secaucus NY6 Data Center (''NY6'')), in addition to the current data centers at NY4 and NY5. The Exchange made NY6 available in response to customer requests in connection with their need for additional space and capacity. In order to make this space available, the Exchange expended significant resources to prepare this space, and will also incur ongoing costs with respect to maintaining this offering, including costs related to power, space, fiber, cabinets, panels, labor and maintenance of racks. The Exchange also incurred a large cost with respect to ensuring NY6 would be latency equalized, as it is for NY4 and NY5.

The Exchange also has made various other improvements since the current physical port rates were adopted in 2018. For example, the Exchange has updated its customer portal to provide more transparency with respect to firms' respective connectivity subscriptions, enabling them to better monitor, evaluate and adjust their connections based on their evolving business needs. The Exchange also performs proactive audits on a weekly basis to ensure that all customer cross connects continue to fall within allowable tolerances for Latency Equalized connections. Accordingly, the Exchange expended, and will continue to expend, resources to innovate and modernize technology so that it may benefit its Members and continue to compete among other equities markets. The ability to continue to innovate with technology and offer new products to market participants allows the Exchange to remain competitive in the equities space which currently has 16 equities markets and potential new entrants.

The Exchange also believes the proposed fee is reasonable as it is still in line with, or even lower than, amounts assessed by other exchanges for similar connections.[12] Indeed, the Exchange believes assessing fees that are a lower rate than fees assessed by other exchanges for analogous connectivity (which were similarly adopted via the rule filing process and filed with the Commission) is reasonable. As noted above, the proposed fee is also the same as is concurrently being proposed for its Affiliate Exchanges. Further, Members are able to utilize a single port to connect to any of the Affiliate Exchanges with no additional fee assessed for that same physical port. Particularly, the Exchange believes the proposed monthly per port fee is reasonable, equitable and not unfairly discriminatory as it is assessed only once, even if it connects with another affiliate exchange since only one port is being used and the Exchange does not wish to charge multiple fees for the same port. Indeed, the Exchange notes that several ports are in fact purchased and utilized across one or more of the

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] *Id.*

[9] 15 U.S.C. 78f(b)(4).

[10] *See* Securities and Exchange Release No. 83449 (June 15, 2018), 83 FR 28890 (June 21, 2018) (SR–CboeEDGA–2018–010).

[11] *See https://www.officialdata.org/us/inflation/2010?amount=1.*

[12] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

Exchange's affiliated Exchanges (and charged only once).

The Exchange also believes that the proposed fee change is not unfairly discriminatory because it would be assessed uniformly across all market participants that purchase the physical ports. The Exchange believes increasing the fee for 10 Gb physical ports and charging a higher fee as compared to the 1 Gb physical port is equitable as the 1 Gb physical port is 1/10th the size of the 10 Gb physical port and therefore does not offer access to many of the products and services offered by the Exchange (*e.g.,* ability to receive certain market data products). Thus, the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb physical ports utilize the most bandwidth and therefore consume the most resources from the network. The Exchange also anticipates that firms that utilize 10 Gb ports will benefit the most from the Exchange's investment in offering NY6 as the Exchange anticipates there will be much higher quantities of 10 Gb physical ports connecting from NY6 as compared to 1 Gb ports. Indeed, the Exchange notes that 10 Gb physical ports account for approximately 90% of physical ports across the NY4, NY5, and NY6 data centers, and to date, 80% of new port connections in NY6 are 10 Gb ports. As such, the Exchange believes the proposed fee change for 10 Gb physical ports is reasonably and appropriately allocated.

The Exchange also notes Members and non-Members will continue to choose the method of connectivity based on their specific needs and no broker-dealer is required to become a Member of, let alone connect directly to, the Exchange. There is also no regulatory requirement that any market participant connect to any one particular exchange. Market participants may voluntarily choose to become a member of one or more of a number of different exchanges, of which, the Exchange is but one choice. Additionally, any Exchange member that is dissatisfied with the proposal is free to choose not to be a member of the Exchange and send order flow to another exchange. Moreover, direct connectivity is not a requirement to participate on the Exchange. The Exchange also believes substitutable products and services are available to market participants, including, among other things, other equities exchanges that a market participant may connect to in lieu of the Exchange and/or trading of any equities product, such as within the Over-the-Counter (OTC) markets which does not require connectivity to the Exchange. Indeed, there are currently 16 registered equities exchanges that trade equities (12 of which are not affiliated with Cboe), some of which have similar or lower connectivity fees.[13] Based on publicly available information, no single equities exchange has more than approximately 16% of the market share.[14] Further, low barriers to entry mean that new exchanges may rapidly enter the market and offer additional substitute platforms to further compete with the Exchange and the products it offers. For example, in 2020 alone, three new exchanges entered the market: Long Term Stock Exchange (LTSE), Members Exchange (MEMX), and Miami International Holdings (MIAX Pearl).

As noted above, there is no regulatory requirement that any market participant connect to any one equities exchange, nor that any market participant connect at a particular connection speed or act in a particular capacity on the Exchange, or trade any particular product offered on an exchange. Moreover, membership is not a requirement to participate on the Exchange. Indeed, the Exchange is unaware of any one equities exchange whose membership includes every registered broker-dealer. By way of example, while the Exchange has 103 members that trade equities, Cboe EDGX has 124 members that trade equities, Cboe BYX has 110 members and Cboe BZX has 132 members. There is also no firm that is a Member of EDGA Equities only. Further, based on publicly available information regarding a sample of the Exchange's competitors, NYSE has 143 members,[15] IEX has 129 members,[16] and MIAX Pearl has 51 members.[17]

Vigorous competition among national securities exchanges provides many alternatives for firms to voluntarily decide whether direct connectivity to the Exchange is appropriate and worthwhile, and as noted above, no broker-dealer is required to become a Member of the Exchange, let alone connect directly to it. In the event that a market participant views the Exchange's proposed fee change as more or less attractive than the competition, that market participant can choose to connect to the Exchange indirectly or may choose not to connect to that exchange and connect instead to one or more of the other 12 non-Cboe affiliated equities markets. Moreover, if the Exchange charges excessive fees, it may stand to lose not only connectivity revenues but also revenues associated with the execution of orders routed to it, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity. Notwithstanding the foregoing, the Exchange still believes that the proposed fee increase is reasonable, equitably allocated and not unfairly discriminatory, even for market participants that determine to connect directly to the Exchange for business purposes, as those business reasons should presumably result in revenue capable of covering the proposed fee.

The Exchange lastly notes that it is not required by the Exchange Act, nor any other rule or regulation, to undertake a cost-of-service or rate-making approach with respect to fee proposals. Moreover, Congress's intent in enacting the 1975 Amendments to the Act was to enable competition—rather than government order—to determine prices. The principal purpose of the amendments was to facilitate the creation of a national market system for the trading of securities. Congress intended that this ''national market system evolve through the interplay of *competitive forces* as unnecessary regulatory restrictions are removed.'' [18] Other provisions of the Act confirm that intent. For example, the Act provides that an exchange must design its rules ''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.'' [19] Likewise, the Act grants the Commission authority to amend or repeal ''[t]he rules of [an] exchange [that] impose any burden on competition not necessary or appropriate in furtherance of the purposes of this chapter.'' [20] In short, the promotion of free and open competition was a core congressional objective in creating the national market system.[21] Indeed, the Commission has

[13] *Id.*

[14] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (April 4, 2024), available at *https://www.cboe.com/us/equities/market_statistics/.*

[15] *See https://www.nyse.com/markets/nyse/membership,.*

[16] *See https://www.iexexchange.io/membership.*

[17] *See https://www.miaxglobal.com/sites/default/files/page-files/20230630_MIAX_Pearl_Equities_Exchange_Members_June_2023.pdf.*

[18] *See* H.R. Rep. No. 94–229, at 92 (1975) (Conf. Rep.) (emphasis added)

[19] 15 U.S.C. 78f(b)(5).

[20] 15 U.S.C. 78f(8).

[21] *See* also 15 U.S.C. 78k–l(a)(1)(C)(ii) (purposes of Exchange Act include to promote ''fair competition among brokers and dealers, among exchange markets, and between exchange markets

historically interpreted that mandate to promote competitive forces to determine prices whenever compatible with a national market system. Accordingly, the Exchange believes it has met its burden to demonstrate that its proposed fee change is reasonable and consistent with the immediate filing process chosen by Congress, which created a system whereby market forces determine access fees in the vast majority of cases, subject to oversight only in particular cases of abuse or market failure. Lastly, and importantly, the Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for the proposed fee would be so complicated that it could not be done practically.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed fee change will not impact intramarket competition because it will apply to all similarly situated Members equally (i.e., all market participants that choose to purchase the 10 Gb physical port). Additionally, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can continue to buy the less expensive 1 Gb physical port (which cost is not changing). While pricing may be increased for the larger capacity physical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most.

The Exchange's proposed fee is also still lower than some fees for similar connectivity on other exchanges and therefore may stimulate intermarket competition by attracting additional firms to connect to the Exchange or at least should not deter interested participants from connecting directly to the Exchange. Further, if the changes proposed herein are unattractive to market participants, the Exchange can, and likely will, see a decline in connectivity via 10 Gb physical ports as a result. The Exchange operates in a highly competitive market in which market participants can determine whether or not to connect directly to the Exchange based on the value received compared to the cost of doing so. Indeed, market participants have numerous alternative venues that they may participate on and direct their order flow, including 12 non-Cboe affiliated equities markets, as well as off-exchange venues, where competitive products are available for trading. 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.'' [22] The fact that this market is competitive has also long been recognized by the courts. In NetCoalition v. Securities and Exchange Commission, the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[23] Accordingly, the Exchange does not believe its proposed 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

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [24] and paragraph (f) of Rule 19b–4 [25] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include file number SR–CboeEDGA–2024–013 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–CboeEDGA–2024–013. 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 (*https://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

and markets other than exchange markets''); Order, 73 FR at 74781 (''The Exchange Act and its legislative history strongly support the Commission's reliance on competition, whenever possible, in meeting its regulatory responsibilities for overseeing the SROs and the national market system.'').

[22] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[23] 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)).

[24] 15 U.S.C. 78s(b)(3)(A).

[25] 17 CFR 240.19b–4(f).

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 the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGA–2024–013 and should be submitted on or before May 17, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–08942 Filed 4–25–24; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-Day notice and request for comments

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the collection of information described below. The Paperwork Reduction Act (PRA) requires federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before June 25, 2024.

FOR FURTHER INFORMATION CONTACT: Adrienne Grierson, Small Business Administration, Office of Financial Program Operations, *adrienne.grierson@sba.gov* or Curtis B. Rich, Agency Clearance Officer *curtis.rich@sba.gov* 202–205–7030.

SUPPLEMENTARY INFORMATION: SBA received funds under the American Rescue Plan Act of 2021 (ARPA), Public Law 117–2, title V, sec. 5003 (March 11, 2021), to provide direct funds to Eating and Drinking establishments that meet certain conditions. Specifically, Section 5003 of ARPA establishes the Restaurant Revitalization Fund (RRF) program to provide direct funds of up to $10 million dollars and limited to $5 million dollars per location to certain eligible persons or entities: A restaurant, food stand, food truck, food cart, caterer, saloon, inn, tavern, bar, lounge, brewpub, tasting room, taproom, licensed facility or premise of a beverage alcohol producer where the public may taste, sample, or purchase products, or other similar place of business in which the public or patrons assemble for the primary purpose of being served food or drink. Section 5003(c)(6) of ARPA requires recipients to return to the Treasury any funds that the recipient did not use for allowable expenses by the end of the covered period, or if the recipient permanently ceased operations, not later than March 11, 2023. SBA plans to update the information collection under OMB control number 3245–0424 to extend the record retention requirements.

Solicitation of Public Comments

SBA is requesting comments on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

PRA Number: 3245–0424

(1) Title: Restaurant Revitalization Fund Program Post Award Report.

Description of Respondents: Recipients of RRF awards.

Form Number: SBA Form 3173.

Total Estimated Annual Responses: 131,306.

Total Estimated Annual Hour Burden: 63,127.

Curtis B. Rich,

Agency Clearance Officer.

[FR Doc. 2024–09025 Filed 4–25–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

National Small Business Development Center Advisory Board

AGENCY: Small Business Administration.

ACTION: Notice of open Federal Advisory Committee meeting.

SUMMARY: The SBA is issuing this notice to announce the date, time and agenda for a meeting of the National Small Business Development Center Advisory Board. The meeting will be open to the public; however, advance notice of attendance is required.

DATES: Tuesday, May 14, 2024, at 2:00 p.m. EDT.

ADDRESSES: Meeting will be held via Microsoft Teams.

FOR FURTHER INFORMATION CONTACT: Rachel Karton, Office of Small Business Development Centers, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416; *Rachel.newman-karton@sba.gov;* 202–619–1816.

If anyone wishes to be a listening participant or would like to request accommodations, please contact Rachel Karton at the information above.

SUPPLEMENTARY INFORMATION: Pursuant to section l0(a) of the Federal Advisory Committee Act (5 U.S.C. appendix 2), the SBA announces the meetings of the National SBDC Advisory Board. This Board provides advice and counsel to the SBA Administrator and Associate Administrator for Small Business Development Centers.

Purpose

The purpose of the meeting is to discuss the following pertaining to the SBDC Program:

- Annual Plan/White Paper
- Outreach and Engagement with the SBDC State Directors

Andrienne Johnson,

Committee Management Officer.

[FR Doc. 2024–08967 Filed 4–25–24; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 12381]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: ''Life Dances On: Robert Frank in Dialogue'' 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

[26] 17 CFR 200.30–3(a)(12).

custodian for temporary display in the exhibition ''Life Dances On: Robert Frank in Dialogue'' at The Museum of Modern Art, New York, New York, 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: Reed Liriano, Program Coordinator, 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), Executive Order 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.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2024–08916 Filed 4–25–24; 8:45 am]

BILLING CODE 4710–05–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36736]

Youngstown & Southeastern Railroad, LLC—Trackage Rights Exemption—Ohio and Pennsylvania Railroad Company

The Youngstown & Southeastern Railroad, LLC (YS), a Class III common carrier railroad, has filed a verified notice of exemption under 49 CFR 1180.2(d)(7) for acquisition of overhead trackage rights over approximately 1.1 miles of rail line, known as the River Track, owned by Ohio and Pennsylvania Railroad Company (OHPA) between milepost 0.4 at Youngstown, Ohio, and milepost 1.5 in Lowellville, Ohio.

Youngstown & Southeastern Railroad Company, a YS predecessor, obtained overhead trackage rights over OHPA incidental to acquisition of certain rail lines between Youngstown and Darlington, Pennsylvania. According to the verified notice, the new overhead trackage rights on the River Track will formalize YS's interchange point with CSX Transportation, Inc. (CSXT) at CSXT's Lowellville Yard. The new rights derive from an amending agreement [1] to an earlier trackage rights agreement governing YS's operations over two related segments of railroad, the Canfield Segment and the Struthers Segment.[2]

As a condition to this exemption, any employees affected by the acquisition of the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified by *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980).

The transaction may be consummated on or after May 11, 2024, the effective date of the exemption. If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than May 3, 2024 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36736, must be filed with the Surface Transportation Board via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on YS's representative, Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

According to YS, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: April 23, 2024.

[1] Redacted versions of the trackage rights agreement and amending agreement were filed with the verified notice. Unredacted versions of the agreements were submitted to the Board under seal concurrently with a motion for protective order, which was granted in a decision served on April 23, 2024.

[2] According to the verified notice, the amending agreement refers to a rail customer, Lally Pipe, but only to provide that YS may serve that customer strictly for the account of (and as agent for) OHPA. YS states that it will have no rights independent of OHPA to serve Lally Pipe.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Eden Besera,

Clearance Clerk.

[FR Doc. 2024–08976 Filed 4–25–24; 8:45 am]

BILLING CODE 4915–01–P

TENNESSEE VALLEY AUTHORITY

Notice of Determinations on the Demand Response and Electric Vehicle Standards

AGENCY: Tennessee Valley Authority.

ACTION: Notice of determinations on the PURPA Standards set forth in the Infrastructure Investment and Jobs Act of 2021.

SUMMARY: At its meeting on November 9, 2023, in Tupelo, Mississippi, the TVA Board made its determinations on the PURPA standards as set forth in the Public Utility Regulatory Policies Act of 1978 (PURPA), as amended by the Infrastructure Investment and Jobs Act of 2021 (IIJA). The TVA Board considered the standards in accordance with PURPA and the objectives and requirements of the Tennessee Valley Authority Act of 1933, as amended (TVA Act).

FOR FURTHER INFORMATION CONTACT: Troy Eichenberger (Demand Response), (423) 751–6187, or Andrew Frye (Electric Vehicles), (423) 751–7060, Tennessee Valley Authority.

SUPPLEMENTARY INFORMATION: The Public Utility Regulatory Policies Act of 1978 (Pub. L. 95–617) (PURPA), as amended by the Infrastructure Investment and Jobs Act of 2021 (Pub. L. 117–58) (IIJA), requires TVA to consider adopting for itself and the distributors of TVA power two new PURPA standards. The standards considered are listed in subsections 111(d)(20)–(21) of PURPA, as amended by the IIJA of 2021. These two standards are identified as Demand-Response Practices and Electric Vehicle Charging Programs. The TVA Board is charged with considering and making determinations on whether or not it is appropriate to implement each standard.

Data, views, and comments were requested from the public as to the need and desirability of adopting the standards. In addition to posting a notice in the **Federal Register** on November 15, 2022 (87 FR 68569), which described the standards and solicited public input on the standards, TVA also provided a PURPA website (*www.tva.com/purpa*) for purposes of educating the public on the standards and soliciting public input. TVA also

provided an overview of the Demand Response and Electric Vehicle standards to the Regional Energy Resource Council (RERC), an advisory committee established under the authority of the TVA in accordance with the provisions of the Federal Advisory Committee Act. All public input received on the standards has been included in the official record and made available to the public through the website.

TVA's process for considering and making determinations on the new PURPA standards was carried out pursuant to the provisions of (a) PURPA, under which TVA is identified as the regulatory authority for electric utilities over which TVA has ratemaking authority, and (b) the Tennessee Valley Authority Act of 1933, 48 Stat. 58, as amended, 16 U.S.C. 831–831dd (2007) (TVA Act). After consideration of the initial comments and materials received, TVA staff developed recommendations on each of the standards. All comments from the public, as well as the TVA staff recommendations, have been made a part of the official record and have been made available to the public through the website.

The TVA Board considered these standards on the basis of the PURPA purposes, which are the (1) conservation of energy, (2) efficient use of facilities and resources, and (3) equity among electric consumers, and the objectives and requirements of the TVA Act. The Board took into account these considerations as well as the official record developed during the consideration process in reaching the determinations below.

The Board's determinations are as follows.

Standard 20: Demand-Response Practices

I. Standard Under Consideration

(A) In General

Each electric utility shall promote the use of demand-response and demand flexibility practices by commercial, residential, and industrial consumers to reduce electricity consumption during periods of unusually high demand.

(B) Rate Recovery

(i) In general—Each State regulatory authority shall consider establishing rate mechanisms allowing an electric utility with respect to which the State regulatory authority has ratemaking authority to timely recover the costs of promoting demand-response and demand flexibility practices in accordance with subparagraph (A).

(ii) Nonregulated electric utilities—A nonregulated electric utility may establish rate mechanisms for the timely recovery of the costs of promoting demand response and demand flexibility in accordance with subparagraph (A).

II. Observations

Demand response (DR) focuses on reduction of peak demand. To reduce peak demand, TVA contracts with local power companies (LPCs) that distribute TVA power, TVA directly served customers, and LPC end-use customers to reduce energy use to specific levels when dispatched by TVA Operations. Through broad internal and external collaboration, TVA has developed a portfolio of program offerings that are designed to benefit TVA's resource planning resources as well as the growing energy needs and reserve requirements. These resources currently provide up to 1,700 MW of carbon-free, dispatchable capacity achieved by three programs: Interruptible Power, Peak Power Partners, and Voltage Optimization. The programs help manage system demand load during peak hours.

Current programs achieve demand reduction targets identified by TVA's long-range planning and annual power supply plans, and demand response is an essential component of the Integrated Resource Plan (IRP), which is a comprehensive study of how TVA can best deliver clean, reliable, and low-cost energy for the Valley's future. These plans each recommend continuing to add capacity to TVA's existing DR programs and to develop new DR programs.

Existing demand response programs, and others that TVA may develop in the future, will continue to be an integral part of TVA's resource planning and system operations. TVA's existing approach to demand response is consistent with the intent of the standard that is under consideration. TVA has a process for LPCs to request cost recovery, which can include the costs associated with promoting demand response. LPC rate requests are reviewed and, where appropriate, approved through a TVA Board-approved rate review procedure. Costs associated with participating in a TVA program would generally be considered appropriate costs for recovery. TVA also factors its own demand response costs into its long-term financial planning.

Because TVA's approach to DR depends upon collaboration with customers and encouraging participation in DR programs, the proposed demand-response practices standard under consideration was revised to build upon historical success and reflect the importance of this collaborative approach.

III. Determination by the TVA Board

The standard under consideration is revised and adopted as follows:

TVA will leverage the public power model and its decades of experience in offering demand response programs to maximize demand response benefits for its power system, local power companies that distribute TVA power, and directly served customers. TVA will consider adding capacity to its existing demand response programs and developing additional demand response programs, when economic, reliability, and decarbonization needs merit changes to the demand response portfolio. As the nation's largest public power producer with a mission to deliver affordable and reliable power, TVA will continue to work with local power companies, directly served customers, federal customers, and end-use customers to ensure demand response programs are effective and meet the needs of the Valley.

Standard 21: Electric Vehicle Charging Programs

I. Standard Under Consideration

Each State shall consider measures to promote greater electrification of the transportation sector, including the establishment of rates that—

(A) promote affordable and equitable electric vehicle charging options for residential, commercial, and public electric vehicle charging infrastructure;

(B) improve the customer experience associated with electric vehicle charging, including by reducing charging times for light-, medium-, and heavy-duty vehicles;

(C) accelerate third-party investment in electric vehicle charging for light-, medium-, and heavy-duty vehicles; and

(D) appropriately recover the marginal costs of delivering electricity to electric vehicles and electric vehicle charging infrastructure.

II. Observations

The importance of electricity and TVA power has had a profound impact on the region. Today, the electrification of transportation offers similar transformative growth with environmental and economic benefits for the region. TVA is partnering with state agencies, local power companies (LPCs) that distribute TVA power, automotive manufacturers and other stakeholders to promote the adoption of electric vehicles (EVs) by addressing the major market barriers facing consumers: improving charging infrastructure availability, setting innovative and supportive policies, expanding EV availability and offerings, and increasing consumer awareness.

TVA is heavily involved in promoting the adoption of EVs, including leading

a collaboration with LPCs and other regional partners to develop one of the nation's most comprehensive publicly accessible EV fast charging networks. TVA also works with LPCs to offer affordable rate options for public EV fast charging that remove demand charges and are designed to accelerate public and private investment in EV infrastructure. Additionally, TVA is focused on increasing awareness and education of electric transportation through resources to educate and support residents with their residential, commercial, and public charging needs.

EV programs are executed in conjunction with and support from LPCs based on the unique relationship between TVA and its wholesale customers and because EV charging deployment occurs at the distribution level. TVA will continue to promote EV adoption in a manner that is consistent with TVA's obligations under the TVA Act. The proposed electric vehicle charging programs standard under consideration was revised to build on existing efforts of TVA and LPCs and to account for the respective roles of TVA and LPCs. TVA will also continue to examine and develop other programs that promote adoption of EVs, including consideration in future rate actions and various energy programs.

III. Determination by the TVA Board

The standard under consideration is revised and adopted as follows:

TVA will continue to leverage its role as a leader in innovation and economic development for the benefit of the Tennessee Valley region. As the wholesale provider of electric power to local power companies (LPCs) that distribute TVA power, TVA will serve as a catalyst for electric vehicle adoption. TVA will also continue to collaborate with LPCs to ensure that affordable energy is available for residential, commercial, and public customers consistent with the requirements of the TVA Act. The public power model will provide the foundation for an improved customer charging experience and competitive charging market to expand electric vehicle adoption in the Tennessee Valley.

Dated: April 18, 2024.

The Executive Vice President, General Counsel & Corporate Secretary of Tennessee Valley Authority, David Fountain, having reviewed and approved this document, is delegating the authority to sign this document to Edward C. Meade, Assistant Corporate Secretary, Associate General Counsel, Director of Commercial Law for publication in the **Federal Register**.

Edward C. Meade,

Assistant Corporate Secretary, Associate General Counsel, Director of Commercial Law, Tennessee Valley Authority.

[FR Doc. 2024–08917 Filed 4–25–24; 8:45 am]

BILLING CODE 8120–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2024–1228]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Passenger Facility Charge (PFC) Application

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves the FAA's administration of the Passenger Facility Charge (PFC) program. The information to be collected will be used to authorize public agencies to impose PFCs and use PFC revenue on airport-related projects and to ensure compliance with PFC program requirements.

DATES: Written comments should be submitted by June 25, 2024.

ADDRESSES: Please send written comments.

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Denise Roper, Office of Airport Planning and Programming. Federal Aviation Administration, 800 Independence Ave. SW, Suite 620, Washington, DC 20591.

By fax: 202–267–5302.

FOR FURTHER INFORMATION CONTACT: Amanda J Shotto by email at: *amanda.j.shotto@faa.gov;* phone: 202–267–8744.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0557.

Title: Passenger Facility Charge (PFC) Application.

Form Numbers: FAA Form 5500–1.

Type of Review: Renewal of an information collection.

Background: The DOT/FAA will use any information submitted in response to this collection to carry out the intent of 49 U.S.C. 40117. This statute authorizes public agencies controlling airports to impose PFCs and use PFC revenues. The information collected enables the FAA to approve the collection of PFC revenue for projects which preserve or enhance safety, security, or capacity of the national air transportation system, or which reduce noise or mitigate noise impacts resulting from an airport, or which furnish opportunities for enhanced competition between or among air carriers, and to provide oversight of the PFC program, as required by statute.

Respondents: Approximately 615 respondents annually.

Frequency: On occasion.

Estimated Average Burden per Response: 2 Hours.

Estimated Total Annual Burden: 33,014 Hours.

Issued in Washington, DC, on April 22, 2024.

David F. Cushing,

Manager, Airports Financial Assistance Division, APP–500.

[FR Doc. 2024–08918 Filed 4–25–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2024–0030]

Agency Information Collection Activities: Notice of Request for Reinstatement of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for reinstatement of a previously approved information collection.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) to reinstate an information collection. We are required to publish this notice in the

Federal Register by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by May 28, 2024.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 0030 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Melissa Corder, 202–366–5853, *melissa.corder@dot.gov;* Office of Real Estate Services, Federal Highway Administration, Department of Transportation, New Jersey Avenue SE, Washington, DC 20590–0001. Office hours are from 7 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: We published a **Federal Register** Notice with a 60-day public comment period on this information collection on May 23, 2023 at 88 FR 33188.

Title: Fixed Residential Moving Cost Schedule.

OMB Control: 2125–0616.

Background: Relocation assistance payments to owners and tenants who move personal property for a Federal or federally assisted program or project are governed by the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (Uniform Act). 49 Code of Federal Regulations (CFR), part 24, is the implementing regulation for the Uniform Act. 49 CFR 24.301 addresses payments for actual and reasonable moving and related expenses. The fixed residential moving cost schedule is an administrative alternative to reimbursement of actual moving costs addressed in 49 CFR 24.302. This option provides flexibility for the agency and affected property owners and tenants. The FHWA requests the State Departments of Transportation (State DOTs) to analyze moving cost data periodically to assure that the fixed residential moving cost schedules accurately reflect reasonable moving and related expenses. The regulation allows State DOTs flexibility in determining how to collect the cost data in order to reduce the burden of government regulation. Updated State fixed residential moving costs are submitted to the FHWA electronically.

Respondents: 56 respondents (50 State DOTs, District of Columbia, Puerto Rico, Guam, American Samoa, N Marina Island, and the Virgin Islands).

Frequency: Once every 3 years.

Estimated Average Burden per Response: 24 hours per respondent.

Estimated Total Annual Burden Hours: 56 respondents × 24 hours = 1,344 burden total burden hours, once every 3 years, or 448 hours annually.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued on: April 23, 2024.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2024–09017 Filed 4–25–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

U.S. Merchant Marine Academy Board of Visitors; Public Meeting

AGENCY: Maritime Administration, DOT

ACTION: Notice of public meeting.

SUMMARY: The U.S. Department of Transportation, Maritime Administration announces a meeting of the U.S. Merchant Marine Academy (USMMA) Board of Visitors (Board).

DATES: May 13, 2024, from 2:00 p.m. to 4:30 p.m. EST.

Written statements to be considered during the meeting must be received via email to *ExternalAffairs@usmma.edu* no later than May 6, 2024. Requests for accommodations for a disability must be received via email to *ExternalAffairs@usmma.edu* no later than May 3, 2024.

ADDRESSES: The meeting will be held through a virtual forum located on the USMMA Board of Visitors' web page at *https://www.usmma.edu/about/leadership/board-visitors.* A link to the virtual forum will be made available on the USMMA Board of Visitors' web page no later than May 6, 2024. General information about the Board is available at *https://www.usmma.edu/about/leadership/board-visitors.*

FOR FURTHER INFORMATION CONTACT: The Board's Designated Federal Officer and Point of Contact, Veronica Barry, 516–726–5594 or *ExternalAffairs@usmma.edu.*

SUPPLEMENTARY INFORMATION:

Background

The Board is a Federal Advisory Committee originally established as a Congressional Board by section 51312 of title 46, United States Code ''to provide independent advice and recommendations on matters relating to the United States Merchant Marine Academy.'' The Board was originally chartered under the Federal Advisory Committee Act (FACA) on October 24, 2017.

Agenda

The meeting agenda will cover, but is not limited to, the following proposed topics:

1. Welcome remarks and Board maintenance items (elections, Charter, etc.).
2. Update on the six priorities from the USMMA Strategic Plan (including educational and athletic programs, Institutional Culture, Sea Year, Sexual Assault Prevention and Response program status, and Academy infrastructure progress);
3. Update on the state of the Regiment of Midshipmen and Midshipman Fee Schedule; and
4. Public comment period (not to exceed 10 minutes).

Public Participation

This meeting is open to the public and will be held through a virtual forum. 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.

Any member of the public is permitted to file a written statement with the Board. Written statements should be sent to the Designated Federal

Officer listed in the **FOR FURTHER INFORMATION CONTACT** section no later than May 6, 2024.

Only written statements will be considered by the Board; no member of the public will be allowed to present questions or speak during the meeting unless requested to do so by a member of the Board.

(Authority: 46 U.S.C. 51312; 5 U.S.C. 552b; 5 U.S.C. Ch.10; 41 CFR parts 102–3.140 through 102–3.165)

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2024–08979 Filed 4–25–24; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See Supplementary Information section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley Smith, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Compliance, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*ofac.treasury.gov*).

Notice of OFAC Action(s)

On April 23, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals

1. HITTA, Sidan Ag (a.k.a. HITTA, Asidan Ag; a.k.a. HITTA, Siddan Ag; a.k.a. ''ABU 'ABD AL–HAKIM''; a.k.a. ''Abu Abdelhakim al-Kidali''; a.k.a. ''Abu Qarwani''; a.k.a. ''AL–QAYRAWANI, Abd-al-Hakim''), Kidal Region, Mali; DOB 1976; POB Kidal, Mali; nationality Mali; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886 (individual) [SDGT] [HOSTAGES–EO14078] (Linked To: JAMA'AT NUSRAT AL–ISLAM WAL–MUSLIMIN).

Designated pursuant to section 6(a)(ii)(A)(1) of Executive Order 14078, ''Bolstering Efforts to Bring Hostages and Wrongfully Detained United States Nationals Home,'' 87 FR 43389 (E.O. 14078), for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, an act of hostage-taking of a United States national or the wrongful detention of a United States national abroad.

2. DICKO, Jafar (a.k.a. DICKO, Abdoul Salam), Burkina Faso; DOB 1980; nationality Burkina Faso; Gender Male (individual) [HOSTAGES–EO14078].

Designated pursuant to section 6(a)(ii)(A)(1) of E.O. 14078, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, an act of hostage-taking of a United States national or the wrongful detention of a United States national abroad.

Dated: April 23, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–09043 Filed 4–25–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Bradley T. Smith, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or the Assistant Director for Compliance, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On April 23, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

BILLING CODE 4810–AL–P

Individuals:

1. HARUNI, Hosein Mohammad (Arabic: حسین محمد هارونی) (a.k.a. HAROONI, Hossein), Tehran, Iran; DOB 09 Nov 1989; POB Iran; nationality Iran; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 1270285696 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: DADEH AFZAR ARMAN).

   Designated pursuant to section 1(a)(iii)(A) of Executive Order 13224 of September 23, 2001, "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism" (E.O. 13224), 3 CFR, 2019 Comp., p. 356., as amended by Executive Order 13886 of September 9, 2019, "Modernizing Sanctions To Combat Terrorism," 84 FR 48041 (E.O. 13224, as amended) for having acted for or on behalf of, directly or indirectly, DADEH AFZAR ARMAN, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

2. NASAB, Alireza Shafie (Arabic: علی رضا شفیعی نسب) (a.k.a. NASAB, Ali Reza Shafi'i; a.k.a. SHAFI'INASAB, Alireza), Tehran, Iran; DOB 21 Feb 1985; POB Iran; nationality Iran; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 1288452152 (Iran); Birth Certificate Number 5160 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224 for having acted for or on behalf of, directly or indirectly, the IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

3. RAHMAN, Reza Kazemifar (Arabic: رضا کاظمیفر رحمان) (a.k.a. KAZEMIFAR, Reza), Tehran, Iran; DOB 02 Jun 1987; POB Ilam, Iran; nationality Iran; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 4501201381 (Iran); Birth Certificate Number 3946 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224 for having acted for or on behalf of, directly or indirectly, the IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

4. SALMANI, Komeil Baradaran (Arabic: كميل برادران سلمانى), No. 29, Tohid Sq., Shahid Mahalati Complex, Mini City, Tehran, Iran; DOB 16 Nov 1985; POB Tehran, Iran; nationality Iran; Gender Male; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 0077605063 (Iran) (individual) [SDGT] [IRGC] [IFSR] (Linked To: IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224 for having acted for or on behalf of, directly or indirectly, the IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

Entities:

1. DADEH AFZAR ARMAN (a.k.a. "DATA EAST"; a.k.a. DATA PROCESSING OF EAST LLC), Tehran, Iran; Website https://daa.computer/; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; Organization Established Date 21 Mar 2015 to 19 Mar 2016; Organization Type: Other information technology and computer service activities [SDGT] [IRGC] [IFSR] (Linked To: IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224 for having acted for or on behalf of, directly or indirectly, the IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

2. MEHRSAM ANDISHEH SAZ NIK (a.k.a. DEHKADEH TELECOMMUNICATION AND SECURITY COMPANY; a.k.a. MAHAK RAYAN AFRAZ), Iran; Secondary sanctions risk: section 1(b) of Executive Order 13224, as amended by Executive Order 13886; National ID No. 14009946460 (Iran) [SDGT] [IRGC] [IFSR] (Linked To: IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND).

   Designated pursuant to section 1(a)(iii)(A) of E.O. 13224 for having acted for or on behalf of, directly or indirectly, IRANIAN ISLAMIC REVOLUTIONARY GUARD CORPS CYBER-ELECTRONIC COMMAND, a person whose property and interests in property are blocked pursuant to E.O. 13224, as amended.

Dated: April 23, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–09046 Filed 4–25–24; 8:45 am]

BILLING CODE 4810–AL–C

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Agency Collection Activities; Requesting Comments on Form 1094–C, Form 1095–C, and Form 4423

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 Form 1094–C, Transmittal of Employer-Provided Health Insurance Offer and Coverage Information Returns, Form 1095–C, Employer-Provided Health Insurance Offer and Coverage, and Form 4423, Application for Filing Affordable Care Act (ACA) Information Returns.

DATES: Written comments should be received on or before June 25, 2024 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. 1545–2251 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Jason Schoonmaker, (801) 620–2128, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *jason.m.schoonmaker@irs.gov*.

SUPPLEMENTARY INFORMATION: The IRS is currently seeking comments concerning the following information collection tools, reporting, and record-keeping requirements:

Title: Information Reporting by Applicable Large Employers on Health Insurance Coverage Offered Under Employer-Sponsored Plans.

OMB Number: 1545–2251.

Form Number: Forms 1099–C, 1095–C, and 4423.

Abstract: Applicable Large Employer Members (ALE Members) use Forms 1094–C and 1095–C to report the information required under Internal Revenue Code sections 6055 and 6056 regarding offers of health coverage and enrollment in health coverage for their full-time employees.

Form 4423 is used when a company is a foreign filer that does not have an Employer Identification Number (EIN) and cannot use the electronic application process to apply for an Affordable Care Act Transmitter Control Code.

Current Actions: There is no change to the existing collection. However, the estimated number of responses was updated based on current filing data.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, Business or other for-profit, and not-for-profit entities.

Estimated Number of Responses: 123,234,664.

Estimated Time per Respondent: 4 hours for 1094–C, 12 minutes for 1095–C, 20 minutes for Form 4423.

Estimated Total Annual Burden Hours: 26,890,001.

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: April 19, 2024.

Jason M. Schoonmaker,

Tax Analyst.

[FR Doc. 2024–09021 Filed 4–25–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Internal Revenue Service (IRS) Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests 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. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before May 28, 2024 to be assured of consideration.

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.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Melody Braswell by emailing *PRA@treasury.gov,* calling (202) 622–1035, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

1. Title: Excise Tax on Repurchase of Corporate Stock.

OMB Number: 1545-New.

Form Project Number: Form 7208.

Abstract: Section 4501 was added to a new chapter 37 of the Code by the enactment of Public Law 117–169, 136 Stat. 1818 (August 16, 2022), commonly referred to as the Inflation Reduction Act of 2022 (IRA). Form 7208 is used to figure the excise tax on stock repurchases. If more lines for any part of the form are needed, taxpayers are to prepare a continuation sheet using the same format as the form. Form 7208 and any continuation sheet is to be attached to Form 720, *Quarterly Federal Excise Tax Return.*

Current Actions: This is a request for new OMB approval.

Type of Review: This is a new collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2700.

Estimated Number of Responses per Respondent: 1.

Estimated Time per Response: 6 hours 30 minutes.

Estimated Total Annual Burden Hours: 2,700.

2. Title: Revenue Procedure 2024–4 (and successor guidance).

OMB Number: 1545–1520.

Revenue Procedure Number: 2024–4.

Abstract: Internal Revenue Code (IRC) § 601.201(a)(1)) provides that it is the practice of the Internal Revenue Service (IRS) to answer inquiries of individuals and organizations, whenever appropriate in the interest of sound tax administration, as to their status for tax purposes and as to the tax effects of their acts or transactions. Under this revenue procedure 2024–4 (and successor guidance), taxpayers can request determination letters and letter rulings from the Commissioner, Tax Exempt and Government Entities, Employee Plans Office (''Employee Plans'') on how the tax laws apply to them. Employee Plans requires information from taxpayers in order to process these requests.

Current Actions: There is no change to the burden previously approved.

Type of Review: Reinstatement without change of a previously approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, not-for-profit institutions, farms, and state, local or tribal governments.

Estimated Number of Respondents: 12,733.

Estimated Number of Responses per Respondent: 1.

Estimated Time per Response: 6 hrs. for the *Letter Ruling* and 3 hrs. for the *Determination Letter.*

Estimated Total Annual Burden Hours: 38,836.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2024–08980 Filed 4–25–24; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Request for Information on the Department of Veterans Affairs; Marriage and Family Therapist Standard of Practice

AGENCY: Department of Veterans Affairs.

ACTION: Request for information.

SUMMARY: The Department of Veterans Affairs (VA) is requesting information to assist in developing a national standard of practice for VA Marriage and Family Therapists. VA seeks comments on various topics to help inform VA's development of this national standard of practice.

DATES: Comments must be received on or before June 25, 2024.

ADDRESSES: Comments must be submitted through *https://www.regulations.gov* Except as provided below, comments received before the close of the comment period will be available at *https://www.regulations.gov/* for public viewing, inspection, copying, including any personally identifiable or confidential business information that is included in a comment. We post the comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov/.* VA will not post on *https://www.regulations.gov/* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm the individual. VA encourages individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments. Any public comment received after the comment period's closing date will not be considered.

FOR FURTHER INFORMATION CONTACT: Ethan Kalett, Office of Regulations, Appeals and Policy (10BRAP), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, 202–461–0500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

Authority

Chapters 73 and 74 of 38 U.S.C. and 38 U.S.C. 303 authorize the Secretary to regulate VA health care professions to make certain that VA's health care system provides safe and effective health care by qualified health care professionals to ensure the well-being of those veterans who have borne the battle.

On November 12, 2020, VA published an interim final rule confirming that VA health care professionals may practice their health care profession consistent with the scope and requirements of their VA employment, notwithstanding any State license, registration, certification, or other State requirements that unduly interfere with their practice. 38 CFR 17.419; 85 FR 71838. Specifically, this rulemaking confirmed VA's current practice of allowing VA health care professionals to deliver health care services in a State other than the health care professional's State of licensure, registration, certification, or other State requirement, thereby enhancing beneficiaries' access to critical VA health care services. The rulemaking also confirmed VA's authority to establish national standards of practice for its health care professionals, which would standardize a health care professional's practice in all VA medical facilities, regardless of conflicting State laws, rules, regulations, or other State requirements.

The rulemaking explained that a national standard of practice describes the tasks and duties that a VA health care professional practicing in the health care profession may perform and may be permitted to undertake. Having a national standard of practice means that individuals from the same VA health care profession may provide the same type of tasks and duties regardless of the State where they are located or the State license, registration, certification, or other State requirement they hold. We emphasized in the rulemaking and reiterate here that VA will determine, on an individual basis, that a health care professional has the proper education, training, and skills to perform the tasks and duties detailed in the national standard of practice, and that they will only be able to perform such tasks and duties after they have been incorporated into the individual's privileges, scope of practice, or functional statement. The rulemaking explicitly did not create any such national standards and directed that all national standards of practice would be subsequently created via policy.

Preemption of State Requirements

The national standard of practice will preempt any State laws, rules, regulations, or requirements that both are and are not listed in the national standard as conflicting, but that do conflict with the tasks and duties as authorized in VA's national standard of practice. In the event that a State changes their requirements and places new limitations on the tasks and duties it allows in a manner that would be inconsistent with what is authorized under the national standard of practice, the national standard of practice will preempt such limitations and authorize the VA health care professional to continue to practice consistent with the tasks and duties outlined in the national standard of practice.

In cases where a VA health care professional's license, registration,

certification, or other State requirement allows a practice that is not included in a national standard of practice, the individual may continue that practice so long as it is permissible by Federal law and VA policy, is not explicitly prohibited by the national standard of practice and is approved by the VA medical facility.

Need for National Standards of Practice

It is critical that VA, the Nation's largest integrated health care system, develops national standards of practice to ensure, first, that beneficiaries receive the same high-quality care regardless of where they enter the system and, second, that VA health care professionals can efficiently meet the needs of beneficiaries when practicing within the scope of their VA employment. National standards are designed to increase beneficiaries' access to safe and effective health care, thereby improving health outcomes. The importance of this initiative has been underscored by the coronavirus disease 2019 (COVID–19) pandemic. The increased need for mobility in VA's workforce, including through VA's Disaster Emergency Medical Personnel System, highlighted the importance of creating uniform national standards of practice to better support VA health care professionals who practice across State lines. Creating national standards of practice also promotes interoperability of medical data between VA and the Department of Defense (DoD), providing a complete picture of a veteran's health information and improving VA's delivery of health care to the Nation's veterans. DoD has historically standardized practice for certain health care professionals, and VA has closely partnered with DoD to learn from their experience.

Process To Develop National Standards of Practice

As authorized by 38 CFR 17.419, VA is developing national standards of practice via policy. There is one overarching directive to describe Veterans Health Administration (VHA) policy on national standards of practice. The directive is accessible on the VHA Publications website at *https://vaww.va.gov/vhapublications/* (internal) and *https://www.va.gov/vhapublications/* (external). As each individual national standard of practice is finalized, it is published as an appendix to the directive and accessible at the same websites.

To develop these national standards, VA is using a robust, interactive process that adheres to the requirements of Executive Order (E.O.) 13132 to preempt conflicting State laws, rules, regulations, or other requirements. The process includes consultation with internal and external stakeholders, including State licensing boards, VA employees, professional associations, Veterans Service Organizations, labor partners, and others. For each VA occupation, a workgroup comprised of VA health care professionals in the identified occupation conducts research to identify internal best practices that may not be authorized under every State license, certification, or registration, but would enhance the practice and efficiency of the profession throughout VA. If a best practice is identified that is not currently authorized by every State, the workgroup determines what education, training, and skills are required to perform such tasks and duties. The workgroup then drafts a proposed VA national standard of practice using the data gathered during the research and incorporates internal stakeholder feedback into the standard. The workgroup may consult with internal or external stakeholders at any point throughout the process.

The proposed national standard of practice is then internally reviewed, to include by an interdisciplinary VA workgroup consisting of representatives from Quality Management, VA medical facility Chief of Staff, Academic Affiliates, Veterans Integrated Services Network (VISN) Chief Nursing Officer, Ethics, Workforce Management and Consulting, Surgery, Credentialing and Privileging, VISN Chief Medical Officer, and Electronic Health Record Modernization.

Externally, VA hosts listening sessions for members of the public, professional associations, and VA employees to provide comments on the variance between State practice acts for specific occupations and what should be included in the national standard of practice for that occupation. The listening session for Marriage and Family Therapists was held on September 21, 2023. At the listening session, there was one presenter who represented the American Association of Marriage and Family Therapy. The presenter supported the Marriage and Family Therapy national standard of practice and urged VA to allow all providers to practice to the full extent of their license and education. The presenter stated that maximizing utilization of provider skills would make access to care more efficient and would lower costs. VA appreciates the thoughtful presentation and considers the information presented at the listening session when drafting the proposed VA national standard of practice.

VA has developed a robust process to engage with partners, members of the public, States, and employees on the proposed national standard of practice. VA provides the proposed national standard of practice to our DoD partners as an opportunity to flag inconsistencies with DoD standards. VA also engages with labor partners informally as part of a pre-decisional collaboration. Consistent with E.O. 13132, VA sends a letter to each State board and certifying organization or registration organization, as appropriate, which includes the proposed national standard and offers the recipient an opportunity to discuss the national standard with VA. After the State boards, certifying organizations, or registration organizations have received notification, the proposed national standard of practice is posted in the **Federal Register** for 60 days to obtain feedback from the public, professional associations, and any other interested parties. At the same time, the proposed national standard is posted to an internal VA site to obtain feedback from VA employees. Responses received through all vehicles—from State boards, professional associations, unions, VA employees, and any other individual or organization who provides comments via the **Federal Register**—will be reviewed. VA will make appropriate revisions in light of the comments, including those that present evidence-based practice and alternatives that help VA meet our mission and goals. VA will publish a collective response to all comments at *https://www.va.gov/standardsofpractice/.*

After the national standard of practice is finalized, approved, and published in VHA policy, VA will implement the tasks and duties authorized by that national standard of practice. Any tasks or duties included in the national standard will be properly incorporated into individual health care professionals' privileges, scope of practice, or functional statement once it has been determined by their VA medical facility that the individual has the proper education, training, and skills to perform the task or duty. Implementation of the national standard of practice may be phased in across all VA medical facilities, with limited exemptions for health care professionals as needed.

Format for the Proposed National Standard for Marriage and Family Therapist

The format for the proposed national standards of practice when there are

State licenses is as follows. The first paragraph provides general information about the profession and what the health care professionals can do. For this national standard, Marriage and Family Therapists are licensed professionals who provide psychotherapy to couples, families, individuals, and groups. We reiterate that the proposed standard of practice does not contain an exhaustive list of every task and duty that each VA health care professional can perform. Rather, it is designed to highlight generally what tasks and duties the health care professionals perform and how they will be able to practice within VA notwithstanding their State license, certification, registration, or other State requirements.

The second paragraph references the education and State license, or other requirement, needed to practice this profession at VA. Qualification standards for employment of health care professionals by VA are outlined in VA Handbook 5005, Staffing, dated November 8, 2023. VA follows the requirements outlined in the VA qualification standards even if the requirements conflict with or differ from a State requirement. National standards of practice do not affect those requirements. For Marriage and Family Therapists, VA qualification standards require an active, current, full, and unrestricted State license.

The second paragraph also notes whether the national standard of practice explicitly excludes individuals who practice under ''grandfathering'' provisions. Qualification standards may include provisions to permit employees who met all requirements prior to revisions to the qualification standards to maintain employment at VA even if they no longer meet the new qualification standards. This practice is referred to as grandfathering. Marriage and Family Therapists have grandfathering provisions included within its qualification standards, and VA proposes to have those individuals be authorized to follow the Marriage and Family Therapist national standard of practice. Therefore, there would be no notation regarding grandfathered employees in the national standard of practice as they would be required to adhere to the same standard as any other VA Marriage and Family Therapist who meets the current qualification standards.

The third paragraph describes what tasks and duties the profession will be able to perform within the scope of their VA employment. It includes whether the profession can practice all duties covered by their State license. For Marriage and Family Therapists, VA reviewed State license requirements and found no variance in how VA Marriage and Family Therapists practice in any State.

This national standard of practice does not address training because it will not authorize VA Marriage and Family Therapists to perform any tasks or duties not already authorized under their State license.

Following public and VA employee comments and revisions, each national standard of practice that is published into policy will also include the date for recertification of the standard of practice and a point of contact for questions or concerns.

Proposed National Standard of Practice for Marriage and Family Therapist

1. Marriage and Family Therapists provide psychotherapy to couples, families, individuals, and groups. These professionals are licensed to diagnose and treat mental health disorders such as depression, post-traumatic stress disorder, anxiety, and other mental health disorders. Marriage and Family Therapists have specialized training in family systems theory and are well qualified to treat relationships issues, including marriage or couples counseling, and child-parent challenges.

2. Marriage and Family Therapists in the Department of Veterans Affairs (VA) possess the education and license required by VA qualification standards. See VA Handbook 5005, Staffing, Part II, Appendix G44, dated April 18, 2018.

3. VA Marriage and Family Therapists can practice all duties covered by their license. VA reviewed license requirements for this occupation in February 2024 and confirmed there is no variance in how VA Marriage and Family Therapists practice in any State.

Request for Information

1. Is VA's assessment of what States allow and do not allow accurate?

2. Are there any other areas of variance between State licenses, certification, or registration that VA should preempt that are not listed?

3. Is there anything else you would like to share with us about this VA national standard of practice?

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on April 5, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

[FR Doc. 2024–09033 Filed 4–25–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0209]

Agency Information Collection Activity Under OMB Review: Application for Work Study Allowance, Student Work Study Agreement-Advance Payment, Extended Student Work Study Agreement, Student Work Study Agreement

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden, and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by clicking on the following link *www.reginfo.gov/public/do/PRAMain, select* ''Currently under Review—Open for Public Comments'', then search the list for the information collection by Title or ''OMB Control No. 2900–0209.''

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email *Maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0209'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: 38 U.S.C. 3485; 38 CFR 21.4145.

Title: Application for Work Study Allowance [VA Form 22–8691]; Student Work Study Agreement-Advance Payment [VA Form 22–8692]; Extended Student Work Study Agreement [VA

Form 22–8692a]; Student Work Study Agreement [VA Form 22–8692b].

OMB Control Number: 2900–0209.

Type of Review: Revision of a currently approved collection.

Abstract: VA uses the information collected to determine the individual's eligibility for the work-study allowance, the number of hours the individual will work, the amount payable, whether the individual desires an advance payment, and whether the individual wants to extend the work-study contract.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 89 FR 12946 on Tuesday, February 20, 2024, page(s) 12946–12947.

Affected Public: Individuals and households.

Estimated Annual Burden: 7,542 hours.

Estimated Average Burden Time per Respondent: 23 minutes [15 min. VAF 22–8691]; [5 min. VAFs 22–8692 and 22–8692b]; [3 min. VAF 22–8692a].

Frequency of Response: Annually.

Estimated Number of Respondents: 75,451.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–08938 Filed 4–25–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 89 Friday,
No. 82 April 26, 2024

Part II

Environmental Protection Agency

40 CFR Parts 141 and 142
PFAS National Primary Drinking Water Regulation; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA–HQ–OW–2022–0114; FRL 8543–02–OW]

RIN 2040–AG18

PFAS National Primary Drinking Water Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In March 2023, the U.S. Environmental Protection Agency (EPA) proposed and requested comment on the National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLGs) for six per- and polyfluoroalkyl substances (PFAS): perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA, commonly known as GenX Chemicals), and perfluorobutane sulfonic acid (PFBS). After consideration of public comment and consistent with the provisions set forth under the Safe Drinking Water Act (SDWA), the EPA is finalizing NPDWRs for these six PFAS. Through this action, the EPA is finalizing MCLGs for PFOA and PFOS at zero. Considering feasibility, the EPA is promulgating individual Maximum Contaminant Levels (MCLs) for PFOA and PFOS at 4.0 nanograms per liter (ng/L) or parts per trillion (ppt). The EPA is also finalizing individual MCLGs and is promulgating individual MCLs for PFHxS, PFNA, and HFPO–DA at 10 ng/L. In addition to the individual MCLs for PFHxS, PFNA, and HFPO–DA, in consideration of the known toxic effects, dose additive health concerns and occurrence and likely co-occurrence in drinking water of these three PFAS, as well as PFBS, the EPA is finalizing a Hazard Index (HI) of 1 (unitless) as the MCLG and MCL for any mixture containing two or more of PFHxS, PFNA, HFPO–DA, and PFBS. Once fully implemented, the EPA estimates that the rule will prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses.

DATES: This final rule is effective on June 25, 2024. The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of June 25, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2022–0114. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Alexis Lan, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 202–564–0841; email address: *PFASNPDWR@epa.gov*.

SUPPLEMENTARY INFORMATION:

Executive Summary

The Environmental Protection Agency (EPA) is issuing an adaptive and flexible National Primary Drinking Water Regulation (NPDWR) under the Safe Drinking Water Act (SDWA) to manage risks of per- and polyfluoroalkyl substances (PFAS) in drinking water. The EPA is establishing drinking water standards for six PFAS in this NPDWR to provide health protection against these individual and co-occurring PFAS in public water systems. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA. For the six PFAS, the EPA considered PFAS health effects information, evidence supporting dose-additive health concerns from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water. SDWA provides a framework for the EPA to regulate emerging contaminants of concern in drinking water. Under the statute, the EPA must act based on the ''best available'' science and information. Thus, the statute recognizes that the EPA may act in the face of imperfect information. It also provides a mechanism for the EPA to update standards as more science becomes available. For the PFAS covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's public water systems.

PFAS are a large class of thousands of organic chemicals that have unique physical and chemical properties. These compounds are designed to be stable and non-reactive because of the applications in which they are used: certain industrial and manufacturing processes; stain and water repellants in clothing, carpets, and other consumer products, as well as certain types of fire-fighting foams. PFAS tend to break down slowly and persist in the environment, and consequently, they can accumulate in the environment and the human body over time. Current scientific research and available evidence have shown the potential for harmful human health effects after being exposed to some PFAS. Although some PFAS have been phased out of use in the United States, they are still found in the environment and in humans based on biomonitoring data.

Drinking water is one of several ways people can be exposed to PFAS. The EPA's examination of drinking water data shows that different PFAS can often be found together and in varying combinations as mixtures. Additionally, decades of research demonstrates that exposure to mixtures of different chemicals can elicit dose-additive health effects: even if the individual chemicals are each present at levels considered ''safe,'' the mixture may cause significant adverse health effects. The high likelihood for different PFAS to co-occur in drinking water; the additive health concerns when present in mixtures; the diversity and sheer number of PFAS; and their general presence and persistence in the environment and the human body are reflective of the environmental and public health challenges the American public faces with PFAS, which poses a particular threat for overburdened communities that experience disproportionate environmental impacts. The final NPDWR includes:

1. Individual Maximum Contaminant Levels (MCLs)
   a. Perfluorooctanoic acid (PFOA) MCL = 4.0 nanograms per liter or parts per trillion (ng/L or ppt)
   b. Perfluorooctane sulfonic acid (PFOS) MCL = 4.0 ng/L
   c. Perfluorohexane sulfonic acid (PFHxS) MCL = 10 ng/L
   d. Perfluorononanoic acid (PFNA) MCL = 10 ng/L
   e. Hexafluoropropylene oxide dimer acid (HFPO–DA) MCL = 10 ng/L
2. A Hazard Index MCL to account for dose-additive health effects for mixtures that could include two or more of four

PFAS (PFHxS, PFNA, HFPO–DA, and perfluorobutane sulfonic acid (PFBS)). The Hazard Index MCL defines when the combined levels of two or more of these four PFAS requires action. A PFAS mixture Hazard Index less than or equal to 1 (unitless) indicates a level at which no known or anticipated adverse effects on the health of persons occur and allows for an adequate margin of safety with respect to health risk associated with a mixture of PFAS in finished drinking water. A PFAS mixture Hazard Index greater than 1 (unitless) indicates an exceedance of the health protective level. To calculate the Hazard Index, a ratio is developed for each PFAS by dividing the measured level of the PFAS in drinking water by the level (in ng/L or ppt) below which adverse health effects are not likely to occur (*i.e.,* the Health Based Water Concentration or HBWC). The HBWCs for each PFAS in the Hazard Index are:

a. PFHxS = 10 ng/L or ppt

b. PFNA = 10 ng/L

c. HFPO–DA = 10 ng/L

d. PFBS = 2,000 ng/L

The individual PFAS ratios are then summed across the mixture to yield the Hazard Index MCL as follows:

$$HI\ MCL = \left(\frac{[HFPO\text{–}DA_{water} ng/L]}{[10\ ng/L]}\right) + \left(\frac{[PFBS_{water} ng/L]}{[2000\ ng/L]}\right) + \left(\frac{[PFNA_{water} ng/L]}{[10\ ng/L]}\right) + \left(\frac{[PFHxS_{water} ng/L]}{[10\ ng/L]}\right) = 1$$

Based on the administrative record for the final PFAS NPDWR and as discussed above, certain PFAS (including PFHxS, PFNA, HFPO–DA, and PFBS) have been shown to be toxicologically similar; *i.e.,* elicit the same or similar profile of adverse effects in several biological organs and systems (see USEPA, 2000a; USEPA, 2007; USEPA, 2024a; USEPA, USEPA, 2024c; and section IV.B of this preamble). Studies with PFAS and other classes of chemicals support the health-protective conclusion that chemicals that have similar observed adverse effects following individual exposure should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise (USEPA, 2024a). Additionally, the record further supports that there is a substantial likelihood that PFBS, PFHxS, PFNA, and HFPO–DA co-occur as mixtures in drinking water at levels of public health concern (see USEPA, 2024b and sections VI.C and D of this preamble). Though the EPA is not promulgating an individual MCL or Maximum Contaminant Level Goal (MCLG) for PFBS at this time as it is for PFHxS, PFNA, and HFPO–DA (see section III.A of this preamble for specific discussion), based on these evaluations, the agency is establishing a Hazard Index MCL that addresses PFBS as part of mixtures where its co-occurrence with other PFAS (PFHxS, HFPO–DA, and/or PFNA) can affect health endpoints when present in these mixtures.

The individual and Hazard Index MCLs are independently applicable for compliance purposes.

Additionally, the EPA is finalizing important public ''right to know'' provisions of the EPA's SDWA regulations, specifically, public notification (PN) and Consumer Confidence Report (CCR) requirements. The changes under this rule will strengthen risk communication and education for the public when elevated levels of these PFAS are found. Finally, the EPA is finalizing monitoring and reporting requirements that enable public water systems (PWSs) and primacy agencies to implement and comply with the NPDWR.

Consistent with the timelines set out under SDWA, PWSs are required to conduct their initial monitoring by April 26, 2027, and to conduct PN and include PFAS information in the CCR. After carefully considering public comment, the EPA is extending the compliance deadline for all systems nationwide to meet the MCL to allow additional time for capital improvements. As such, PWSs are required to make any necessary capital improvements and comply with the PFAS MCLs by April 26, 2029.

As part of its *Health Risk Reduction and Cost Analysis* (HRRCA), the EPA evaluated quantifiable and nonquantifiable health risk reduction benefits and costs associated with the final NPDWR. At a two percent discount rate, the EPA estimates the quantifiable annual benefits of the final rule will be $1,549.40 million per year and the quantifiable costs of the rule will be $1,548.64 million per year. The EPA's quantified benefits are based on the agency's estimates that that there will be 29,858 fewer illnesses and 9,614 fewer deaths in the communities in the decades following actions to reduce PFAS levels in drinking water. While the modeled quantified net benefits are nearly at parity, under SDWA, the EPA must consider whether the costs of the rule are justified by the benefits based on all statutorily prescribed costs and benefits, not just the quantified costs and benefits (see SDWA 1412(b)(3)(c)(i)).

The EPA expects that the final rule will result in additional nonquantifiable costs, including costs with generally greater uncertainty, which the EPA has examined in quantified sensitivity analyses in the Economic Analysis for the final rule. First, the EPA had insufficient nationally representative data to precisely characterize occurrence of HFPO–DA, PFNA, and PFBS. In an effort to better consider and understand the costs associated with treatment of these regulated compounds at systems both with and without PFOA, PFOS and PFHxS occurrence in exceedance of the MCLs, the EPA performed a quantitative sensitivity analysis of the costs associated with Hazard Index and/or MCL exceedances resulting from HFPO–DA, PFNA, and PFBS. The EPA expects that the quantified national costs, which do not include HFPO–DA, PFNA, and PFBS treatment costs are marginally underestimated (on the order of 5 percent). Second, stakeholders have expressed concern to the EPA that a hazardous substance designation for certain PFAS may limit their disposal options for drinking water treatment residuals (*e.g.,* spent media, concentrated waste streams) and/or potentially increase costs. The EPA has conducted a sensitivity analysis and found that should all water systems use hazardous waste disposal options national costs would increase by 7 percent.

The EPA anticipates significant additional benefits that cannot be quantified, will result from avoided negative developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects as a result of reductions in the levels of the regulated PFAS and other co-removed contaminants. For example, elevated

concentrations of both PFOA and PFOS negatively impact the immune and endocrine systems, impacts which the agency is unable to quantify at this time. As another example, the EPA assessed the developmental benefits associated with PFNA exposure reductions semi-quantitively in sensitivity analysis, and the analysis demonstrates significant additional benefits associated with reductions in PFNA. There are other nonquantifiable benefits for other PFNA health endpoints, and numerous endpoints for PFHxS, HFPO–DA, PFBS, and other PFAS that are anticipated to be removed as a result of the final NPDWR. Additionally, as a result of the ability for available treatment technologies to remove co-occurring contaminants, there are benefits not quantified for removal of co-occurring contaminants for this regulation (*e.g.,* certain pesticides, volatile organic compounds). Considering both quantifiable and nonquantifiable costs and benefits of the rule, the EPA is reaffirming the Administrator's determination at the time of proposal, that the quantifiable and nonquantifiable benefits of the final rule justify the quantifiable and nonquantifiable costs.

To help communities on the frontlines of PFAS contamination, the passage of the Infrastructure Investment and Jobs Act (IIJA), also referred to as the Bipartisan Infrastructure Law (BIL), invests billions of dollars over a 5-year period. BIL appropriates over $11.7 billion in the Drinking Water State Revolving Fund (DWSRF) General Supplemental; $4 billion to the DWSRF for Emerging Contaminants; and $5 billion in grants to the Emerging Contaminants in Small or Disadvantaged Communities. These funds will assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging.

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I. General Information

A. What are the EPA's final rule requirements?

The Safe Drinking Water Act (SDWA) provides a framework for the Environmental Protection Agency (EPA) to regulate emerging contaminants of concern in drinking water. Under the statute, the EPA may act based on the ''best available'' science and information. Thus, the statute recognizes that the EPA may act in the face of imperfect information and provides a mechanism for the EPA to update standards as more science becomes available. For the per- and polyfluoroalkyl substances (PFAS) covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's public water systems. In this final action, the EPA is finalizing the PFAS National Primary Drinking Water Regulation (NPDWR) that is based upon the best available peer-reviewed

science. The final NPDWR for PFAS establishes Maximum Contaminant Level Goals (MCLGs) and enforceable Maximum Contaminant Levels (MCLs) for six PFAS compounds: perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA, commonly known as GenX Chemicals), and perfluorobutane sulfonic acid (PFBS). The final rule requirements and references to where additional discussion can be found on these topics are summarized here:

The EPA is finalizing MCLGs for PFOA and PFOS at zero (0) and enforceable MCLs for PFOA and PFOS at 4.0 ng/L (ng/L or ppt). Please see section IV of this preamble on the MCLG derivation for PFOA and PFOS. Additionally, please see section V of this preamble for discussion on the MCL for PFOA and PFOS.

The EPA is finalizing individual regulatory determinations to regulate PFHxS, PFNA, and HFPO–DA (commonly known as ''GenX Chemicals''). The EPA is deferring the individual regulatory determination to regulate PFBS in drinking water. Concurrent with the final determinations, the EPA is promulgating individual MCLGs and MCLs for PFHxS, PFNA, and HFPO–DA at 10 ng/L each.

Additionally, the EPA is finalizing a regulatory determination for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS due to their substantial likelihood for co-occurrence and dose-additive health concerns when present as a mixture in drinking water. Concurrent with this final determination, the EPA is finalizing a Hazard Index (HI) of 1 as the MCLG and enforceable MCL to address mixtures of PFHxS, PFNA, HFPO–DA, and PFBS where they co-occur in drinking water. Please see section III of this preamble for discussion on the EPA's final regulatory determinations; section IV of this preamble for discussion on the MCLG derivation for these additional compounds; and section V of this preamble for a discussion on the final MCLs.

This action also lists feasible technologies for public water systems (PWSs) that can be used to comply with the MCLs. The EPA notes that systems are not required to use the listed technologies to meet the MCL; rather, the MCL is a numeric regulatory limit systems must meet that is developed while considering treatment feasibility and cost. Please see section X for additional discussion on feasible treatment technologies.

The EPA is finalizing SDWA Right-to-Know requirements for the final rule, including Consumer Confidence Report (CCR) and Public Notification (PN) requirements. Community water systems (CWSs) must prepare and deliver to its customers an annual CCR in accordance with 40 CFR part 141, subpart O. Under this rule, CWSs will be required to report detected PFAS in their CCRs and provide health effects language in the case of MCL violations. Additionally, under the final rule, MCL violations require Tier 2 public notification, or notification provided as soon as practicable but no later than 30 days after a system learns of the violation, as per 40 CFR 141.203. Additionally, monitoring and testing procedure violations require Tier 3 notification, or notice no later than one year after the system learns of the violation. Please see section IX of this preamble for additional discussion on SDWA Right-to-Know requirements.

Additionally, the EPA is finalizing monitoring and reporting requirements for PWSs to comply with the NPDWR. PWSs are required to sample each EP using a monitoring regime generally based on the EPA's Standard Monitoring Framework (SMF) for Synthetic Organic Contaminants (SOCs). As a part of these requirements, to establish baseline levels of regulated PFAS, water systems must complete initial monitoring within three years following rule promulgation and/or use results of recent, previously acquired monitoring to satisfy the initial monitoring requirements. Following initial monitoring, beginning three years following rule promulgation, to demonstrate that finished drinking water does not exceed the MCLs for regulated PFAS, PWSs will be required to conduct compliance monitoring for all regulated PFAS at a frequency specifically based on sample results. Compliance with the NPDWRs will be based on analytical results obtained at each sampling point. PWSs are required to report to primacy agencies the results of all initial and compliance monitoring to ensure compliance with the NPDWRs. Please see section VIII of this preamble for additional discussion on these requirements.

Finally, the EPA is exercising its authority under SDWA section 1412(b)(10) to implement a nationwide capital improvement extension to comply with the MCL. All systems must comply with the MCLs by April 26, 2029. All systems must comply with all other requirements of the NPDWR, including initial monitoring, by April 26, 2027. For additional discussion on extensions and exemptions, please see section XI.

B. Does this action apply to me?

Entities regulated by this action are CWSs and non-transient non-community water systems (NTNCWSs). A PWS, as defined in 40 CFR 141.2, provides water to the public for human consumption through pipes or ''other constructed conveyances, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year.'' A PWS is either a CWS or a non-community water system (NCWS). A CWS, as defined in § 141.2, is ''a public water system which serves at least fifteen service connections used by year-round residents or regularly serves at least twenty-five year-round residents.'' The definition in § 141.2 for a NTNCWS is ''a public water system that is not a [CWS] and that regularly serves at least 25 of the same persons over 6 months per year.'' The following table provides examples of the regulated entities under this rule:

Category	Examples of potentially affected entities
Public water systems	CWSs; NTNCWSs.
State and Tribal agencies	Agencies responsible for drinking water regulatory development and enforcement.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table includes the types of entities that the EPA is now aware could potentially be regulated by this action. To determine whether your entity is regulated by this action, this final rule should be carefully examined. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

All new systems that begin operation after, or systems that use a new source of water after, April 26, 2024, must demonstrate compliance with the MCLs

within a period of time specified by the Primacy Agency. The EPA has defined in 40 CFR chapter I, subchapter D, part 141, § 141.2, a wholesale system as a PWS that supplies finished PWSs and a consecutive system as a PWS that buys or otherwise receives some or all its finished water from a wholesale system. In this action, the EPA reiterates that all CWS and NTNCWS must comply with this regulation. This includes consecutive CWS and NTNCWS systems; however, the requirements these consecutive systems must implement to comply with the regulation may be, and often are, much less extensive. For finished water that is provided through a system interconnection, the wholesale systems will be responsible for conducting the monitoring requirements at the entry point (EP) to the distribution system. The final regulation does not require that any monitoring be conducted at a system interconnection point. Where a violation does occur, the wholesale system must notify any consecutive systems of this violation and it is the responsibility of the consecutive system to provide PN to their customers pursuant to § 141.201(c)(1). In addition, wholesale systems must also provide information in Subpart O to consecutive systems for developing CCRs (§ 141.201(c)(1)). Consecutive systems are responsible for providing their customers with the reports (§ 141.153(a)).

II. Background

A. What are PFAS?

Per- and polyfluoroalkyl substances (PFAS) are a large class of thousands of synthetic chemicals that have been in use in the United States and around the world since the 1940s (USEPA, 2018a). The ability for PFAS to withstand heat and repel water and stains makes them useful in a wide variety of consumer, commercial, and industrial products, and in the manufacturing of other products and chemicals. This rule applies directly to six specific PFAS: perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). Due to their widespread use, physicochemical properties, and prolonged persistence, many PFAS co-occur in air, water, ice, and soil, and in organisms, such as humans and wildlife. Exposure to some PFAS can lead to bioaccumulation in tissues and blood of aquatic as well as terrestrial organisms, including humans (Domingo and Nadal, 2019; Fromme et al., 2009). Pregnant and lactating women, as well as infants and children, may be more sensitive to the harmful effects of certain PFAS, such as PFOA, PFOS, PFNA, and PFBS. For example, studies indicate that PFOA and PFOS exposure above certain levels may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast- or formula-fed infants, increased risk for certain cancers, and negative immunological effects, among others (USEPA, 2024c; USEPA, 2024d). It has been documented that exposure to other PFAS are associated with a range of adverse health effects (USEPA, 2021a; USEPA, 2021b; ATSDR, 2021; NASEM, 2022).

The Environmental Protection Agency (EPA) is aware that PFAS still enter the environment and there are viable pathways for human exposure. Most United States production of PFOA, PFOS, and PFNA, along with other long-chain PFAS, was phased out and then generally replaced by production of PFHxS, HFPO–DA, PFBS, and other PFAS. The EPA is also aware of ongoing use of PFOA, PFOS, PFNA, and other long-chain PFAS (USEPA, 2000b; ATSDR, 2021). Long-chain PFAS are typically defined as including perfluoroalkyl sulfonic acids containing ≥ 6 carbons, and perfluoroalkyl carboxylic acids with ≥7 carbons. While domestic production and import of PFOA has been phased out in the United States by the companies participating in the 2010/2015 PFOA Stewardship Program, small quantities of PFOA may be produced, imported, and used by companies not participating in the PFOA Stewardship Program (USEPA, 2021c). The EPA is also aware of ongoing use of PFAS available from existing stocks or newly introduced via imports (see USEPA, 2022a). Additionally, the environmental persistence of these chemicals and formation as degradation products from other compounds may contribute to their ongoing release in the environment (ATSDR, 2021).

The six PFAS in this rule and their relevant Chemical Abstract Service registry numbers (CASRNs) are:

- PFOA ($C_8F_{15}O_2^-$; CASRN: 45285–51–6)
- PFOS ($C_8F_{17}SO_3^-$; CASRN: 45298–90–6)
- PFHxS ($C_6F_{13}SO_3^-$; CASRN: 108427–53–8)
- PFNA ($C_9F_{17}O_2^-$; CASRN: 72007–68–2)
- HFPO–DA ($C_6F_{11}O_3^-$; CASRN: 122499–17–6)
- PFBS ($C_4F_9SO_3^-$; CASRN: 45187–15–3)

These PFAS may exist in multiple forms, such as isomers or associated salts, and each form may have a separate CAS registry number or no CASRN at all. Additionally, these compounds have various names under different classification systems. However, at environmentally relevant pHs, these PFAS are expected to dissociate in water to their anionic (negatively charged) forms. For instance, International Union of Pure and Applied Chemistry substance 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate (CASRN: 122499–17–6), also known as HFPO–DA, is an anionic molecule which has an ammonium salt (CASRN: 62037–80–3), a conjugate acid (CASRN: 13252–13–6), a potassium salt (CASRN: 67118–55–2), and an acyl fluoride precursor (CASRN: 2062–98–8), among other variations. At environmentally relevant pHs these all dissociate into the propanoate/anion form (CASRN: 122499–17–6). Each PFAS listed has multiple variants with differing chemical connectivity, but the same molecular composition (known as isomers). Commonly, the isomeric composition of PFAS is categorized as 'linear,' consisting of an unbranched alkyl chain, or 'branched,' encompassing a potentially diverse group of molecules including at least one, but potentially more, offshoots from the linear molecule. While broadly similar, isomeric molecules may have differences in chemical properties. This rule covers all salts, isomers and derivatives of the chemicals listed, including derivatives other than the anionic form which might be created or identified.

B. Human Health Effects

The publicly available landscape of human epidemiological and experimental animal-based exposure-effect data from repeat-dose studies across PFAS derive primarily from carboxylic and sulfonic acid species such as PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS (ATSDR, 2021; USEPA, 2021a; USEPA, 2021b; USEPA, 2024c; USEPA, 2024d). Many other PFAS have some human health effects data available (Mahoney et al., 2022) and some PFAS, such as PFBS, HFPO–DA, PFNA, and PFHxS, have sufficient data that has allowed Federal agencies to publish toxicity assessments (USEPA, 2021a; USEPA, 2021b; USEPA, 2024c; USEPA, 2024d; ATSDR, 2021) and derive toxicity values (*e.g.,* a reference dose), which is an estimate of daily exposure to the human population

(including sensitive populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime). The adverse health effects associated with exposure to such PFAS include (but are not limited to): effects on the liver (*e.g.,* liver cell death), growth and development (*e.g.,* low birth weight), hormone levels, kidney, the immune system (reduced response to vaccines), lipid levels (*e.g.,* high cholesterol), the nervous system, and reproduction, as well as increased risk of certain types of cancer.

Exposure to PFAS may have disproportionate health effects on children. Adverse health effects relevant to children associated with exposure to some PFAS include developmental effects to fetuses during pregnancy or to breast-fed infants, cardiovascular effects, immune effects, endocrine effects, and reproductive effects. Additionally, PFAS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk (USEPA, 2021a; USEPA, 2021b; USEPA, 2024c; USEPA, 2024d; ATSDR, 2021).

Please see sections III.B and IV of this rule for additional discussion on health considerations for the six PFAS the EPA is regulating in this document.

C. Statutory Authority

Section 1412(b)(1)(A) of SDWA requires the EPA to establish National Primary Drinking Water Regulations (NPDWRs) for a contaminant where the Administrator determines that the contaminant: (1) may have an adverse effect on the health of persons; (2) is known to occur or there is a substantial likelihood that the contaminant will occur in PWSs (public water systems) with a frequency and at levels of public health concern; and (3) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

D. Statutory Framework and PFAS Regulatory History

Section 1412(b)(1)(B)(i) of the Safe Drinking Water Act (SDWA) requires the EPA to publish a Contaminant Candidate List (CCL) every five years. The CCL is a list of contaminants that are known or anticipated to occur in PWSs, are not currently subject to any proposed or promulgated NPDWRs and may require regulation under the drinking water program. In some cases, developing the CCL may be the first step in evaluating drinking water contaminants. The EPA uses the CCL to identify priority contaminants for regulatory decision-making (*i.e.,* regulatory determinations), and for data collection. Publishing a CCL does not impose any requirements on PWSs. The EPA included PFOA and PFOS on the third and fourth CCLs published in 2009 (USEPA, 2009a) and 2016 (USEPA, 2016a). The EPA then included PFAS as a chemical group in its most recent list, the fifth CCL (CCL 5) (USEPA, 2022b). This group is inclusive of the PFAS the EPA is regulating through this action; however, the fifth CCL did not include PFOA and PFOS as they had already had final positive regulatory determinations completed for them in March 2021 (USEPA, 2021d).

The EPA collects data on the CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in PWSs. SDWA 1412(b)(1)(B)(ii) requires that, every five years and after considering public comments on a ''preliminary'' regulatory determination, the EPA issues a determination to regulate or not regulate at least five contaminants on each CCL. In addition, section 1412(b)(1)(B)(ii)(III) authorizes the EPA to make a determination to regulate a contaminant not listed on the CCL at any time so long as the contaminant meets the three statutory criteria based on available public health information. SDWA 1412(b)(1)(B)(iii) requires that ''each document setting forth the determination for a contaminant under clause (ii) shall be available for public comment at such time as the determination is published.'' To implement these requirements, the EPA issues preliminary regulatory determinations subject to public comment and then issues a final regulatory determination after consideration of public comment. Section 1412(b)(1)(E) requires that the EPA propose an NPDWR no later than 24 months after a final determination to regulate. The statute also authorizes the EPA to issue a proposed rule concurrent with a preliminary determination to regulate. The EPA must then promulgate a final regulation within 18 months of the proposal (which may be extended by 9 additional months).

The EPA also implements a monitoring program for unregulated contaminants under SDWA 1445(a)(2) that requires the EPA to issue a list once every five years of priority unregulated contaminants to be monitored by PWSs. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems (CWSs) and non-transient community water systems (NTNCWSs) to better improve the EPA's understanding of the frequency of unregulated contaminants of concern occurring in the nation's drinking water systems and at what levels. The first four UCMRs collected data from a census of large water systems (serving more than 10,000 people) and from a statistically representative sample of small water systems (serving 10,000 or fewer people).

Between 2013–2015, water systems collected monitoring data for six PFAS (PFOA, PFOS, PFHxS, PFNA, PFBS, and perfluoroheptanoic acid (PFHpA)) as part of the third UCMR (UCMR 3) monitoring program. The fifth UCMR (UCMR 5), published December 2021, requires sample collection and analysis for 29 PFAS, including PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS, to occur between January 2023 and December 2025 using drinking water analytical methods developed by the EPA. Section 2021 of America's Water Infrastructure Act of 2018 (AWIA) (Pub. L. 115–270) amended SDWA and specifies that, subject to the availability of the EPA appropriations for such purpose and sufficient laboratory capacity, the EPA must require all public water systems (PWSs) serving between 3,300 and 10,000 people to monitor and ensure that a nationally representative sample of systems serving fewer than 3,300 people monitor for the contaminants in UCMR 5 and future UCMR cycles. All large water systems continue to be required to participate in the UCMR program. Section VI of this preamble provides additional discussion on PFAS occurrence. While the complete UCMR 5 dataset was not available to inform this rule and thus not a basis for informing the agency's decisions for the final rule, the EPA acknowledges that the small subset of data released (7 percent of the total results that the EPA expects to receive) as of July 2023 confirms the EPA's conclusions supported by the extensive amount of data utilized in its UCMR 3, state data, and modelling analyses. This final rule allows utilities and primacy agencies to use the UCMR 5 data to support implementation of monitoring requirements. Sections VI and VIII of this preamble further discusses these occurrence analyses as well as monitoring and compliance requirements, respectively.

After careful consideration of public comments, the EPA issued final regulatory determinations for contaminants on the fourth CCL (CCL 4) in March of 2021 (USEPA, 2021d) which included determinations to regulate two contaminants, PFOA and PFOS, in drinking water. The EPA found that PFOA and PFOS may have

an adverse effect on the health of persons; that these contaminants are known to occur, or that there is a substantial likelihood that they will occur, in PWSs with a frequency and at levels that present a public health concern; and that regulation of PFOA and PFOS presents a meaningful opportunity for health risk reduction for persons served by PWSs. As discussed in the final Regulatory Determinations 4 Notice for CCL 4 contaminants (USEPA, 2021d) and the EPA's *PFAS Strategic Roadmap* (USEPA, 2022c), the agency has also evaluated additional PFAS chemicals for regulatory consideration as supported by the best available science. The agency finds that additional PFAS compounds also meet SDWA criteria for regulation. The EPA's regulatory determination for these additional PFAS is discussed in section III of this preamble.

Section 1412(b)(1)(E) provides that the Administrator ''may publish such proposed regulation concurrent with the determination to regulate.'' The EPA interprets this provision as allowing concurrent processing of a preliminary determination with a proposed rule, not a final determination (as urged by some commenters—see responses in section III of this preamble). Under this interpretation, section 1412(b)(1)(E) authorizes the EPA to issue a preliminary determination to regulate a contaminant and a proposed NPDWR addressing that contaminant concurrently and request public comment at the same time. This represents the only interpretation that accounts for the statutory language in context and is the only one that fulfills Congress's purpose of permitting the agency to adjust its stepwise processes where appropriate to avoid any unnecessary delay in regulating contaminants that meet the statutory criteria. To the extent the statute is ambiguous, the EPA's interpretation is the best interpretation of this provision for these same reasons. As a result, this rule contains both a final determination to regulate four PFAS contaminants (individually and/or as part of a PFAS mixture), and regulations for those contaminants as well as the two PFAS contaminants (PFOA and PFOS) for which the EPA had already issued a final Regulatory Determination. The EPA developed an MCLG and an NPDWR for six PFAS compounds pursuant to the requirements under section 1412(b)(1)(B) of SDWA. The final Maximum Contaminant Level Goals (MCLGs) and NPDWR are discussed in more detail in the following section.

E. Bipartisan Infrastructure Law

The passage of the Infrastructure Investment and Jobs Act (IIJA), often referred to as the Bipartisan Infrastructure Law or BIL, invests over $50 billion to improve drinking water, wastewater, and stormwater infrastructure—the single largest investment in water by the Federal Government. This historic investment specific to safe drinking water includes $11.7 billion in the Drinking Water State Revolving Fund (DWSRF) General Supplemental (referred to as BIL DWSRF General Supplemental); $4 billion to the Drinking Water SRF for Emerging Contaminants (referred to as BIL DWSRF EC); and $5 billion in grants for Emerging Contaminants in Small or Disadvantaged Communities (referred to as EC–SDC) from Federal fiscal years 2022 through 2026 (USEPA, 2023a). For the BIL DWSRF General Supplemental and BIL DWSRF EC, states must provide 49% and 100%, respectively, as additional subsidization in the form of principal forgiveness and/or grants. The EC–SDC grant has no cost-share requirement. Together, these funds will assist many disadvantaged communities, small systems, and others with the costs of addressing emerging contaminants, like PFAS, when it might otherwise be cost-challenging. This financial assistance can be used to address emerging contaminants in drinking water through actions such as technical assistance, certain water quality testing, operator and contractor training and equipment, and treatment upgrades and expansion. Investments in these areas which will allow communities additional funding to meet their obligations under this regulation and help ensure protection from PFAS contamination of drinking water. The Drinking Water SRF can be used by water systems to reduce the public health concerns around PFAS in their drinking water and is already being successfully utilized. Additionally, to support BIL implementation, the EPA is offering water technical assistance (WaterTA) to help communities identify water challenges and solutions, build capacity, and develop application materials to access water infrastructure funding (USEPA, 2023b). The EPA collaborates with states, Tribes, territories, community partners, and other stakeholders with the goal of more communities with applications for Federal funding, quality water infrastructure, and reliable water services.

F. EPA PFAS Strategic Roadmap

In October 2021, the EPA published the *PFAS Strategic Roadmap* (or *Roadmap*) that outlined the whole-of-agency approach to ''further the science and research, to restrict these dangerous chemicals from getting into the environment, and to immediately move to remediate the problem in communities across the country'' (USEPA, 2022c). The *Roadmap* offers timelines by which the EPA acts on key commitments the agency made toward addressing these contaminants in the environment, while continuing to safeguard public health. These include the EPA proposing to designate certain PFAS as Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) hazardous substances; issuing advance notice of proposed rulemakings on various PFAS under CERCLA; and issuing updated guidance on destroying and disposing of certain PFAS and PFAS-containing materials. Additionally, the EPA is issued a memorandum to states in December 2022 that provides direction on how to use the National Pollutant Discharge Elimination System (NPDES) program to protect against PFAS (USEPA, 2022d; USEPA, 2022e). The EPA also announced revisions to several Effluent Limitation Guidelines (ELGs) including, Organic Chemical, Plastic, Synthetic Fibers manufacturing, Metal Finishing & Electroplating, and Landfills to address PFAS discharge from these point source categories. These ELGs collectively will, if finalized, restrict and reduce PFAS discharges to waterways used as sources for drinking water. The EPA is taking numerous other actions to advance our ability to understand and effectively protect people from PFAS, such as the October 11, 2023, rule finalized under the Toxic Substances Control Act (TSCA) that will provide the EPA, its partners, and the public with a dataset of PFAS manufactured and used in the United States. The rule requires all manufacturers (including importers) of PFAS and PFAS-containing articles in any year since 2011 to report information to the extent known or reasonably ascertainable: chemical identity, uses, volumes made and processed, byproducts, environmental and health effects, worker exposure, and disposal to the EPA. With this final NPDWR, the EPA is delivering on another key goal in the *Roadmap* to ''establish a National Primary Drinking Water Regulation'' for PFAS. This rule will protect the American people directly from everyday PFAS exposures that might otherwise occur from PFAS-contaminated drinking water,

complementing the many other actions in the *Roadmap* to protect public health and the environment from PFAS.

III. Final Regulatory Determinations for Additional PFAS

A. Agency Findings

As noted earlier, in 2021, the EPA made a determination to regulate two per- and polyfluoroalkyl substances—perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS)—in drinking water under the Safe Drinking Water Act. This section describes the EPA's regulatory determination findings with respect to three additional PFAS and mixtures of four PFAS.

Pursuant to sections 1412(b)(1)(A) and 1412(b)(1)(B)(ii)(II) of SDWA, the EPA is making a final determination to individually regulate as contaminants PFHxS, PFNA, and HFPO–DA and is publishing Maximum Contaminant Level Goals (MCLGs) and promulgating National Primary Drinking Water Regulations (NPDWRs) for these compounds individually. Under this authority, the EPA is also making a final determination to regulate as a contaminant a mixture of two or more of the following: perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS), and is publishing an MCLG and promulgating an NPDWR for mixtures of these compounds. The agency has determined that PFHxS, PFNA, and HFPO–DA may have individual adverse health effects, and any mixture of these three PFAS and PFBS may also have dose-additive adverse effects on the health of persons; that there is a substantial likelihood that PFHxS, PFNA, and HFPO–DA occur individually with a frequency and at levels of public health concern and that mixtures of these three PFAS and PFBS occur and co-occur in public water systems (PWSs) with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, individual regulation of PFHxS, PFNA, and HFPO–DA, and regulation of mixtures of these three PFAS and PFBS, presents a meaningful opportunity for health risk reduction for persons served by PWSs. The EPA refers to ''mixtures'' in its regulatory determinations to make clear that its determinations cover all the combinations of PFHxS, PFNA, HFPO–DA, and PFBS that could co-occur in a mixture but that each regulated mixture is itself a contaminant.

While the final determination includes mixtures of PFBS in combinations with PFHxS, HFPO–DA, and PFNA, the EPA is deferring the final individual regulatory determination for PFBS to further evaluate it individually under the three SDWA regulatory determination criteria; consequently, the agency is not promulgating an individual MCLG or NPDWR for PFBS in this action. The EPA is deferring its final individual regulatory determination because after considering the public comments, the EPA has decided to further consider whether occurrence information supports a finding that there is a substantial likelihood that PFBS will individually occur in public water systems and at levels of health concern. However, as stated previously, when evaluating PFBS in mixtures combinations with PFHxS, PFNA, and/or HFPO–DA, the EPA has determined that based on the best available information it does meet all three statutory criteria for regulation when a part of these mixtures, including that it is anticipated to have dose-additive adverse health effects (see sections III.B and IV.B.1), there is a substantial likelihood of its co-occurrence in combinations with PFHxS, PFNA, and/or HFPO–DA with a frequency and at levels of public health concern (see sections III.C, VI.C, VI.D, and USEPA 2024b), and there is a meaningful opportunity for health risk reduction by regulating mixture combinations of these four PFAS (see section III.D of this preamble). Hence, although the agency is deferring the individual final regulatory determination for PFBS, it is included in the final determination to regulate mixture combinations containing two or more of PFHxS, PFNA, HFPO–DA, and PFBS.

This section describes the best available science and public health information used by the agency to support the regulatory determinations. The MCLGs and NPDWR, including the MCLs, are discussed further in sections IV and V of this preamble.

1. Proposal

The agency proposed preliminary determinations to regulate PFHxS, PFNA, HFPO–DA, and PFBS individually, and to regulate mixtures of these four PFAS contaminants, in drinking water. In the proposal, the agency concluded that PFHxS, PFNA, HFPO–DA, and PFBS, and mixtures of these PFAS, may cause adverse effects on the health of persons; there is a substantial likelihood that they will occur and co-occur in PWSs with a frequency and at levels of public health concern, particularly when considering them in a mixture; and in the sole judgment of the Administrator, regulation of PFHxS, PFNA, HFPO–DA, PFBS, and mixtures of these PFAS, presents a meaningful opportunity for health risk reductions for people served by PWSs.

Within the proposal, the agency described section 1412(b)(1)(E) which provides that the Administrator may publish a proposed drinking water regulation concurrent ''with the determination to regulate.'' This provision authorizes a more expedited process by allowing the EPA to make concurrent the regulatory determination and rulemaking processes. As a result, for the proposal, the EPA interpreted the relevant reference to ''determination to regulate'' in section 1412(b)(1)(E) as referring to the regulatory process in 1412(b)(1)(B)(ii) that begins with a preliminary determination. Under this interpretation, section 1412(b)(1)(E) authorizes the EPA to issue a preliminary determination to regulate a contaminant and a proposed NPDWR addressing that contaminant concurrently and request public comment at the same time. This allows the EPA to act expeditiously where appropriate to issue a final determination to regulate concurrently with a final NPDWR to avoid delays to address contaminants that meet the statutory criteria.

Additionally, as part of the proposal, the EPA explained why mixtures of PFAS qualify as a ''contaminant'' for purposes of section 1412. SDWA section 1401(6) defines the term ''contaminant'' to mean ''*any* physical, chemical or biological or radiological substance or matter in water.'' A mixture of two or more of the regulated PFAS qualifies as a ''contaminant'' because the mixture itself is ''*any* physical, chemical or biological or radiological substance or matter in water'' (emphasis added). Therefore, pursuant to the provisions outlined in section 1412(b)(1)(A) and 1412(b)(1)(B) of SDWA, the agency made a preliminary determination to regulate PFHxS, PFNA, HFPO–DA, PFBS, and any mixtures of these PFAS as a contaminant in drinking water. In the past and in this instance, the EPA's approach to regulating contaminant groups or mixtures under SDWA considers several factors, including health effects, similarities in physical and chemical properties, contaminant co-occurrence, ability for treatment technology co-removal, or where such a regulatory structure presents a meaningful opportunity to improve public health protection.

2. Summary of Major Public Comments and EPA Responses

The EPA requested comments on its preliminary regulatory determinations for PFHxS, PFNA, HFPO–DA, and PFBS, and mixtures of these PFAS, including the agency's evaluation of the statutory criteria and any additional data or studies the EPA should consider that inform the preliminary regulatory determinations for these contaminants and their mixtures. The EPA also requested comment on its preliminary determination that regulation of PFHxS, PFNA, HFPO–DA, PFBS, and their mixtures, in addition to regulation of PFOA and PFOS, will also provide protection from PFAS (*e.g.,* PFDA, PFDoA, PfHpA, PFHxA, PFHpS, PFPeS) that will not be regulated because the treatment technologies that would be used to ensure compliance for these PFAS are also effective in reducing concentrations of other unregulated PFAS.

Many commenters expressed support for the EPA's preliminary regulatory determinations, including that the EPA has appropriately determined that the three statutory criteria for regulation have been met for all four contaminants and their mixtures using the best available information. Many other commenters did not agree that the agency presented sufficient information to make a preliminary determination to regulate PFHxS, PFNA, HFPO–DA, PFBS, and their mixtures, with some commenters recommending that that the agency withdraw the portion of the proposed rule associated with these four PFAS because in their view there is insufficient health effects and/or occurrence data at this time to support the EPA's action. For some of the four contaminants and their mixtures, a few commenters stated that the EPA had not met the statutory criteria for regulation or that data suggests a determination not to regulate is more appropriate. The EPA disagrees with these commenters because there is information to support individual regulation of PFHxS, PFNA, and HFPO–DA, as well as mixtures of these three PFAS and PFBS, based on the three statutory criteria (these findings are discussed in this section).

As discussed earlier in this section, after consideration of all the public comments on this issue, the agency is deferring the determination to individually regulate PFBS for further evaluation under the statutory criteria. This determination is informed by public comment suggesting that the three statutory criteria for individual regulation of PFBS, particularly related to the occurrence criterion have not been met. The EPA will continue to consider other available occurrence information, including from UCMR 5, to determine whether the information supports a finding that there is a substantial likelihood that PFBS will individually occur in PWSs and at a level of public health concern. The record demonstrates that exposure to a mixture with PFBS may cause adverse health effects; that there is a substantial likelihood that PFBS co-occurs in mixtures with PFHxS, PFNA, and/or HFPO–DA in PWSs with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, regulation of PFBS in mixtures with PFHxS, PFNA, and/or HFPO–DA presents a meaningful opportunity for health risk reduction for persons served by PWSs.

Furthermore, the EPA is making a final determination to regulate PFHxS, PFNA, and HFPO–DA individually. While the EPA recognizes there will be additional health, occurrence, or other relevant information for these PFAS and others in the future, the EPA has determined that there is sufficient information to make a positive regulatory determination and the agency concludes that these three PFAS currently meet all of the statutory criteria for individual regulatory determination. Therefore, the agency is proceeding with making final determinations to regulate these contaminants both individually and as part of mixtures with PFBS and is concurrently promulgating individual MCLs for PFHxS, PFNA, and HFPO–DA (see section V of this preamble). For detailed information on the EPA's evaluation of the three regulatory determination statutory criteria for PFHxS, PFNA, and HFPO–DA individually and mixtures of these three PFAS and PFBS, as well as more specific comments and the EPA responses related to each of the three statutory criteria, see subsections III.B, C, and D.

Several commenters requested that the EPA evaluate additional occurrence data to further inform its analysis for the regulatory determinations. In response to public comments on the proposal, the EPA evaluated updated and new occurrence data and the updates are presented within subsection III.C. and section VI of this preamble. These additional occurrence data further confirm that the SDWA criteria for regulation have been met for PFHxS, PFNA, and HFPO–DA as individual contaminants and for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS.

A couple of commenters questioned the EPA's rationale for selecting PFHxS, PFNA, HFPO–DA, and PFBS for regulation. The agency's process is allowable under SDWA and, as described within this section of the preamble, there is available health, occurrence, and other meaningful opportunity information for three PFAS (PFHxS, PFNA, and HFPO–DA) to meet the SDWA statutory criteria for regulation individually and four PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) as a mixture. The EPA disagrees with commenters who suggested that the agency should not develop national regulations that differ from state-led actions. While states may establish drinking water standards for systems in their jurisdiction prior to regulation under SDWA, once an NPDWR is in place, SDWA 1413(a)(1) requires that states or Tribes adopt standards that are no less stringent than the NPDWR to maintain primacy. Moreover, the agency further notes that all four PFAS the EPA is regulating individually or as a mixture are currently regulated by multiple states as shown in table 4–17 of USEPA, 2024e.

The EPA received several comments related to the EPA's interpretation in the proposal that the agency may, as it did here, issue a preliminary regulatory determination concurrent with a proposed NPDWR. Many stated that the EPA is authorized under SDWA to process these actions concurrently and agreed with the EPA's interpretation of the statute, noting that the EPA has followed all requirements under SDWA including notice and opportunity for public comment on both the preliminary regulatory determination and proposed NPDWR, and that simultaneous public comment periods are not precluded by SDWA. Several other commenters expressed disagreement with the EPA's interpretation. These dissenting commenters contend that the statute only allows the EPA to ''publish such proposed regulation concurrent with the determination to regulate'' (*i.e.,* in their view, the final determination), not the ''preliminary determination to regulate.'' Moreover, some of these commenters further indicated that they believe the EPA's final determination to regulate must precede the EPA's proposed regulation. The EPA disagrees with commenters who stated that the EPA cannot issue a preliminary determination concurrent with a proposed NPDWR. Section 1412(b)(1)(e) states that ''[t]he Administrator shall propose the maximum contaminant level goals and national primary drinking water regulation for a contaminant *not later than 24 months*

after the determination to regulate under subparagraph (B), and may publish such proposed regulation *concurrent with the determination to regulate*'' (emphasis added). The EPA maintains its interpretation that ''determination to regulate'' in the second phrase of 1412(b)(1)(E) allows for concurrent processing of a preliminary determination and proposed rule, not a final determination and proposed rule.

The first clause of the provision provides an enforceable 24-month deadline for the EPA to issue a proposed rule once it has decided to regulate. Contrary to the suggestion of some commenters, the statutory language providing that the EPA ''shall'' propose an NPDWR ''not later than 24 months *after* the determination to regulate'' states when the 24 months to issue a proposed rule begins, *i.e.,* the deadline is 24 months *after* making a final determination to issue a proposed regulation. The phrase ''after the determination to regulate'' here simply identifies when SDWA's deadline begins to run; there is no textual or other indication in the language that Congress meant it to constitute the beginning of an exclusive 24-month window in which the EPA is permitted to propose an NPDWR. Further, though the EPA's reading is clear on the face of the provision, it is also supported by language elsewhere in SDWA illustrating that when Congress intends to provide a window for action (as opposed to a deadline for action) it knows how to do so clearly. In fact, Congress did so in this very provision when it required the EPA to ''publish a maximum contaminant level goal and promulgate a national primary drinking water regulation *within* 18 months after the proposal thereof.'' See also, 42 U.S.C. 1448 (providing, among other things, that petitions for review of the EPA regulations under SDWA ''shall be filed *within* the 45-day period *beginning on* the date of the promulgation of the regulation . . .'') (emphasis added). In addition, the phrase ''not later than,'' expressly acknowledges that the EPA may issue a proposed rule concurrent with a final determination. And because this language only provides a deadline without a beginning trigger, the language in the first clause of this provision would also not preclude the EPA from issuing a proposed rule at any time prior to the expiration of the 24 months after a final regulatory determination, including issuing the proposed rule on the same day as the preliminary regulatory determination.

The second clause, which states that the Administrator ''may publish such proposed regulation concurrent with the determination to regulate'' should not be read to limit when the EPA can issue a proposed rule *prior* to a final determination. First, Congress's use of the phrase ''determination to regulate'' elsewhere in SDWA is not consistent, requiring the agency to discern its meaning based on statutory context. Second, reading ''determination to regulate'' to refer to a final determination would, without good reason, hinder Congress' goal in enacting this provision, to accelerate the EPA action under SDWA. Finally, the EPA's interpretation to allow for concurrent processes is fully consistent with, and indeed enhances, the deliberative stepwise process provided in the statute for regulating new contaminants.

Language throughout the statute demonstrates that Congress did not use the term ''determination to regulate'' consistently. In fact, ''preliminary determination'' only appears once in the entire provision, ''final determination'' is never used, and the remainder of the references simply refer to ''determination.'' Specifically, section 1412(b)(1)(B)(ii)(I) expressly requires public comment on a ''preliminary'' regulatory determination made as part of the contaminant candidate listing process. The rest of section 1412(b)(1)(B)(ii) and (iii) as well as the title of the provision only refer to a ''determination to regulate'' or ''determination.'' For example, 1412(b)(1)(B)(iii) states that ''[e]ach document setting forth the determination for a contaminant under clause (ii) shall be available for public comment at such time as the determination is published.'' [1] Although this provision only refers to a ''determination for a contaminant under clause (ii),'' this language clearly refers to public comment on a preliminary determination and not a final determination to regulate. The EPA has interpretated ''determination'' in this paragraph to refer to ''preliminary determination'' because that is the best interpretation to effectuate Congressional intent to provide public comment prior to issuing a final determination. The EPA has done the same with section 1412(b)(1)(E) here, as only a reading that allows for, in appropriate cases, concurrent processing of a preliminary determination to regulate and proposed NPDWR allows for rulemaking acceleration by the EPA as Congress envisioned. To the extent there is ambiguity, the EPA's reading of section 1412(b)(1)(E) is the best one to effectuate these purposes.

The EPA could issue a proposed rule concurrent with a final determination; there is nothing in the statute or the APA that requires the EPA to wait. The SDWA gives the EPA 24 months to act after a final determination but does not require the agency to wait 24 months. The ''no later than'' language in the first clause of section 1412(b)(1)(E), expressly acknowledges that the EPA may issue a proposed rule concurrent with a final determination. Therefore, construing the second phrase of section 1412(b)(1)(E) simply to authorize the EPA to issue a proposed rule concurrent with a final determination renders that provision of the statute authorizing the EPA to publish such proposed regulation concurrent with the determination to regulate a nullity. The well-known tools of statutory construction direct the agencies and courts not to construe statutes so as to render Congress's language mere surplusage, yet that it is what commenters' interpretation would do. The EPA's construction is the one which gives meaning to that language.

Moreover, the EPA's interpretation of ''determination to regulate'' in the phrase ''may publish such proposed regulation concurrent with the determination to regulation'' in section 1412(b)(1)(E) to be a preliminary determination best effectuates Congress' goal in enacting this provision, to accelerate the EPA action under SDWA when the EPA determines such a step is necessary and the EPA has, as it does here, a sufficient record to proceed with both regulatory determination and regulation actions concurrently. In addition to authorizing concurrent processes, Congress' intent to expedite regulatory determinations when necessary is evidenced more generally by the text and structure of section 1412(b)(1)(B)(ii). The statute contemplates regulatory determinations could be made as part of the 5-year cycle for the contaminant candidate list under section 1412(b)(1)(B)(ii)(I) but may also be made at any time under section 1412(b)(1)(B)(ii)(III). The fact that Congress provided the EPA with express authority to make a regulatory determination at any time is a recognition that the EPA may need to act expeditiously to address public

[1] Even the first clause of section 1412(b)(1)(E) setting the 24-month deadlines use ''regulatory determination'' without further clarifying whether it is preliminary or final. Again, it is clear when viewed in context that the term refers to a final determination, as triggering a deadline to propose regulations on a preliminary decision to regulate would not be reasonable, as the agency may change its mind after reviewing publicv comment, obviating the need for a proposed NPDWR.

health concerns between the statutory periodic 5-year cycle. The EPA's interpretation of the relevant language in section 1412(b)(1)(E) best effectuates all provisions of the statute because simultaneous public processes for off-cycle regulatory determinations and NPDWRs allow for administrative efficiency that may be needed to address pressing public health concerns.

Finally, the EPA's interpretation of the statute allowing for concurrent processes is fully consistent with the stepwise process for issuing an NPDWR set out by the statute. Here, the EPA provided for public comment on an extensive record for both the regulatory determinations and the proposed regulatory levels and it is not clear what further benefit would be provided by two separate public comment periods. This is especially true given the D.C. Circuit's ruling in *NRDC* v. *Regan,* 67 F.4th 397 (D.C. Cir 2023), which held that the EPA cannot withdraw a final determination to regulate a contaminant. Thus, even if the EPA were to provide two separate comment periods, the information provided on a proposed rule cannot be used to undo a final regulatory determination. Indeed, although not required by the statute, the EPA in proposing actions concurrently provides commenters with much more information to evaluate the preliminary regulatory determinations. This is because the EPA has provided not just the information to support the preliminary determinations to regulate but also the full rulemaking record and supporting risk, cost, occurrence, and benefit analysis that supports the proposed Maximum Contaminant Levels (MCLs). Further, the EPA has a much more comprehensive record for the regulatory determinations to ensure that the final determination, which cannot be withdrawn, is based on the comprehensive record provided by the rulemaking and Health Risk Reduction and Cost Analysis (HRRCA) development processes.

The EPA received comments on its statutory authority to regulate mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS, specifically the agency's interpretation under section 1401(6) that a mixture of two or more contaminants also qualifies as the definition of a contaminant under SDWA since a mixture itself meets the same definition. A few commenters disagreed and contended that a mixture does not meet the definition of being a single contaminant under SDWA. The EPA disagrees with these commenters, as the SDWA definition of a contaminant does not specify that a contaminant is only a singular chemical. The SDWA definition is very broad, specifically stating that a contaminant is ''*any* physical, chemical or biological or radiological substance or matter'' (emphasis added), with no specific description or requirement for how it is formed. Matter for example, by definition, is comprised of either pure substances or mixtures of pure substances. A pure substance is either an element or compound, which would include any PFAS chemical. The statute encompasses ''matter'' which is a broad term that includes mixtures and therefore definitionally includes PFAS mixtures, comprised of a combination of PFAS (chemical substances), as itself qualifying as a ''contaminant'' under SDWA. Moreover, other provisions of the statute, would be restricted in a manner inconsistent with Congressional intent if the EPA were to adopt the cabined approach to ''contaminant'' suggested by some commenters. For example, section 1431 of SDWA provides important authority to the EPA to address imminent and substantial endangerment to drinking water supplies posed by ''a contaminant'' that is present in or threatened those supplies. Congress clearly intended this authority to be broad and remedial, but it would be significantly hampered if the EPA would be restricted to only addressing individual chemicals and not mixtures threatening a water supply. For these reasons, the EPA's interpretation of the definition of contaminant is the only reading that is consistent with the statutory definition and use of the term in context and at to the extent the definition of contaminant is ambiguous, the EPA's interpretation represents the best interpretation of that term. Finally, even if a mixture is considered a group, as some commenters suggest, Congress clearly contemplated that the EPA could regulate contaminants as groups. *See* H.R. Rep. No 93–1185 (1974), reprinted in 1974 U.S.C.C.A.N. 6454, 6463–64) (noting the tens of thousands of chemical compounds in use commercially, with many more added each year, of which many will end up in the nation's drinking water and finding that ''[i]t is, of course, impossible for EPA to regulate each of these contaminants which may be harmful to health on a contaminant-by-contaminant basis. Therefore, the Committee anticipates that the Administrator will establish primary drinking water regulations for some groups of contaminants, such as organic and asbestos.'') Thus, the EPA has the authority to regulate a mixture as a contaminant under SDWA.

The commenters also suggested that the EPA has not followed its *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000a), specifically that the agency did not use a ''sufficiently similar mixture'' where ''components and respective portions exist in approximately the same pattern'' and suggested that there has to be consistent co-occurrence of the mixture components. The EPA disagrees with these comments. It is not possible or necessary to use a whole-mixture approach for PFHxS, PFNA, HFPO–DA, and PFBS or a ''sufficiently similar mixture.'' Instead, the EPA is using a longstanding component-based mixture approach called the Hazard Index, which was endorsed in the context of assessing potential risk associated with PFAS mixtures by the Science Advisory Board (SAB) during its 2021 review of the EPA's *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* (USEPA, 2021e) (see section IV of this preamble). The goal of this component-based approach is to approximate what the whole-mixture toxicity would be if the whole mixture could be tested and relies on toxicity information for each individual component in a mixture (USEPA, 2000a). A whole-mixture approach for regulating these four PFAS in drinking water is not possible because it would entail developing a single toxicity value (*e.g.,* a reference dose (RfD)) for one specific mixture of PFHxS, PFNA, HFPO–DA, and PFBS with defined proportions of each PFAS. Toxicity studies are typically conducted with only one test substance to isolate that particular substance's effects on the test organism, and whole-mixture data are exceedingly rare. There are no known whole-mixture studies for PFHxS, PFNA, HFPO–DA, and PFBS, and even if they were available, the corresponding toxicity value (*i.e.,* a single RfD for a specific mixture of these four PFAS) would only be directly applicable to that specific mixture. Thus, a more flexible approach that takes into account the four component PFAS in different combinations and at different concentrations (*i.e.,* the Hazard Index approach) is necessary. The Hazard Index indicates risk from exposure to a mixture and is useful in this situation to ensure a health-protective MCLG in cases where the mixture is spatially and/or temporally variable. For a more detailed discussion on whole-mixture and component-based approaches for PFAS health assessment, please see the EPA's *Framework for*

Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (USEPA, 2024a).

Many other commenters supported the EPA's interpretation of regulating a mixture as a ''contaminant'' that consists of a combination of certain PFAS, citing the EPA's broad authority under SDWA to set regulatory standards for groups of related contaminants and the EPA precedent for doing so under other NPDWRs including disinfection byproducts (DBPs; for total trihalomethanes [TTHMs] and the sum of five haloacetic acids [HAA5] (USEPA, 1979; USEPA, 2006a)), as well as radionuclides (USEPA, 2000c) and polychlorinated biphenyls (PCBs). The EPA also noted some of these examples within the proposed rule. One commenter disagreed that these previous EPA grouping approaches are applicable to the mixture of the four PFAS, noting that TTHMs and HAA5 are byproducts of the disinfection process and are the result of naturally occurring compounds reacting with the disinfectants used in drinking water treatment; thus, their formation cannot be controlled and is dependent on the presence and amount of disinfectant. As a result of these factors, measuring them as a class is required; however, the four PFAS are not byproducts, and the presence of one PFAS does not change the presence of the other PFAS. Moreover, the commenter provided that related to radionuclides, alpha particles are identical regardless of their origination and using this example for PFAS is not supported since the four PFAS are fundamentally different. The EPA disagrees with this commenter. As noted above, the SDWA definition of contaminant is very broad (''*any* physical, chemical or biological or radiological substance or matter'' (emphasis added)) with no limitations, specific description or requirement for how it is formed. The statute therefore easily encompasses a mixture, comprised of a combination of PFAS (chemical substances), as itself qualifying as a ''contaminant'' under SDWA. Moreover, as also noted above, to the extent the mixture is considered a ''group,'' Congress clearly anticipated that the EPA would regulate contaminants by group. As a result, even if the PFAS ''group'' is different than other SDWA regulatory groupings, such a regulation is clearly authorized under the statute. Furthermore, it makes sense to treat these mixtures as a ''contaminant'' because the four PFAS share similar characteristics: it is substantially likely that they co-occur; the same treatment technologies can be used for their removal; they are measured simultaneously using the same analytical methods; they have shared adverse health effects; and they have similar physical and chemical properties resulting in their environmental persistence.

3. The EPA's Final Determination

The EPA is making determinations to regulate PFHxS, PFNA, and HFPO–DA individually and to regulate mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS. A mixture of PFHxS, PFNA, HFPO–DA, and PFBS can contain any two or more of these PFAS. The EPA refers to ''mixtures'' in its final regulatory determinations to make clear that its determinations cover all of the combinations of PFHxS, PFNA, HFPO–DA, and PFBS that could co-occur in a mixture but that any combination itself qualifies as a contaminant.

In this preamble, as discussed earlier, the EPA is deferring the final determination to regulate PFBS individually to further evaluate the three criteria specified under SDWA 1412(b)(1)(A), particularly related to its individual known or likely occurrence, but is making a final determination to regulate PFBS as part of a mixture with PFHxS, PFNA, and/or HFPO–DA.

To support the agency's regulatory determinations, the EPA carefully considered the public comments and examined health effects information from available final peer-reviewed human health assessments and studies, as well as drinking water monitoring data collected as part of the UCMR 3 and state-led monitoring efforts. The EPA finds that oral exposure to PFHxS, PFNA, and HFPO–DA individually, and combinations of these three PFAS and PFBS in mixtures, may result in a variety of adverse health effects, including similar or shared adverse effects on several biological systems including the endocrine, cardiovascular, developmental, immune, and hepatic systems (USEPA, 2024f). Based on the shared toxicity types, exposure to PFHxS, PFNA, or HFPO–DA individually, or combinations of these three PFAS and PFBS in a mixture, is anticipated to affect common target organs, tissues, or systems to produce dose-additive effects from co-exposures. Additionally, based on the agency's evaluation of the best available science, including a review of updated data from state-led drinking water monitoring efforts discussed in subsection III.C of this preamble, the EPA finds that PFHxS, PFNA, and HFPO–DA each have a substantial likelihood to occur in finished drinking water and that these three PFAS and PFBS are also likely to co-occur in mixtures and result in increased total PFAS exposure above levels of public health concern. Therefore, as discussed further in this section, the agency is determining that:

- exposure to PFHxS, PFNA, or HFPO–DA individually, and any mixture of these three PFAS and PFBS, may have adverse effects on the health of persons;
- there is a substantial likelihood that PFHxS, PFNA, and HFPO–DA will occur and there is a substantial likelihood that combinations of these three PFAS plus PFBS will co-occur in mixtures in PWSs with a frequency and at levels of public health concern; and
- in the sole judgment of the Administrator, individual regulation of PFHxS, PFNA, and HFPO–DA, and mixtures of the three PFAS plus PFBS, presents a meaningful opportunity for health risk reductions for persons served by PWSs.

The EPA is making a final individual regulatory determination for PFHxS, HFPO–DA, and PFNA and promulgating individual MCLGs and NPDWRs for PFHxS, HFPO–DA, and PFNA. These NPDWRs ensure public health protection when one of these PFAS occurs in isolation above their MCLs and also support risk communication efforts for utilities (see section V of this preamble for more information). The EPA is also making a final mixture regulatory determination and promulgating a Hazard Index MCLG and NPDWR for mixtures containing two or more of PFHxS, PFNA, HFPO–DA, and PFBS. The Hazard Index is a risk indicator and has been shown to be useful in chemical mixtures decision contexts (USEPA, 2023c).[2] Individual NPDWRs do not address dose additive risks from co-occurring PFAS. However, the Hazard Index NPDWR accounts for PFAS co-occurring in mixtures where the individual concentrations of one or more PFAS may not exceed their individual levels of public health concern, but the combined levels of these co-occurring PFAS result in an overall exceedance of the health-protective level. In this way, the Hazard Index NPDWR protects against dose-additive effects. This approach also recognizes that exposure to the PFAS included in the Hazard Index is associated with adverse health effects at differing potencies (*e.g.,* the toxicity reference value for PFHxS is lower than

[2] Some describe the Hazard Index as an indicator of potential hazard because it does not estimate the probability of an effect; others characterize the Hazard Index as an indicator of potential risk because the measure integrates both exposure and toxicity (USEPA 2000c; USEPA, 2023c).

the one for PFBS) and that, regardless of these potency differences, all co-occurring PFAS are included in the hazard calculation (*i.e.,* the health effects and presence of lower toxicity PFAS are neither ignored nor are they over-represented). Furthermore, the approach accounts for all the different potential combinations of these PFAS that represent a potential public health concern that would not be addressed if the EPA only finalized individual NPDWRs and considered individual PFAS in isolation.

B. Statutory Criterion 1—Adverse Health Effects

The agency finds that exposure to PFHxS, PFNA, and HFPO–DA individually, and any mixture of these three PFAS and PFBS, may have an adverse effect on the health of persons. Following is a discussion of health effects information for each of these four individual PFAS and the levels at which those health effects may be adverse. The agency developed health reference levels (HRLs) for PFHxS, PFNA, HFPO–DA, and PFBS as part of its effort to identify the adverse effects each contaminant may have on the health of persons. In this instance, the EPA identified the HRL as the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages, and allows for an adequate margin of safety. The HRLs are also used as health-based water concentrations (HBWCs) in the calculation of the Hazard Index MCLG (see section IV).

1. PFHxS

Studies have reported adverse health effects, including on the liver, thyroid, and development, after oral exposure to PFHxS (ATSDR, 2021). For a detailed discussion on adverse effects associated with oral exposure to PFHxS, please see ATSDR (2021) and USEPA (2024f).

The EPA derived the individual HRL/HBWC for PFHxS using a chronic reference value of 0.000002 (2E–06) mg/kg/day based on adverse thyroid effects (follicular epithelial hypertrophy/hyperplasia), a sensitive noncancer effect determined to be adverse and relevant to humans, observed in male rats after oral PFHxS exposure during adulthood (ATSDR, 2021; USEPA, 2024f). The EPA applied a bodyweight-adjusted drinking water intake (DWI–BW) exposure factor for adults within the general population (0.034 L/kg/day; 90th percentile direct and indirect consumption of community water, consumer-only two-day average, adults 21 years and older) and a relative source contribution (RSC) of 0.20 to calculate the HRL/HBWC (USEPA, 2024f). The HRL/HBWC for PFHxS is 10 ng/L which was used to evaluate individual occurrence of PFHxS for the final regulatory determination as discussed in section III.C of this preamble.

2. PFNA

Studies have reported adverse health effects, including on development, reproduction, immune function, and the liver, after oral exposure to PFNA (ATSDR, 2021). For a detailed discussion of adverse effects associated with oral exposure to PFNA, please see ATSDR (2021) and USEPA (2024f).

The EPA derived the HRL/HBWC for PFNA using a chronic reference value of 0.000003 (3E–06) mg/kg/day based on decreased body weight gain and impaired development (*i.e.,* delayed eye opening, delayed sexual maturation) in mice born to mothers that were orally exposed to PFNA during gestation (with presumed continued indirect exposure of offspring via lactation) (ATSDR, 2021; USEPA, 2024f). These sensitive noncancer effects were determined to be adverse and relevant to humans (ATSDR, 2021; USEPA, 2024f). The EPA applied a DWI–BW exposure factor for lactating women (0.0469 L/kg/day; 90th percentile direct and indirect consumption of community water, consumer-only two-day average) and an RSC of 0.20 to calculate the HRL/HBWC (USEPA, 2024f). The HRL/HBWC for PFNA is 10 ng/L which was used to evaluate individual occurrence of PFNA for the final regulatory determination as discussed in section III.C of this preamble.

3. HFPO–DA

Animal toxicity studies have reported adverse health effects after oral HFPO–DA exposure, including liver and kidney toxicity and immune, hematological, reproductive, and developmental effects (USEPA, 2021b). The EPA determined that there is Suggestive Evidence of Carcinogenic Potential after oral exposure to HFPO–DA in humans, but the available data are insufficient to derive a cancer risk concentration for oral exposure to HFPO–DA. For a detailed discussion of adverse effects of oral exposure to HFPO–DA, please see USEPA (2021b).

The most sensitive noncancer effects observed among the available data were the adverse effects on liver (*e.g.,* increased relative liver weight, hepatocellular hypertrophy, apoptosis, and single-cell/focal necrosis), which were observed in both male and female mice and rats across a range of exposure durations and dose levels, including the lowest tested dose levels and shortest exposure durations. The EPA derived the HRL/HBWC for HFPO–DA from a chronic oral RfD of 0.000003 (3E–06) mg/kg/day that is based on adverse liver effects, specifically a constellation of liver lesions including cytoplasmic alteration, single-cell and focal necrosis, and apoptosis, observed in parental female mice following oral exposure to HFPO–DA from pre-mating through day 20 of lactation (USEPA, 2021b). The EPA applied a DWI–BW exposure factor for lactating women (0.0469 L/kg/day; 90th percentile direct and indirect consumption of community water, consumer-only two-day average) and an RSC of 0.20 to calculate the HRL/HBWC (USEPA, 2024f). The HRL/HBWC for HFPO–DA is 10 ng/L which was used to evaluate individual occurrence of HFPO–DA for the final regulatory determination as discussed in section III.C of this preamble.

4. PFBS

Toxicity studies of oral PFBS exposure in animals have reported adverse health effects on development, as well as on the thyroid and kidneys (USEPA, 2021a). Human and animal studies evaluated other health effects following PFBS exposure including effects on the immune, reproductive, and hepatic systems and lipid and lipoprotein homeostasis, but the evidence was determined to be equivocal (USEPA, 2021a). No studies evaluating the carcinogenicity of PFBS in humans or animals were identified. The EPA concluded that there is Inadequate Information to Assess Carcinogenic Potential for PFBS and its potassium salt (K + PFBS) by any route of exposure based on the EPA's *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). For a detailed discussion on adverse effects after oral exposure to PFBS, please see USEPA (2021a).

As noted previously, the agency is deferring the final individual regulatory determination for PFBS. For the purposes of evaluating PFBS in mixture combinations with PFHxS, PFNA, and HFPO–DA (see section III.B.5 of this preamble), the EPA derived the HRL/HBWC for PFBS from a chronic RfD of 0.0003 (3E–04) mg/kg/day that is based on adverse thyroid effects (decreased serum total thyroxine) observed in newborn mice following gestational exposure to the potassium salt of PFBS (USEPA, 2021a). The EPA applied a DWI–BW exposure factor for women of child-bearing age (0.0354 L/kg/day; 90th percentile direct and indirect consumption of community water, consumer-only two-day average) and an

RSC (relative score contribution) of 0.20 to calculate the HRL/HBWC (USEPA, 2024f). The HRL/HBWC for PFBS is 2000 ng/L.

5. Mixtures of PFHxS, PFNA, HFPO–DA, and PFBS

Exposure to per- and polyfluoroalkyl acids (PFAAs), a subclass of PFAS that includes PFHxS, PFNA, HFPO–DA, and PFBS, can disrupt signaling of multiple biological pathways, resulting in a shared set of adverse effects, including effects on thyroid hormone levels, lipid synthesis and metabolism, development, and immune and liver function (ATSDR, 2021; EFSA et al., 2018; EFSA et al., 2020; USEPA, 2021a; USEPA, 2021b; USEPA, 2024f; see further discussion in section III.B.6.e of this preamble).

Studies with PFAS and other classes of chemicals support the health-protective conclusion that chemicals that have similar observed adverse effects following individual exposure should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise (USEPA, 2024a). Dose additivity means that the combined effect of the component chemicals in the mixture (in this case, PFHxS, PFNA, HFPO–DA, and/or PFBS) is equal to the sum of their individual doses or concentrations scaled for potency (USEPA, 2000a). In other words, exposure to these PFAS, at doses that individually would not likely result in adverse health effects, when combined in a mixture may result in adverse health effects. See additional discussion of PFAS dose additivity in section IV of this preamble.

The EPA used a Hazard Index (HI) HRL of 1 (unitless) to evaluate co-occurrence of combinations PFHxS, PFNA, HFPO–DA, and PFBS in mixtures for the final regulatory determination as discussed in section III.C of this preamble. For technical details on the Hazard Index approach, please see section IV of this preamble, USEPA (2024a), and USEPA (2024f).

6. Summary of Major Public Comments and EPA Responses

Commenters referred to the HRLs and HBWCs interchangeably, so comments related to those topics are addressed in this section. (Other comments related to the MCLGs are addressed in section IV of this preamble.)

Many commenters expressed support for the EPA's derivation of HRLs/HBWCs and use of best available peer-reviewed science, specifically the use of the final, most recently published Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels for PFHxS and PFNA as chronic reference values. Other commenters criticized the EPA for using ATSDR minimal risk levels and stated that they are inappropriate for SDWA rulemaking.

The EPA finds that the ATSDR minimal risk levels for PFHxS and PFNA currently represent the best available, peer-reviewed science for these chemicals. SDWA specifies that agency actions must rely on ''the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices.'' At this time, the 2021 ATSDR *Toxicological Profile for Perfluoroalkyls,* which covers 10 PFAS including PFHxS and PFNA, represents the best available peer-reviewed scientific information on the human health effects of PFHxS and PFNA. ATSDR minimal risk levels for PFHxS and PFNA are appropriate for use under SDWA because ATSDR uses scientifically credible approaches, its work is internally and externally peer-reviewed and undergoes public comment, and its work represents the current best available science for these two chemicals. The 2021 ATSDR *Toxicological Profile for Perfluoroalkyls* underwent intra- and interagency review and subsequent external peer review by seven experts with knowledge of toxicology, chemistry, and/or health effects.

The agency acknowledges that ATSDR minimal risk levels and EPA RfDs are not identical. The two agencies sometimes develop toxicity values for different exposure durations (*e.g.,* intermediate, chronic) and/or apply different uncertainty/modifying factors to reflect data limitations. Additionally, ATSDR minimal risk levels and EPA RfDs are developed for different purposes: ATSDR minimal risk levels are intended to serve as screening levels and are used to identify contaminants and potential health effects that may be of concern at contaminated sites, whereas EPA RfDs are used to support regulatory and nonregulatory actions, limits, and recommendations in various environmental media. However, from a practical standpoint, an oral minimal risk level and an oral RfD both represent the level of daily oral human exposure to a hazardous substance for a specified duration of exposure below which adverse health effects are not anticipated to occur. The EPA has routinely used and continues to use ATSDR minimal risk levels in human health assessments when they represent the best available science—for example, in the context of Clean Air Act section 112(f)(2) risk assessments in support of setting national emission standards for Hazardous Air Pollutants (HAPs), developing Clean Water Act ambient water quality criteria, evaluating contaminants for the CCL, and site evaluations under the Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

Some commenters questioned the EPA's external peer-review process for the four underlying final toxicity assessments used to calculate the HRLs/HBWCs. Some commenters noted that the EPA does not yet have completed Integrated Risk Information System (IRIS) assessments for PFHxS and PFNA, questioning the EPA's use of non-EPA assessments (see above). The EPA notes that all four toxicity assessments containing the toxicity values (RfD or minimal risk level) used to calculate the HRLs/HBWCs (*i.e.,* the EPA human health toxicity assessments for HFPO–DA and PFBS (USEPA, 2021a; USEPA, 2021b) and the ATSDR toxicity assessments of PFNA and PFHxS (ATSDR, 2021)) underwent rigorous, external peer review (ATSDR, 2021; USEPA, 2021a; USEPA, 2021b). The EPA is not required under SDWA to exclusively use EPA assessments to support an NPDWR, and in fact, SDWA's clear direction in section 1412(b)(3)(A)(i) is to use the best *available,* peer-reviewed science when developing NPDWRs (emphasis added). Final EPA assessments for PFHxS and PFNA are under development but are not currently available; final, peer reviewed ATSDR assessments are available.

Other commenters offered critical comments on the HRLs/HBWCs for PFHxS, PFNA, HFPO–DA, and PFBS and raised technical and process concerns with the underlying human health assessments. Some commenters asserted that the human health toxicity values (EPA RfDs, ATSDR minimal risk levels) upon which the HRLs/HBWCs are based have too much uncertainty (*e.g.,* inappropriately apply a composite uncertainty factor (UF) of 3,000) and are therefore inadequate to support a SDWA regulatory determination. The EPA disagrees with these comments. The HRLs/HBWCs are data-driven values that incorporate UFs based on the EPA guidance and guidelines thus, represent the levels below which adverse health effects are not expected to occur over a lifetime. According to the EPA guidelines and longstanding practices (USEPA, 2002a; USEPA, 2022f), UFs reflect the limitations of the data across the five areas used in the current EPA human health risk assessment development: (1) human interindividual

variability (UF_H); (2) extrapolation from animal to human (UF_A); (3) subchronic-to-chronic duration extrapolation (UF_S); (4) lowest-observed-adverse-effect level-to-no-observed-adverse-effect level (LOAEL-to-NOAEL) extrapolation (UF_L); and (5) database uncertainty (UF_D). In minimal risk level development, ATSDR also applies uncertainty factors as appropriate to address areas of uncertainty, with the exception of subchronic-to-chronic duration extrapolation (ATSDR, 2021). For the ATSDR minimal risk levels on which the HRLs/HBWCs for PFNA and PFHxS are based, ATSDR utilized UF_Hs, UF_As, and what ATSDR calls a modifying factor to address database deficiencies (equivalent to the EPA's UF_D) (ATSDR, 2021). The EPA carefully reviewed ATSDR's application of uncertainty and modifying factors for PFNA and PFHxS and applied additional uncertainty factors as warranted. Specifically, the EPA applied an additional UF (UF_S) for PFHxS to extrapolate from subchronic to chronic duration per agency guidelines (USEPA, 2002a) and standard practice because the critical effect was not observed during a developmental lifestage (*i.e.,* the effect was in parental male rats). A chronic toxicity value (*i.e.,* RfD, MRL) represents the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime; the EPA is using a chronic toxicity value to derive the MCLG to ensure that it is set at a level at or below which no known or anticipated adverse effects on human health occur and allowing an adequate margin of safety. The EPA guidelines indicate that the composite (total) UF may be equal to or below 3,000; composite UFs greater than that represent ''excessive uncertainty'' (USEPA, 2002a; USEPA, 2022f). In the case of this final NPDWR, a composite UF of 3,000 was appropriately applied to derive toxicity values used to develop HRLs/HBWCs for two of the four PFAS (HFPO–DA and PFHxS) following peer-reviewed agency guidance and longstanding practice (see USEPA (2024f) for complete discussion of UF application for all four PFAS). The EPA has previously developed an MCLG for a chemical that had a composite UF of 3,000 applied to derive a toxicity value (*e.g.,* thallium [USEPA, 1992]). Further, a composite uncertainty factor of 3,000 has been applied in the derivation of oral RfDs for several chemicals that have been evaluated within the EPA's IRIS (Integrated Risk Information System) program (*e.g.,* fluorene, cis- and trans-1,2-dichloroethylene, 2,4-dimethylphenol; please see the EPA's IRIS program website [*https://www.epa.gov/iris*] for further information).

Some commenters opposed the EPA's application of a 20 percent RSC (relative source contribution) in the HRL/HBWC calculations and stated that it was a ''conservative default'' approach not supported by available information and that adequate exposure data exist to justify an RSC other than 20 percent (although commenters did not offer a suggested alternative RSC). The EPA disagrees with these comments. The EPA applies an RSC to account for potential aggregate risk from exposure routes and exposure pathways other than oral ingestion of drinking water to ensure that an individual's total exposure to a contaminant does not exceed the daily exposure associated with toxicity (*i.e.,* threshold level or reference dose). Application of the RSC in this context is consistent with EPA methods (USEPA, 2000d) and long-standing EPA practice for establishing drinking water MCLGs and NPDWRs (*e.g.,* see USEPA, 1989; USEPA, 2004; USEPA, 2010). The RSC represents the proportion of an individual's total exposure to a contaminant that is attributed to drinking water ingestion (directly or indirectly in beverages like coffee, tea, or soup, as well as from dietary items prepared with drinking water) relative to other exposure pathways. The remainder of the exposure equal to the RfD (or minimal risk level) is allocated to other potential exposure sources (USEPA, 2000d). The purpose of the RSC is to ensure that the level of a contaminant (*e.g.,* MCLG) in drinking water, when combined with other identified potential sources of exposure for the population of concern, will not result in total exposures that exceed the RfD (or minimal risk level) (USEPA, 2000d). This ensures that the MCLG under SDWA meets the statutory requirement that it be a level of a contaminant in drinking water at or below which no known or anticipated adverse effects on human health occur and allowing an adequate margin of safety.

To determine the RSCs for the four HRLs/HBWCs, the agency assessed the available scientific literature on potential sources of human exposure other than drinking water. The EPA conducted literature searches and reviews for each of the four HRLs/HBWCs to identify potential sources of exposure and physicochemical properties that may influence occurrence in environmental media (Deluca et al., 2022; USEPA, 2024f). Considering this exposure information, the EPA followed its longstanding, peer-reviewed Exposure Decision Tree Approach in the EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000d) to determine the RSC for each PFAS. As discussed by the EPA in the Hazard Index MCLG document (USEPA, 2024f), the EPA carefully evaluated studies that included information on potential exposure to these four PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) via sources other than drinking water, such as food, soil, sediment, and air. For each of the four PFAS, the findings indicated that there are significant known or potential uses/sources of exposure beyond drinking water ingestion (*e.g.,* food, indoor dust) (Box 6 in the EPA Exposure Tree; USEPA, 2000d), but that data are insufficient to allow for quantitative characterization of the different exposure sources (Box 8A in USEPA, 2000d). The EPA's Exposure Decision Tree approach states that when there are insufficient environmental and/or exposure data to permit quantitative derivation of the RSC, the recommended RSC for the general population is 20 percent (Box 8B in USEPA, 2000d). This means that 20 percent of the exposure equal to the RfD is allocated to drinking water, and the remaining 80 percent is attributed to all other potential exposure sources.

Some commenters disagreed with the bodyweight-adjusted drinking water intake (DWI–BWs) that the EPA used to calculate the HRLs/HBWCs and thought the selected DWI–BWs were too high (overly health protective). One commenter stated that the DWI–BW used in the calculation of the HRL/HBWC for HFPO–DA is inappropriate and that the EPA should have used a DWI–BW for general population adults instead of for lactating women. The EPA disagrees with this comment. To select an appropriate DWI–BW for use in derivation of the HRL/HBWC for HFPO–DA, the EPA considered the HFPO–DA exposure interval used in the oral reproductive/developmental toxicity study in mice that served as the basis for chronic RfD derivation (the critical study). In this study, parental female mice were dosed from pre-mating through lactation, corresponding to three potentially sensitive human adult life stages that may represent critical windows of HFPO–DA exposure: women of childbearing age, pregnant women, and lactating women (Table 3–63 in USEPA, 2019a). Of these three, the highest DWI–BW, for lactating women (0.0469 L/kg/day), is anticipated to be protective of the other two sensitive life

stages and was used to calculate the HRL/HBWC for HFPO–DA (USEPA, 2024f).

Other commenters urged the EPA to consider infants as a sensitive life stage for PFHxS, PFNA, and PFBS and use the DWI–BW for infants to calculate the HRLs/HBWCs. The EPA disagrees with this comment. The EPA's approach to DWI–BW selection includes a step to identify the sensitive population(s) or life stage(s) (*i.e.,* those that may be more susceptible or sensitive to a chemical exposure) by considering the available data for the contaminant, including the adverse health effects observed in the toxicity study on which the RfD/minimal risk level was based (known as the critical effect within the critical or principal study). Although data gaps can complicate identification of the most sensitive population (*e.g.,* not all windows or life stages of exposure and/or health outcomes may have been assessed in available studies), the critical effect and point of departure (POD) that form the basis for the RfD (or minimal risk level) can provide some information about sensitive populations because the critical effect is typically observed at the lowest tested dose among the available data. Evaluation of the critical study, including the exposure window, may identify a sensitive population or life stage (*e.g.,* pregnant women, formula-fed infants, lactating women). In such cases, the EPA can select the corresponding DWI–BW for that sensitive population or life stage from the *Exposure Factors Handbook* (USEPA, 2019a). DWI–BWs in the *Exposure Factors Handbook* are based on information from publicly available, peer-reviewed studies, and were updated in 2019. In the absence of information indicating a sensitive population or life stage, the DWI–BW corresponding to the general population may be selected. Following this approach, the EPA selected appropriate DWI–BWs for each of the four PFAS included in the Hazard Index MCLG (see USEPA, 2024f). The EPA did consider infants as a sensitive life stage for all four PFAS; however, the agency did not select the infant DWI–BW because the exposure intervals of the critical studies supporting the chronic toxicity values did not correspond to infants. Instead, the exposure intervals were relevant to other sensitive target populations (*i.e.,* lactating women or women of childbearing age) or the general population. (See also comments related to DWI–BW selection under PFBS section III.B.6.d. of this preamble).

a. PFHxS

Some commenters noted a typographical error in the HRL/HBWC calculation for PFHxS which was reported as 9.0 ng/L in the proposal. The agency has corrected the value in this NPDWR and within the requirements under 40 CFR part 141, subpart Z. The correct HRL/HBWC for PFHxS is 10 ng/L.

Two commenters questioned the human relevance of thyroid effects (*i.e.,* changes in tissue structure (*e.g.,* enlarged cells; increased numbers of cells) in the thyroids of adult male rats) observed in the critical study used to derive the ATSDR minimal risk level and the EPA's PFHxS HRL/HBWC because, as noted in the ATSDR *Toxicological Profile for Perfluoroalkyls,* this observed effect may have been secondary to liver toxicity and, therefore, the commenters state that its significance is unclear. The EPA disagrees with this comment. SDWA requires that the EPA use ''the best available, peer reviewed science'' to inform decision making on drinking water regulations. Although there is some uncertainty regarding the selection of thyroid alterations as the critical effect (as the ATSDR toxicological profile notes), at this time, the 2021 ATSDR toxicological profile represents the best available peer reviewed scientific information regarding the human health effects of PFHxS. As the most sensitive known effect as supported by the weight of the evidence, the thyroid effect was appropriately selected by ATSDR as the critical effect. Additionally, published studies in rats have shown that PFHxS exposure results in other thyroid effects, including decreases in thyroid hormone (primarily T4) levels in serum (NTP, 2018a; Ramhøj et al., 2018). Similarly, peer-reviewed final EPA assessments of other PFAS, including PFBS (USEPA, 2021a) and perfluorobutanoic acid (PFBA) (USEPA, 2022g), have concluded that these changes in rodents are adverse and human-relevant, and appropriate for RfD derivation. Furthermore, it is appropriate to use other health protective (toxicity) values developed by other authoritative governmental agencies, including ATSDR minimal risk levels, if available, as these agencies use scientifically credible approaches and their work is peer-reviewed (the ATSDR toxicological profile underwent intra- and interagency review and external peer review by seven experts with knowledge of toxicology, chemistry, and/or health effects). The ATSDR minimal risk levels reflect the best available, peer-reviewed science.

Furthermore, the EPA's draft *IRIS Toxicological Review of Perfluorohexanesulfonic Acid (PFHxS) and Related Salts (Public Comment and External Review Draft)* (USEPA, 2023d), which is in the public domain, preliminarily provides confirmatory evidence that PFHxS significantly affects human development (emphasis added): ''Overall, the available evidence indicates that *PFHxS exposure is likely to cause thyroid and developmental immune effects in humans,* given sufficient exposure conditions. For thyroid effects, the primary supporting evidence for this hazard conclusion included evidence of decreased thyroid hormone levels, abnormal histopathology results, and changes in organ weight in experimental animals. For immune effects, the primary supporting evidence included decreased antibody responses to vaccination against tetanus or diphtheria in children.'' Although the EPA did not rely on this draft IRIS toxicological review for PFHxS in this rule, the draft is available to the public and offers confirmation that PFHxS elicits developmental effects in humans.

b. PFNA

Some commenters questioned the human relevance of developmental effects observed in PFNA animal studies (*i.e.,* decreased body weight gain, delayed eye opening, delayed sexual maturation) used to derive the ATSDR minimal risk level and the EPA's PFNA HRL/HBWC. The EPA disagrees with this comment. At this time, the 2021 ATSDR *Toxicological Profile for Perfluoroalkyls* represents the best available peer-reviewed scientific information regarding the human health effects of PFNA. In addition, according to the March 2023 *Interagency PFAS Report to Congress,* PFNA is documented to affect the developmental health domain (United States OSTP, 2023), and a recently published meta-analysis (Wright et al., 2023) specifically supports decreases in birth weight as an effect of PFNA exposure in humans. Published studies have shown that PFNA exposure results in statistically significant, dose-responsive developmental effects, including reduced fetal/pup bodyweight, reduced fetal/pup survival, changes in fetal/pup liver gene expression, increased fetal/pup liver weight, and delayed onset of puberty. Also, the EPA's 1991 *Guidelines for Developmental Toxicity Risk Assessment* (USEPA, 1991a; pp. vii-ix and pp. 1–2) cites evidence that, in the absence of clear evidence to the

contrary, developmental effects observed in experimental animals are interpreted as relevant to humans.

c. HFPO–DA

A few commenters submitted critical comments related to the adverse health effects associated with exposure to HFPO–DA and how these health effects are quantified to derive the RfD in the human health toxicity assessment for HFPO–DA (USEPA, 2021b). Commenters claimed that the RfD for HFPO–DA is not scientifically sound, and cited one or more of the following reasons why: (1) the selected critical effect from the study (constellation of liver lesions) includes different liver effects that were not consistently observed across male and female mice and were not necessarily all adverse; (2) the hepatic effects in mice (the selected critical effect) are mediated by a rodent specific MOA, peroxisome proliferator-activated receptor alpha (PPARα), and therefore not relevant to humans; (3) the EPA incorporated results of a pathology working group which misapplied diagnostic criteria classifying apoptotic and necrotic lesions; and (4) the EPA misapplied uncertainty factors (UFs) (*i.e.,* the subchronic to chronic UF and database UF) according to agency guidance resulting in the maximum possible UF of 3,000 (USEPA, 2002a; USEPA, 2022f). Another commenter thought that the interspecies UF should be further increased. Also, some commenters stated that the EPA did not properly consider all available epidemiological data. These comments are addressed in this preamble.

Overall, the EPA disagrees with the commenters and maintains that the final published peer-reviewed human health toxicity assessment that derived the RfD for HFPO–DA is appropriate and sound, reflects the best available peer-reviewed science, and is consistent with agency guidance, guidelines, and best practices for human health risk assessment. Notably, the EPA sought external peer review of the toxicity assessment *twice* (USEPA, 2018b; USEPA, 2021f), released the draft toxicity assessment for public comment and provided responses to public comment (USEPA, 2021g), and engaged a seven-member pathology working group at the National Institutes of Health—an entirely separate and independent organization—to re-analyze pathology slides from two critical studies (USEPA, 2021b, appendix D), all of which supported the EPA's conclusions in the toxicity assessment, including the RfD derivation.

Regarding critical effect selection: the EPA's approach to critical effect selection for the RfD derivation considers a range of factors, including dose at which effects are observed, biological variability (which can produce differences in effects observed between sexes), and relevance of the effect(s) seen in animals to human health. The EPA maintains that selection of the constellation of liver lesions as the critical effect for HFPO–DA RfD derivation is appropriate and scientifically justified, and that the constellation of liver lesions represents an adverse effect. The EPA engaged a pathology working group within the National Toxicology Program (NTP) at the National Institutes of Health to perform an independent analysis of the liver tissue slides. The pathology working group determined that the tissue slides demonstrated a range of adverse effects and that the constellation of liver effects caused by HFPO–DA exposure, which included cytoplasmic alteration, apoptosis, single cell necrosis, and focal necrosis, constitutes an adverse liver effect in these studies (USEPA, 2021b, appendix D). The EPA evaluated the results of the pathology working group and determined that the effects were relevant to humans according to the best available science (*e.g.,* Hall et al., 2012). Additionally, the EPA convened a second independent peer-review panel of human health risk assessment experts to review the EPA's work on HFPO–DA, including critical effect selection. The panel unanimously agreed with the selection of the constellation of liver lesions as the critical effect, the adversity of this effect and its relevance to humans (USEPA, 2021f).

The commenters' assertion that the hepatic effects observed in mice are not relevant to humans because they are PPARα-mediated is unsupported. The commenter claims that one specific effect—apoptosis—can be PPARα-mediated in rodents (a pathway that some data suggest may be of limited or no relevance to humans). However, in supporting studies cited by commenters, a decrease in apoptosis is associated with a PPARα MOA, with Corton et al. (2018) stating, ''[t]he data indicate that a physiological function of PPARα activation is to increase hepatocyte growth through an increase in hepatocyte proliferation or a decrease in apoptosis or a combination of both effects'' while HFPO–DA is associated with increased apoptosis (USEPA, 2021b). Therefore, the commenter's claim that apoptosis is associated with the known PPARα MOA is unsupported. the critical study selected by the EPA, and indeed other studies as well, reported not only apoptosis but also other liver effects such as necrosis that are not associated with a PPARα MOA and therefore are relevant for human health (Hall et al., 2012). Further, according to the available criteria, effects such as cytoplasmic alteration in the presence of liver cell necrosis are considered relevant to humans (Hall et al., 2012). Additionally, commenters asserted that a 2020 study by Chappell et al. reported evidence demonstrating that the rodent liver effects are not relevant to humans, and that the EPA failed to consider this study. It is important to note that while Chappell et al. (2020) was published after the assessment's literature search cut-off date (USEPA, 2021b, appendix A; USEPA, 2022h), the EPA considered this paper initially through the Request for Correction process (USEPA, 2022h) and noted that this study specifically assessed evidence for PPARα-driven apoptosis and did not investigate other potential modes of action or types of cell death, specifically necrosis. The authors state that they could ''not eliminate the possibility that necrotic cells were also present.'' The EPA again considered Chappell et al., (2020), in addition to other studies submitted through public comment (Heintz et al., 2022; Heintz et al., 2023; Thompson et al., 2023), and determined that these studies do not fully explore a necrotic/cytotoxic MOA with Thompson et al., 2023 stating that ''there are no gene sets for assessing necrosis in transcriptomic databases.'' Critically, the commenter and these cited studies fail to recognize that increased apoptosis is a key criterion to establish a cytotoxic MOA. As outlined in the toxicity assessment (USEPA, 2021b), Felter et al., (2018) ''identified criteria for establishing a cytotoxicity MOA, which includes: . . . (2) clear evidence of cytotoxicity by histopathology, such as presence of necrosis and/or increased apoptosis.'' Overall, the EPA has determined that these studies support the mechanistic conclusions of the toxicity assessment ''that multiple MOAs could be involved in the liver effects observed after GenX chemical exposure'' including PPARα and cytotoxicity (USEPA, 2021b).

With respect to claims that the EPA misapplied diagnostic criteria classifying apoptotic and necrotic lesions: as mentioned above, the EPA engaged a pathology working group within the NTP at the National Institutes of Health to perform an independent analysis of the liver tissue slides. Seven pathologists—headed by Dr. Elmore, who was the lead author of the pathology criteria that the

commenter cites (Elmore et al., 2016)—concluded that exposure to HFPO–DA caused a ''constellation of liver effects'' that included cytoplasmic alteration, apoptosis, single cell necrosis, and focal necrosis, and that this full ''constellation of lesions'' should be considered the adverse liver effect within these studies. The EPA then used the established Hall criteria (Hall et al., 2012) to determine that since liver cell death was observed, all effects, including cytoplasmic alteration, were considered adverse and relevant to humans.

The EPA disagrees with the commenters' assertion about UF application. As noted above, agency guidance (USEPA, 2002a; USEPA, 2022f) have established the appropriateness of the use of UFs to address uncertainty and account for data limitations. UFs reflect the limitations of the data across the five areas used in the current EPA human health risk assessment development (referenced above); all individual UFs that are applied are multiplied together to yield the composite or total UF. The EPA guidance dictates that although a composite UF greater than 3,000 represents ''excessive uncertainty'' (USEPA, 2002a; USEPA, 2022f), a composite UF can be equal to 3,000. For HFPO–DA, a composite UF of 3,000 was appropriately applied to account for uncertainties, including variability in the human population, database uncertainties, and possible differences in the ways in which humans and rodents respond to HFPO–DA that reaches their tissues. Furthermore, the composite UF of 3,000 and specifically the database UF and subchronic-to-chronic UF used for HFPO–DA was peer-reviewed by a panel of human health risk assessment experts, and the panel supported the application of the database UF of 10 and the subchronic-to-chronic UF of 10 (USEPA, 2021f). Additionally, a UF_A of 3 was appropriately applied, consistent with peer-reviewed EPA methodology (USEPA, 2002a), to account for uncertainty in characterizing the toxicokinetic and toxicodynamic differences between rodents and humans. As noted in the toxicity assessment for HFPO–DA (USEPA, 2021b), in the absence of chemical-specific data to quantify residual uncertainty related to toxicokinetics and toxicodynamic processes, the EPA's guidelines recommend use of a UF_A of 3.

Finally, some commenters claimed that the EPA did not consider available epidemiological evidence showing no increased risk of cancers or liver disease attributable to exposure to HFPO–DA. The EPA disagrees with this comment because the agency considered all available scientific evidence, including epidemiological studies (USEPA, 2021b). The exhibit submitted by the commenter presents an observational analysis comparing cancer and liver disease rates in North Carolina to rates in other states. It does not present the results of a new epidemiological study that included HFPO–DA exposure measures, health outcome measures, or an assessment of association between exposure and health outcome. The exhibit submitted by the commenter consists of a secondary analysis of disease rate information that was collected from various sources and does not provide new, high-quality scientific information that can be used to assess the impact of exposure to concentrations of HFPO–DA on human health.

d. PFBS

A few commenters suggested that the EPA lower the HRL/HBWC for PFBS to account for thyroid hormone disruption during early development and cited the Washington State Action Level for PFBS, which is 345 ng/L. Washington State used the same RfD (3E–04 mg/kg-d) but a higher DWI–BW to develop their Action Level as compared to the EPA's HRL/HBWC (Washington State used the 95th percentile DWI–BW of 0.174 L/kg/day for infants, whereas the EPA selected the 90th percentile DWI–BW of 0.0354 L/kg/day for women of child-bearing age). The EPA disagrees that the infant DWI–BW is more appropriate for HRL/HBWC calculation. The EPA selected the thyroid hormone outcome (decreased serum total thyroxine in newborn mice seen in a developmental toxicity study) as the critical effect in its PFBS human health toxicity assessment (USEPA, 2021a). Notably, the RfD derived from this critical effect included application of a 10X UF to account for life-stage-specific susceptibility (UF_H). To select a DWI–BW for use in deriving the HRL/HBWC for PFBS, the EPA followed its established approach of considering the PFBS exposure interval used in the developmental toxicity study in mice that was the basis for chronic RfD derivation. In this study, pregnant mice were exposed throughout gestation, which is relevant to two human adult life stages: women of child-bearing age who may be or become pregnant, and pregnant women and their developing embryos or fetuses (Table 3–63 in USEPA, 2019a). To be clear, the critical study exposed mice to PFBS only during pregnancy and not during postnatal development; newborn mice in early postnatal development, which would correspond to the human infancy life stage, were not exposed to PFBS. Of the two relevant adult stages, the EPA selected the 90th percentile DWI–BW for women of child-bearing age (0.0354 L/kg/day) to derive the HRL/HBWC for PFBS because it is the higher of the two, and therefore more health-protective. Please see additional information related to DWI–BW selection above.

Other commenters stated that the EPA's human health toxicity assessment for PFBS is overly conservative, uncertain, and that the confidence in the chronic RfD is low. The EPA disagrees with these comments. Confidence in the critical study (Feng et al., 2017) and corresponding thyroid hormone critical effect in newborn mice was rated by the EPA as 'High;' this rating was a result of systematic study evaluation and risk of bias analysis by a team of EPA experts. The Feng et al. (2017) study, the critical effect of thyroid hormone disruption in offspring, dose-response assessment, and corresponding RfD were subjected to extensive internal EPA, interagency, and public/external peer review. While confidence in the critical study was rated 'High,' the 'Low' confidence rating for the PFBS chronic RfD was in part a result of the lack of a chronic exposure duration study in any mammalian species; this lack of a chronic duration study was one of the considerations that resulted in the EPA applying a UF of 10 to account for database limitations (UF_D). Based on the EPA's human health assessment practices, the lowest confidence rating across the areas of consideration (*e.g.,* existent hazard/dose-response database) is assigned to the corresponding derived reference value (*e.g.,* RfD). Thus, the EPA has high confidence in the critical study (Feng et al., 2017) and critical effect/thyroid endpoint, but the database is relatively limited. Although the PFBS RfD was based on best available peer-reviewed science, there is uncertainty as to the hazard profile associated with PFBS after prolonged (*e.g.,* lifetime) oral exposure. In the toxicity assessment for PFBS (USEPA, 2021a), the EPA noted data gaps in specific health effects domains, as is standard practice. Toxicity assessments for most chemicals identify data gaps; the issue of uncertainty due to toxicological study data gaps is not unique to PFBS. Data gaps are considered when selecting the UF_D because they indicate the potential for exposure to lead to adverse health effects at doses lower than the POD derived from the assessment's critical

study. There is a potential that effects with greater dose-response sensitivity (*i.e.,* occurring at lower daily oral exposures) might be discovered from a chronic duration exposure study. Due to this uncertainty, the EPA applied a UF_D of 10.

One commenter questioned the EPA's approach to estimating the human equivalent dose (HED) from the animal data using toxicokinetic (TK) data rather than using default body-weight scaling and suggested that the default allometric approach is more appropriate for estimating an HED. The EPA disagrees with this comment. In human health risk assessment practice, the EPA considers a hierarchical approach to cross-species dosimetric scaling consistent with technical guidance to calculate HEDs (USEPA, 2011; see pp. X–XI of the Executive Summary in '*Recommended Use of Body Weight$^{3/4}$ as the Default Method in Derivation of the Oral Reference Dose*'). The preferred approach is physiologically based toxicokinetic (PBTK) modeling; however, there are rarely sufficient chemical-specific data to properly parameterize such a model. In the absence of a PBTK model, the EPA considers an intermediate approach in which chemical-specific data across species, such as clearance or plasma half-life, are used to calculate a dosimetric adjustment factor (DAF) (USEPA, 2011). If chemical-specific TK data are not available, only then is a default approach used wherein allometric scaling, based on body weight raised to the ¾ power, is used to calculate a DAF. The human health toxicity assessment for PFBS invoked the intermediate approach, consistent with guidance, as TK data were available for humans and rodents.

e. Mixtures of PFHxS, PFNA, HFPO–DA, and PFBS

Comments on the EPA's preliminary regulatory determination on the mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS were varied. Many commenters supported the EPA's proposal to regulate a mixture of these PFAS and agreed with the EPA's scientific conclusions about PFAS dose additivity. Many commenters urged the EPA to consider making a determination to regulate for additional PFAS (in a mixture) or all PFAS as a class. As described throughout section III of this preamble, the agency is required to demonstrate a contaminant meets the SDWA statutory criteria to make a regulatory determination. In this preamble, in addition to PFOA and PFOS which the EPA has already made a final determination to regulate, the agency is making final determinations for all PFAS with sufficiently available information to meet these statutory criteria either individually and/or as part of mixture combinations. As information becomes available, the agency will continue to evaluate other PFAS for potential future preliminary regulatory determinations.

Many commenters opposed the EPA's conclusion about PFAS dose additivity and use of the Hazard Index approach to regulate co-occurring PFAS. A few commenters agreed with the EPA's decision to regulate mixtures of certain PFAS and the EPA's conclusion about dose additivity but questioned the EPA's use of the general Hazard Index, and instead, suggested alternative approaches. Please see section IV of this preamble for a summary of comments and the EPA responses on the Hazard Index MCLG and related topics.

There is substantial evidence that PFHxS, PFNA, HFPO–DA, and PFBS act in a dose additive manner, that these four PFAS elicit similar health effects, and that exposure to mixtures of these PFAS may have adverse health effects. Following is a discussion of dose additivity and similarity of adverse effects of PFHxS, PFNA, HFPO–DA, and PFBS.

As noted in this section, the available data indicate that PFHxS, PFNA, HFPO–DA, and PFBS, while not necessarily toxicologically identical, elicit many of the same or similar adverse health effects across different levels of biological organization, tissues/organs, lifestages, and species (ATSDR, 2021; EFSA et al., 2018; EFSA et al., 2020; USEPA, 2021d; USEPA, 2021f; USEPA, 2024f). Each of these PFAS disrupts signaling of multiple biological pathways, resulting in a shared set of adverse effects including effects on thyroid hormone levels, lipid synthesis and metabolism, development, and immune and liver function (ATSDR, 2021; EFSA et al., 2018; EFSA et al., 2020; USEPA, 2021d; USEPA, 2021f; USEPA, 2024f). Please also see USEPA (2024a) for an overview of recent studies that provide supportive evidence of similar effects of PFAS.

Available health effects studies indicate that PFAS mixtures act in a dose-additive manner when the individual components share some health endpoints/outcomes. Individual PFAS, each at doses that are not anticipated to result in adverse health effects, when combined in a mixture may result in adverse health effects. Dose additivity means that when two or more of the component chemicals (in this case, PFHxS, PFNA, HFPO–DA, and/or PFBS) exist in one mixture, the risk of adverse health effects following exposure to the mixture is equal to the sum of the individual doses or concentrations scaled for potency (USEPA, 2000a). Thus, exposure to these PFAS, at doses that individually would not likely result in adverse health effects, when combined in a mixture may pose health risks.

Many commenters supported the EPA's scientific conclusions about PFAS dose additivity and agreed that considering dose-additive effects is a health-protective approach. Many other commenters disagreed with the EPA's scientific conclusions regarding PFAS dose additivity and a few commenters questioned the agency's external peer-review process and whether the agency sufficiently responded to SAB (Science Advisory Board) comments. For example, these commenters stated that the evidence base of PFAS mixture studies is too limited to support dose additivity for these four PFAS and recommended that the EPA re-evaluate its conclusion about dose additivity as new data become available. A few commenters stated that the EPA failed to adequately follow the SAB recommendation that ''discussion of studies of toxicological interactions in PFAS mixtures in the EPA mixtures document be expanded to also include studies that do not indicate dose additivity and/or a common MOA [mode of action] for PFAS.'' The EPA's responses to these comments are summarized in this section.

The EPA continues to support its conclusion that PFAS that elicit similar adverse health effects following individual exposure should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise. Numerous published studies across multiple chemical classes, biological effects, and study designs support a dose-additive mixture assessment approach for PFAS because they demonstrate that experimentally observed responses to exposure to PFAS and other chemical mixtures are consistent with modeled predictions of dose additivity (see the EPA's *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* (USEPA, 2024a)). Since the EPA's draft PFAS Mixtures Framework underwent SAB review in 2021, new studies from the EPA and others have published robust evidence of combined toxicity of PFAS in mixtures, corroborating and confirming earlier findings (*e.g.,* Conley et al., 2022a; Conley et al., 2022b; USEPA, 2023c; see USEPA, 2024a for additional examples). Additionally, the National Academies of

Sciences, Engineering, and Medicine (NASEM, 2022) recently recommended that clinicians apply an additive approach for evaluating patient levels of PFAS currently measured in the National Health and Nutrition Examination Survey (NHANES) in order to protect human health from additive effects from PFAS co-exposure.

The EPA directly asked the SAB for feedback on PFAS dose additivity in the charge for the 2021 review of the EPA's draft PFAS Mixtures Framework. Specifically, the EPA asked the SAB to, ''[p]lease comment on the appropriateness of this approach for a component-based mixture evaluation of PFAS under an assumption of dose additivity'' (USEPA, 2022i). The SAB strongly supported the scientific soundness of this approach when evaluating PFAS and concurred that it was a health protective conclusion. For example, the SAB said:

> . . . The information included in the draft framework supports the conclusion that toxicological interactions of chemical mixtures are frequently additive or close to additive. It also supports the conclusion that dose additivity is a public health protective assumption that typically does not underestimate the toxicity of a mixture . . . (USEPA, 2022i)
>
> The SAB Panel agrees with use of the default assumption of dose additivity when evaluating PFAS mixtures that have similar effects and concludes that this assumption is health protective. (USEPA, 2022i)

Regarding the commenters' assertion that the agency did not adequately follow the SAB recommendation to expand its discussion of PFAS mixtures study results that did not show evidence of dose additivity and/or a common MOA, the EPA disagrees. The EPA reviewed all studies provided by the SAB and in response, included a discussion of relevant additional studies in its public review draft PFAS Mixtures Framework (see section 3 in USEPA, 2023w). Since then, the EPA has included additional published studies and those findings further confirm dose additive health concerns associated with PFAS mixtures (see section 3 in USEPA, 2024a). Data from *in vivo* studies that rigorously tested accuracy of Dose Additivity (DA), Integrated Addition (IA), and Response Additivity (RA) model predictions of mixtures with components that disrupted common pathways demonstrated that DA models provided predictions that were better than or equal to IA and RA predictions of the observed mixture effects (section 3.2 in USEPA, 2024a). The National Academy of Sciences (NAS) conclusions on phthalates (and related chemicals) (NRC, 2008) and systematic reviews of the published literature (Boobis et al., 2011 and Martin et al., 2021; see also section 3.2 in USEPA, 2024a) support DA as the default model for estimating mixture effects in some circumstances, even when the mixtures included chemicals with diverse MOAs (but common target organs/effects) (Boobis et al., 2011; Martin et al., 2021; USEPA, 2024a). Recent efforts to investigate *in vitro* and *in vivo* PFAS mixture effects have provided robust evidence that PFAS behave in a dose-additive manner (see section 3 in USEPA, 2024a).

As supported by the best available science, the SAB, the agency's chemical mixtures guidance (USEPA, 1991b; USEPA, 2000a), and the EPA Risk Assessment Forum's *Advances in Dose Addition for Chemical Mixtures: A White Paper* (USEPA, 2023c), the EPA proposed a Hazard Index MCLG for a mixture of up to four PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) based on dose additivity because published studies show that exposure to each of these individual four PFAS elicits some of the same or similar adverse health effects/outcomes. As noted above, many commenters, as well as the SAB (USEPA, 2022i), supported this conclusion of dose additivity based on similarity of adverse effects.

While the SAB also noted that there remain some questions about PFAS interaction in mixtures (USEPA, 2022i), the available data justify an approach that accounts for PFAS dose additivity. Studies that have assessed PFAS mixture-based effects do not offer evidence for synergistic/antagonistic effects (USEPA, 2024a). For example, Martin et al. (2021), following a review of more than 1,200 mixture studies (selected from > 10,000 reports), concluded that there was little evidence for synergy or antagonism among chemicals in mixtures and that dose additivity should be considered as the default. Experimental data demonstrate that PFAS disrupt signaling in multiple biological pathways resulting in common adverse effects on several of the same biological systems and functions including thyroid hormone signaling, lipid synthesis and metabolism, developmental toxicity, and immune and liver function (USEPA 2024a). Additionally, several EPA Office of Research and Development (ORD) studies provide robust evidence that PFAS behave in a dose-additive manner (Conley et al., 2022a; Conley et al., 2022b; Conley et al., 2023; Gray et al., 2023).

Several commenters opposed the conclusion of dose additivity based on similarity of adverse effects and stated that the EPA failed to establish that the four PFAS included in the Hazard Index (PFHxS, PFNA, HFPO–DA, and PFBS) elicit similar adverse health effects. The EPA disagrees with these comments because the available epidemiology and animal toxicology studies demonstrate that these four PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) have multiple health endpoints and outcomes in common (USEPA, 2024f). Further, these four PFAS are well-studied PFAS for which the EPA or ATSDR have developed human health assessments and toxicity values (*i.e.,* RfDs, minimal risk levels). As shown in Table 1, available animal toxicological data and/or epidemiological studies demonstrate that PFHxS, PFNA, HFPO–DA, and PFBS are documented to affect at least five (5) of the same health outcomes for this evaluation: lipids, developmental, immune, endocrine, and hematologic (USEPA, 2024g). Similarly, according to the 2023 Interagency PFAS Report to Congress (United States OSTP, 2023), available animal toxicological data show that PFHxS, PFNA, HFPO–DA, and PFBS are documented to significantly affect at least eight (8) of the same major health effect domains: body weight, respiratory, hepatic, renal, endocrine, immunological, reproductive, and developmental. In short, multiple evaluation efforts have clearly demonstrated that each of the PFAS regulated by this NPDWR impact numerous of the same or similar health outcomes or domains.

Table 1: Affected health outcomes in animal toxicity and/or epidemiological studies for the four PFAS included in the Hazard Index MCLG (adapted from Table 6-7 in USEPA, 2024g)

Health Outcome	PFNA	PFHxS	PFBS	HFPO-DA
Lipids	X	X	X	X
Developmental	X	X	X	X
Hepatic	X	X	-	X
Immune	X	X	X	X
Endocrine	X	X	X	X
Renal	-	-	X	X
Hematologic	X	X	X	X

Notes: (X) Health outcome examined, evidence of association; (-) health outcome examined, no evidence of association.

In summary, there is substantial evidence that mixtures of PFHxS, PFNA, HFPO–DA, and PFBS act in a dose-additive manner and elicit multiple similar toxicological effects. Studies by the EPA and others provide evidence that corroborates the dose-additive toxicity of PFAS mixtures, and data on different chemical classes and research also provide support for dose additivity. Additionally, numerous *in vivo* and *in vitro* studies demonstrate that these four PFAS share many common health effects across diverse health outcome categories (*e.g.,* developmental, immunological, and endocrine effects), and that they induce some of the same effects at the molecular level along biological pathways (USEPA, 2024f).

C. Statutory Criterion 2—Occurrence

The EPA has determined that there is a substantial likelihood that PFHxS, PFNA, and HFPO–DA will individually occur and combinations of these three PFAS and PFBS will co-occur in mixtures in PWSs with a frequency and at levels of public health concern based on the EPA's evaluation of the best available occurrence information. In this preamble, while the EPA is making a final determination to regulate PFBS in mixtures with PFHxS, PFNA, and/or HFPO–DA, the agency is deferring the final individual regulatory determination for PFBS so that the agency can continue to evaluate this contaminant relative to the SDWA criteria for regulation, particularly related to its individual known or likely occurrence. For the other three PFAS, the EPA is making a final determination to regulate them individually in this preamble (*i.e.,* PFHxS, PFNA, and HFPO–DA). The EPA recognizes there will be additional occurrence or other relevant information for these and other PFAS in the future. The EPA has, however, determined that there is more than sufficient occurrence information to satisfy the statutory criterion to regulate PFNA, PFHxS, and HFPO–DA.

The EPA's evaluation of the second statutory criterion for regulation of PFHxS, PFNA, and HFPO–DA individually and regulation of combinations of these PFAS and PFBS in mixtures follows a similar process to previous rounds of regulatory determinations including the written Protocol developed under Regulatory Determination 3 (USEPA, 2014a) and also described in detail in the Preliminary Regulatory Determination 4 (USEPA, 2020a). Using the Protocol, and as conducted for the regulatory determinations in this action, the agency compares available occurrence data relative to the contaminant HRL, a health-based concentration against which the agency evaluates occurrence data when making regulatory determinations, as a preliminary factor in informing the level of public health concern. For both this regulatory determination and previous regulatory determinations, this is the first screening factor in informing if there is a substantial likelihood the contaminant will occur at a frequency and level of public health concern. Consistent with the Protocol and similar to all past regulatory determinations, these regulatory determinations are also based on other factors, not just the direct comparison to the HRL. As described clearly in the proposal, the EPA has not been able to determine a simple threshold of public health concern for all contaminants the agency considers for regulation under SDWA; rather, it is a contaminant-specific decision which ''involves consideration of a number of factors, some of which include the level at which the contaminant is found in drinking water, the frequency at which the contaminant is found and at which it co-occurs with other contaminants, whether there is an sustained upward trend that these contaminant will occur at a frequency and at levels of public health concern, the geographic distribution (national, regional, or local occurrence), the impacted population, health effect(s), the potency of the contaminant, other possible sources of exposure, and potential impacts on sensitive populations or lifestages.'' (USEPA, 2023f). It also includes consideration of production and use trends and environmental fate and transport parameters which may indicate that the contaminant would persist and/or be mobile in water. Appropriately, the EPA has considered these relevant factors in its evaluation

that there is a substantial likelihood that PFHxS, PFNA, and HFPO–DA will individually occur and combinations of these three PFAS and PFBS will co-occur in mixtures in PWSs with a frequency and at levels of public health concern.

The EPA's evaluation of the second statutory criterion is based on the best available health information, which includes UCMR 3 data and more recent PFAS drinking water data collected by several states. Based on suggestions in public comments to update state occurrence data, the EPA supplemented the data used to inform the rule proposal with new data from states included in the original proposal and additional states that have made monitoring data publicly available since the rule proposal (USEPA, 2024b). Consistent with section 1412(b)(1)(B)(II), this information combined represents best available occurrence data. It includes results from tens of thousands of samples and the assembled data represent one of the most robust occurrence datasets ever used to inform development of a drinking water regulation of a previously unregulated contaminant. The state data were primarily gathered after the UCMR 3 using improved analytical methods that could measure more PFAS at lower concentrations. These additional data demonstrate greater occurrence and co-occurrence of the PFAS monitored under UCMR 3 (PFHxS, PFNA, and PFBS) at significantly greater frequencies than UCMR 3 and the data initially included in the analysis. Furthermore, the state data show the co-occurrence of PFAS at levels of public health concern, as well as the demonstrated occurrence and co-occurrence of HFPO–DA which was not included within UCMR 3. As discussed subsequently, these data demonstrate that there is a substantial likelihood PFHxS, PFNA, and HFPO–DA will occur and combinations of PFHxS, PFNA, HFPO–DA, and PFBS will co-occur in mixtures with a frequency and at levels of public health concern. When determining that there is a substantial likelihood PFHxS, PFNA, and HFPO–DA will occur and PFHxS, PFNA, HFPO–DA, and/or PFBS will co-occur at levels of public health concern, the EPA considered both the occurrence concentration levels for PFHxS, PFNA, and HFPO–DA individually, as well as their collective co-occurrence and corresponding dose additive health concerns from co-exposures with PFBS for purposes of considering a regulatory determination for mixtures of these four PFAS. The EPA also considered other factors in evaluating the second criterion and informing level of public health concern for PFHxS, PFNA, and HFPO–DA individually and combinations of these three PFAS and PFBS in mixtures, including the frequency at which the contaminant is found, the geographic representation of the contaminant's occurrence, and the environmental fate and transport characteristics of the contaminant. As the EPA noted previously, while the agency is not making an individual regulatory determination for PFBS at this time, PFBS is an important component in mixtures with PFHxS, PFNA, and HFPO–DA and the EPA presents occurrence information for PFBS as part of section III.C.5 and its co-occurrence analyses in sections VI.C and D of this preamble.

The EPA focused the evaluation of the state data on the non-targeted or non-site specific (*i.e.,* monitoring not conducted specifically in areas of known or potential contamination) monitoring efforts from 19 states. Non-targeted or non-site-specific monitoring is likely to be more representative of general occurrence because its framework and monitoring results will be less likely to potentially over-represent concentrations at locations of known or suspected contamination. Sixteen (16) of 19 states reported detections of at least three of PFHxS, PFNA, HFPO–DA, or PFBS.

The EPA considered the targeted state monitoring data separately since a higher rate of detections may occur as a result of specifically looking in areas of suspected or known contamination. For the targeted state data nearly all these states also reported detections at systems serving millions of additional people, as well as at levels of public health concern, both individually for PFHxS, PFNA, and HFPO–DA, and as mixtures of these three PFAS and PFBS. State data detection frequency and concentration results vary for PFHxS, PFNA, HFPO–DA, and PFBS, both between these four different PFAS and across different states, with some states showing much higher reported detections and concentrations of these PFAS than others. The overall results demonstrate the substantial likelihood that individually PFHxS, PFNA, and HFPO–DA and mixtures of these three PFAS with PFBS will occur and co-occur at frequencies and levels of public health concern. Tables 2 and 3 show the percent of samples with state reported detections of PFHxS, PFNA, HFPO–DA, and PFBS, and the percentage of monitored systems with detections of PFHxS, PFNA, HFPO–DA, and PFBS, respectively, across the non-targeted state finished water monitoring data. The EPA notes that Alabama is not included in Tables 2 and 3 as only detections were reported and there was no information on the total number of samples collected to determine percent detection.

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Table 2. Non-Targeted State PFAS Finished Water Data – Summary of Samples with State Reported Detections[1] of PFHxS, PFNA, HFPO-DA, and PFBS

State	PFHxS	PFNA	PFBS	HFPO-DA
Colorado	10.8%	0.9%	11.0%	0.2%
Illinois	13.4%	0.6%	17.6%	0.0%
Indiana	1.5%	0.2%	5.6%	0.0%
Kentucky	8.6%	2.5%	12.3%	13.6%
Maine	3.0%	3.5%	10.1%	N/A[2]
Maryland	18.2%	2.3%	19.3%	0.0%
Massachusetts	23.6%	2.9%	39.8%	0.1%
Michigan	4.3%	0.6%	7.5%	0.1%
Missouri	3.3%	0.0%	6.1%	0.0%
New Hampshire	16.8%	3.3%	32.1%	3.8%
New Jersey	26.2%	7.7%	28.1%	N/A[2]
New York	21.6%	8.6%	28.8%	0.7%
North Dakota	5.3%	0.0%	8.8%	0.0%
Ohio	6.6%	0.3%	5.0%	0.1%
South Carolina	8.1%	0.1%	13.7%	1.3%
Tennessee	0.0%	0.0%	0.0%	N/A[2]
Vermont	4.2%	2.5%	7.1%	0.2%
Wisconsin	27.2%	2.2%	28.0%	0.0%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] N/A indicates the analyte was not sampled as part of the state monitoring.

Table 3: Non-Targeted State PFAS Finished Water Data – Summary of Monitored Systems with State Reported[1] Detections of PFHxS, PFNA, HFPO-DA, and PFBS

State	PFHxS	PFNA	PFBS	HFPO-DA
Colorado	13.4%	1.0%	13.4%	0.3%
Illinois	4.6%	0.5%	8.0%	0.0%
Indiana	1.3%	0.3%	6.5%	0.0%
Kentucky	9.5%	2.7%	13.5%	12.2%
Maine	2.8%	3.9%	10.3%	N/A[2]
Maryland	12.7%	3.2%	12.7%	0.0%
Massachusetts	18.1%	4.4%	27.8%	0.3%
Michigan	4.1%	0.6%	7.9%	0.3%
Missouri	2.7%	0.0%	6.2%	0.0%
New Hampshire	22.5%	5.5%	38.1%	5.1%
New Jersey	32.9%	16.5%	35.2%	N/A[2]
New York	25.0%	9.7%	36.7%	1.1%
North Dakota	5.4%	0.0%	9.0%	0.0%
Ohio	2.2%	0.3%	2.4%	0.1%
South Carolina	13.7%	0.3%	22.1%	2.0%
Tennessee	0.0%	0.0%	0.0%	N/A[2]
Vermont	2.7%	0.9%	6.0%	0.5%
Wisconsin	31.8%	3.9%	33.9%	0.0%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] N/A indicates the analyte was not sampled as part of the state monitoring.

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As shown in Tables 2 and 3, all states except three report sample and system detections for at least three of the four PFAS. For those states that reported detections, the percentage of samples and systems where these PFAS were found ranged from 1 to 39.8 percent and 0.1 to 38.1 percent, respectively. While these percentages show occurrence variability across states, several of these states demonstrate that a significant number of samples (*e.g.,* detections of PFHxS in 26.2 percent of New Jersey samples) and systems (*e.g.,* detections of HFPO–DA in 12.2 percent of monitored systems in Kentucky) contain some or all four PFAS. This occurrence information, as well as the specific discussion related to individual occurrence for PFHxS, PFNA, and HFPO–DA and co-occurrence of these three PFAS and PFBS, supports the agency's determination that there is a substantial likelihood that PFHxS, PFNA, HFPO–DA occur and PFHxS, PFNA, HFPO–DA, and PFBS co-occur in combinations of mixtures with a frequency of public health concern. Additionally, the agency emphasizes that occurrence and co-occurrence of these PFAS is not only at a regional or local level, rather it covers many states throughout the country; therefore, a national level regulation is necessary to ensure all Americans served by PWSs are equally protected.

1. PFHxS

The occurrence data presented above, throughout section VI of this preamble and discussed in the USEPA (2024b) support the agency's final determination that there is a substantial likelihood PFHxS occurs with a frequency and at levels of public health concern in drinking water systems across the United States. PFHxS was found under UCMR 3 in approximately 1.1 percent of systems, serving 5.7 million people across 25 states, Tribes, and U.S. territories. However, under UCMR 3, the minimum reporting level for PFHxS was 30 ng/L. As this reporting level is three times greater than the health-based HRL for PFHxS (10 ng/L), it is extremely likely there is significantly greater occurrence and associated population exposed in the range between the HRL of 10 ng/L and the UCMR 3 minimum reporting level of 30 ng/L (as demonstrated by both the more recent state data and the EPA's occurrence model discussed in this section and in section VI of this preamble showing many results in this concentration range). Through analysis of available state data, which consisted of approximately 48,000 samples within 12,600 systems, 18 out of the 19 states that conducted non-targeted monitoring had reported detections of PFHxS in 1.3 to 32.9 percent of their systems (Tables 2 and 3). These same systems reported concentrations ranging from 0.2 to 856

ng/L with median sample concentrations ranging from 1.17 to 12.1 ng/L, demonstrating concentrations above the HRL of 10 ng/L.

Targeted state monitoring data of PFHxS show similar results. For example, in its targeted monitoring efforts, California reported 38.5 percent of monitored systems found PFHxS, where concentrations ranged from 1.1 to 160 ng/L, also demonstrating concentrations above the HRL. In total, considering both the non-targeted and targeted state data, PFHxS was found above the HRL in at least 184 PWSs in 21 states serving a population of approximately 4.3 million people.

The EPA also evaluated PFHxS in a national occurrence model that has been developed and utilized to estimate national-scale PFAS occurrence for four PFAS that were included in UCMR 3 (Cadwallader et al., 2022). The model has been peer reviewed and is described extensively in Cadwallader et al. (2022). The model and results are described in section VI.E of this preamble; briefly, both the UCMR 3 and some state data were incorporated into a Bayesian hierarchical model which supported exposure estimates for select PFAS at lower levels than were measured under UCMR 3. Hundreds of systems serving millions of people were estimated to have mean concentrations exceeding the PFHxS HRL (10 ng/L). Therefore, the UCMR 3 results, the national occurrence model results, and the substantial state data demonstrate the substantial likelihood PFHxS occurs at a frequency and level of public health concern. Finally, UCMR 5 data are being reported to the EPA while this final rule is being prepared. See section VI of this preamble for more information on the preliminary results. While these UCMR 5 PFHxS data are too preliminary to provide the basis for the regulatory determination, these preliminary UCMR 5 results appear to confirm state data and model results.

Further supporting this final determination, PFHxS is very stable and persistent in the environment. While PFHxS was phased out in the U.S. in the early 2000's there are still detections as previously demonstrated. In addition, legacy stocks may also still be used, production continues in other countries, and products containing PFHxS may be imported into the U.S. (USEPA, 2000b). Since PFHxS is environmentally persistent and products containing PFHxS are still in use and may be imported into the United States, the EPA anticipates environmental contamination to sources of drinking water will continue. To illustrate this point further, PFOA and PFOS, two of the most extensively sampled PFAS, are also very environmentally persistent and have similarly been phased out in the U.S. for many years, though these two contaminants continue to often be found at levels of public health concern as discussed in section VI of this preamble. Currently, this also appears to be a similar trend for PFHxS occurrence, where the drinking water sample data demonstrates it continues to occur at levels of public health concern. Therefore, in consideration of factors relating to the environmental persistence of PFHxS, its presence in consumer products and possible continued use, and the observed occurrence trend of PFOA and PFOS, the EPA finds that there is a substantial likelihood PFHxS occurs or will occur at a frequency and level of public health concern.

2. PFNA

The occurrence data presented above, throughout section VI of this preamble, and discussed in USEPA (2024b) support the agency's final determination that there is a substantial likelihood PFNA occurs with a frequency and at levels of public health concern in drinking water systems across the U.S.

PFNA was found under UCMR 3 in approximately 0.28 percent of systems, serving 526,000 people in 7 states, Tribes, and U.S. territories, using a minimum reporting level of 20 ng/L. As this reporting level is two times greater than the health-based HRL of 10 ng/L, the EPA expects there is even greater occurrence and exposed population in the range between 10 and 20 ng/L. Additionally, through analysis of the extensive amount of available state data, which consisted of approximately 57,000 samples within approximately 12,400 systems, 16 of 19 non-targeted monitoring states reported detections of PFNA within 0.3 to 16.5 percent of their systems (Tables 2 and 3). These same states reported sample results ranging from 0.23 to 330 ng/L, demonstrating levels above the HRL of 10 ng/L, with median sample results ranging from 0.35 to 7.5 ng/L.

Targeted state monitoring data of PFNA are also consistent with non-targeted state data; for example, Pennsylvania reported 5.8 percent of monitored systems found PFNA, where concentrations ranged from 1.8 to 18.1 ng/L, also showing concentrations above the HRL. When considering all available state data, there are at least 480 systems in 19 states serving more than 8.4 million people that reported any concentration of PFNA, and at least 52 systems in 12 states within different geographic regions serving a population of 177,000 people with reported concentrations above the HRL of 10 ng/L. Furthermore, when evaluating only a subset of the available state data representing non-targeted monitoring, PFNA was reported in approximately 3.6 percent of monitored systems; if these results were extrapolated to the nation and those system subject to the final rule requirements, the agency estimates that PFNA would be detectable in over 2,300 PWSs serving 24.9 million people. If those results were further compared to the HRL for PFNA (10 ng/L), PFNA would be detected above the HRL in 228 systems with 830,000 people exposed. Thus, in addition to the UCMR 3 results, these extensive state data also reflect there is a substantial likelihood PFNA occurs at a frequency and level of public health concern because it is observed or likely to be observed within numerous water systems above levels of public health concern across a range of geographic locations. Finally, UCMR 5 data are being reported to the EPA while this final rule is being prepared. See section VI of this preamble for more information on the preliminary results. While these PFNA UCMR 5 data are too preliminary to provide the basis for the regulatory determination, these preliminary UCMR 5 results appear to confirm state data discussed above.

Further supporting this final determination, PFNA is very stable and persistent in the environment. While it has generally been phased out in the U.S. there are still detections as demonstrated previously. Additionally, legacy stocks may still be used and products containing PFNA may still be produced internationally and imported to the U.S. (ATSDR, 2021). Since PFNA is environmentally persistent and products containing PFNA are still in use and may be imported into the U.S., there is a substantial likelihood that environmental contamination of sources of drinking water will continue. To illustrate this point further, PFOA and PFOS, two of the most extensively sampled PFAS, are also very environmentally persistent and have similarly been phased out in the U.S. for many years, though these two contaminants continue to often be found at levels of public health concern as discussed in section VI of this preamble. Currently, this also appears to be a similar trend for PFNA occurrence, where the drinking water sample data demonstrates it continues to occur at levels of public health concern. Therefore, in consideration of factors relating to the environmental persistence of PFNA, its presence in

consumer products and possible continued use, and the observed occurrence trend of PFOA and PFOS, the EPA finds that there is a substantial likelihood PFNA occurs or will co-occur at a frequency and level of public health concern.

3. HFPO–DA

The occurrence data presented above, throughout section VI of this preamble, and discussed in the USEPA (2024b) support the agency's final determination that there is a substantial likelihood HFPO–DA occur with a frequency and at levels of public health concern in drinking water systems across the U.S. HFPO–DA was not included as a part of the UCMR 3; however, through analysis of available state data, which consisted of approximately 36,000 samples within approximately 10,100 systems, 10 of the 16 states that conducted non-targeted monitoring had state reported detections of HFPO–DA within 0.1 to 12.2 percent of their systems (Tables 2 and 3). These same states reported sample results ranging from 0.7 to 100 ng/L and median sample results ranging from 1.7 to 29.6 ng/L, demonstrating concentrations above the HRL of 10 ng/L.

Additionally, targeted state monitoring in North Carolina included sampling across six finished drinking water sites and 438 samples with HFPO–DA. Concentrations ranged from 9.52 to 1100 ng/L, a median concentration of 40 ng/L, and 433 (99 percent) samples exceeding the HRL (10 ng/L). When considering all available state data, there are at least 75 systems in 13 states serving more than 2.5 million people that reported any concentration of HFPO–DA, and at least 13 systems in 5 states within different geographic regions of the country serving a population of 227,000 people with reported concentrations above the HRL of 10 ng/L. Additionally, when evaluating only a subset of the available state data representing non-targeted monitoring to ensure that the data were not potentially over-represented by sampling completed in areas of known or suspected contamination, HFPO–DA was reported in approximately 0.48 percent of monitored systems; if these results were extrapolated to the nation and those system subject to the final rule requirements, the agency estimates that HFPO–DA would be detectable in over 320 PWSs serving 9.9 million people. If those results were further compared to the HRL for HFPO–DA (10 ng/L), HFPO–DA would be detected above the HRL in 42 systems with at least 495,000 people exposed. Finally, UCMR 5 data are being reported to the EPA while this final rule is being prepared. See section VI of this preamble for more information on the preliminary results. While these HFPO–DA UCMR 5 data are too preliminary to provide the basis for the regulatory determination, these preliminary UCMR 5 results appear to confirm the state data discussed above.

Further supporting this final determination, HFPO–DA is very stable and persistent in the environment. Additionally, unlike PFOA, PFOS, PFHxS, and PFNA which have been phased out in the U.S, HFPO–DA continues to be actively produced and used within the country and is generally considered to have replaced the production of PFOA. Since HFPO–DA is environmentally persistent and products containing HFPO–DA are still being actively produced and used, the EPA anticipates that contamination will continue, if not increase, due to disposal and breakdown in the environment. To illustrate this point further, PFOA and PFOS, two of the most extensively sampled PFAS, are also very environmentally persistent and have been phased out in the United States for many years, though these two PFAS continue to often be found at levels of public health concern as discussed in section VI of this preamble. Therefore, in consideration of factors relating to the environmental persistence of HFPO–DA, its continued and possibly increasing presence in consumer products and use, and the observed occurrence trend of PFOA and PFOS, the EPA anticipates that occurrence levels of HFPO–DA will similarly continue to be found at least to the levels described in this preamble demonstrating that there is a substantial likelihood HFPO–DA will occur at a frequency and level of public health concern.

As discussed, HFPO–DA continues to be actively produced and used throughout the U.S., it currently occurs at levels above its HRL, and it occurs within geographically diverse areas of the country demonstrating it is not a local or regional issue only. While the current individual occurrence profile of HFPO–DA is not as pervasive and is found at somewhat lower frequency as the currently observed levels of PFOA, PFOS, or PFHxS, based upon the available substantial amount of state occurrence data and given factors previously described, the EPA has determined that there is a substantial likelihood HFPO–DA occurs or will occur at a frequency and level of public health concern.

4. PFBS

The agency is deferring the final individual regulatory determination for PFBS to further consider whether occurrence information supports a finding that there is substantial likelihood that PFBS will individually occur in PWSs and at a level of public health concern. While current information demonstrates that PFBS frequently occurs, it has not been observed to exceed its HRL of 2,000 ng/L in isolation. However, when considered in mixture combinations with other PFAS, including PFHxS, PFNA, and HFPO–DA, PFBS is anticipated to have dose-additive adverse health effects (based on available data on PFAS and dose additivity) and there is a substantial likelihood of its co-occurrence in combinations of mixtures with PFHxS, PFNA, and HFPO–DA with a frequency and at levels of public health concern. This is described further in sections III.C.5 and VI.C. and VI.D of this preamble.

5. Mixtures of PFHxS, PFNA, HFPO–DA, and PFBS

Through the information presented within this section and in USEPA (2024b), along with the co-occurrence information presented in sections VI.C and VI.D of this preamble, the EPA's evaluation of all available UCMR 3 and state occurrence data demonstrates that there is a substantial likelihood that combinations of PFHxS, PFNA, HFPO–DA, and PFBS (collectively referred to as ''Hazard Index PFAS'') co-occur or will co-occur in mixtures at a frequency and level of public health concern.

As discussed throughout section III.C of this preamble, the EPA has determined that PFHxS, PFNA, and HFPO–DA each meet the second statutory criterion for individual regulation. Additionally, as demonstrated in sections VI.C. and D. of this preamble, the EPA has determined that these three PFAS also meet the second statutory criterion when present in mixture combinations. PFBS has not been observed to exceed its HRL of 2,000 ng/L in isolation; therefore, the EPA is deferring the individual regulatory determination for this PFAS to further consider future occurrence information. However, the agency has determined that PFBS frequently occurs (as shown in Table 2 and Table 3), and that when considering dose additivity there is a substantial likelihood of its co-occurrence in mixtures of PFHxS, PFNA, and/or HFPO–DA with a frequency and at a level of public health concern. Therefore, the agency has

determined that PFBS also meets the criterion when present in mixture combinations with PFHxS, PFNA, and/or HFPO–DA.

In sections VI.C and D of this preamble, the EPA has presented its evaluation and findings related to the likelihood and frequency of co-occurrence of the four Hazard Index PFAS, including both through groupwise and pairwise analyses for the Hazard Index PFAS, in non-targeted state monitoring datasets. The groupwise co-occurrence analysis established the broad occurrence frequency of Hazard Index PFAS through a linkage to the presence of PFOA and PFOS. Because not as many states have monitored for the Hazard Index PFAS as compared to PFOA and PFOS, their occurrence information is less extensive than the occurrence information for PFOA and PFOS. Therefore, though the agency has previously made a final regulatory determination for PFOA and PFOS, establishing co-occurrence of Hazard Index PFAS with PFOA and PFOS is important to better understand the likelihood of Hazard Index PFAS occurrence. In this analysis, the six PFAS were separated into two groups—one consisted of PFOS and PFOA and the other group included the four Hazard Index PFAS. The analysis broke down the systems and samples according to whether chemicals from the two respective groups were detected. Given that the groupwise co-occurrence analysis established that there is a substantial likelihood that the Hazard Index PFAS frequently occur, particularly alongside PFOA or PFOS, the pairwise co-occurrence was relevant for understanding how the Hazard Index PFAS co-occur with each other instead of occurring independently. Pairwise co-occurrence analysis explored the odds ratios for each unique pair of PFAS included in the regulation. For every pair of PFAS chemicals included in the final regulation, the odds ratio, a statistic that, in this context, quantifies the strength of association between two PFAS being present, was found to be statistically significantly greater than 1. This means there was a statistically significant increase in the odds of reporting a chemical as present after knowing that the other chemical was detected. In most instances the odds appeared to increase in excess of a factor of ten. Thus, based on the large amount of available data, the chemicals are clearly demonstrated to frequently co-occur rather than occur independently of one another, supporting the agency's determination for mixtures of the four PFAS.

For the groupwise analysis, results generally indicated that when PFOA and PFOS were found, Hazard Index PFAS were considerably more likely to also be present. Additionally, for systems that only measured PFOA and/or PFOS and did not measure the Hazard Index PFAS, it can be assumed that the Hazard Index PFAS are more likely to be present in those systems, and that Hazard Index occurrence may be underestimated. Moreover, while PFOA and PFOS are not included within the Hazard Index PFAS or the determination to regulate mixtures of these PFAS, the pervasive occurrence of PFOA and PFOS shown in section VI of this preamble is a strong indicator that these other Hazard Index PFAS are also more likely to be found than what has been reported in state monitoring data to date. In this analysis, comparisons were also made between the number of Hazard Index PFAS analyzed and the number of Hazard Index PFAS reported present. As more Hazard Index PFAS were analyzed, more Hazard Index PFAS were reported present. Systems and samples where Hazard Index PFAS were found were more likely to find multiple Hazard Index PFAS than a single Hazard Index PFAS (when monitoring for three or four Hazard Index PFAS), demonstrating an increased likelihood of their co-occurrence. Additionally, for both system-level and sample-level analyses where PFOA and/or PFOS were reported present and all four Hazard Index PFAS were monitored, two or more Hazard Index PFAS were reported present more than half of the time, exhibiting they are more likely to occur together than in isolation. Furthermore, the EPA notes that when evaluating only a subset of the available state data representing non-targeted monitoring where either three or four Hazard Index PFAS were monitored, regardless of whether PFOA or PFOS were reported present, two or more of the Hazard Index PFAS were reported in approximately 12.1 percent of monitored systems; if these results were extrapolated to the nation, two or more of these four PFAS would co-occur in about 8,000 PWSs (see section VI.C.1 of this preamble for additional information).

The EPA uses a Hazard Index of 1 as the HRL to further evaluate the substantial likelihood of the Hazard Index PFAS co-occurring at a frequency and level of public health concern. As discussed in greater detail in section VI.D, of this preamble based on available state data the EPA finds that across 21 states there are at least 211 PWSs serving approximately 4.7 million people with results above a Hazard Index of 1 for mixtures including two or more of the Hazard Index PFAS. Specifically evaluating the presence of PFBS, in these same 211 systems where the Hazard Index was found to be greater than 1, PFBS was observed at or above its PQL in mixtures with one or more of the other three Hazard Index PFAS in at least 72 percent (152) of these systems serving approximately 4.5 million people. Additionally, as described previously in sections III.C.1–3, PFHxS, PFNA, HFPO–DA, and PFBS are all very stable and persistent in the environment. All are either still being actively used or legacy stocks may be used and imported into the U.S. Consequently, there is a substantial likelihood that environmental contamination of sources of drinking water from these PFAS will continue to co-occur to at least the levels described in this preamble.

Therefore, in consideration of the environmental persistence of these PFAS, their presence in consumer products and continued use, the findings of both the pairwise and groupwise co-occurrence analyses, and demonstration of combinations of Hazard Index PFAS mixtures exceeding the Hazard Index of 1, the EPA has determined there is sufficient occurrence information available to support the second criterion that there is a substantial likelihood that combinations of the four Hazard Index PFAS in mixtures co-occur at frequencies and levels of public health concern.

6. Summary of Major Public Comments and EPA Responses

The EPA requested comment on its preliminary regulatory determination for all four PFAS and their mixtures and its evaluation of the statutory criteria that supports the finding. The EPA also requested comment on additional occurrence data the agency should consider regarding its decision that PFHxS, PFNA, HFPO–DA, and PFBS and their mixtures occur or are substantially likely to occur in PWSs with a frequency and at levels of public health concern. The EPA received many comments on the agency's evaluation of the second statutory criterion under section 1412(b)(1)(A) of SDWA. Many commenters supported the EPA's preliminary determination that PFHxS, PFNA, HFPO–DA, and PFBS and mixtures of these four contaminants meet the second statutory occurrence criterion under SDWA.

A couple of commenters claimed that the EPA does not have a robust understanding of available occurrence data that supports any of the regulatory determinations for the four PFAS in this rule. Additionally, some commenters suggested that the preliminary determinations were ''rushed'' and ''non-scientific,'' and that the agency should wait until some or all of the UCMR 5 data is available and considered. The EPA disagrees. Sufficient occurrence data are available to establish a substantial likelihood of occurrence at frequencies and levels of health concern. Per the intent of the statute, the agency used the best available data in an expeditious manner, which, as the agency described earlier, was also a very large dataset consisting of tens of thousands of samples and representing one of the most robust occurrence datasets ever used to inform development of a drinking water regulation of a previously unregulated contaminant. The agency also disagrees that the occurrence analyses undertaken and available in the preamble as well as the technical support document for occurrence were non-scientific. Based on publicly available information within the state data, the EPA verified that the very large majority of samples (at least 97 percent) were collected using EPA-approved methods; the slight percentage the agency was unable to verify would not result in different agency conclusions. Additionally, the EPA notes that the aggregated data were assessed using precedented statistical metrics and analyses. In addition, the Cadwallader et al. (2022) model uses a robust, widely accepted Bayesian statistical approach for modeling contaminant occurrence. Based on these analyses, the EPA has a clear understanding of the occurrence of the modeled contaminants. As discussed in section III.C of this preamble and USEPA, 2024b, the EPA also has sufficient state data which consist of a greater number of total systems and samples than that included within the monitoring under UCMR 3, to confidently establish that there is a substantial likelihood of occurrence at frequencies and levels of public health concern.

As discussed above, the agency believes that the best currently available occurrence data demonstrate substantial likelihood of occurrence for the chemicals included in the final rule as they are demonstrated at frequencies and levels of public health concern. UCMR 5 data are being reported to the EPA while this final rule is being prepared. See section VI of this preamble for more information on the EPA's evaluation of the preliminary results. While these data are too preliminary to provide the basis for a regulatory determination, these preliminary UCMR 5 results appear to support the data discussed previously.

Several commenters disagreed that the available occurrence information supports a preliminary determination for HFPO–DA, with a few citing a lack of nationally representative data and suggesting a delay until UCMR 5 data is collected. The EPA disagrees with these comments, as the state monitoring data for the proposed rule demonstrates HFPO–DA occurrence in 13 geographically diverse states, including at 75 systems serving at least 2.5 million people. Moreover, non-national datasets may serve to demonstrate occurrence of a contaminant to warrant a positive determination and subsequent development of an NPDWR. For example, the best available HFPO–DA state data consists of approximately 36,000 samples within 10,000 systems and is representative of multiple geographic locations.

One commenter stated that a regulatory determination for PFNA was unnecessary as they do not believe it occurred with frequency under UCMR 3 monitoring, and a couple of other commenters suggested that a negative determination was appropriate for PFNA citing occurrence levels. The EPA disagrees that a negative determination is appropriate for PFNA as it has been demonstrated to occur at levels of public health concern in at least 52 water systems across 12 states. Furthermore, as described previously, when evaluating only a subset of the available state data representing non-targeted monitoring, PFNA was reported in approximately 3.6 percent of monitored systems and if those results were extrapolated across the country, PFNA would be detectable at any concentration in over 2,300 PWSs serving 21.2 million people and detectable above 10 ng/L in 227 systems serving 711,000 people. Additionally, PFNA frequently co-occurs with other PFAS, and as previously discussed in this section, presents dose additive health concerns with other PFAS demonstrating it is also an important component of the determination to regulate it in mixtures with PFHxS, HFPO–DA, and/or PFBS.

Commenters both agreed and disagreed with the EPA's individual preliminary determination for PFBS. With respect to commenters who suggested that the EPA has not met the occurrence criterion, while PFBS occurs at significant frequency, the agency is deferring the individual determination to regulate PFBS when it occurs individually until it conducts further evaluation under the statutory criteria. The EPA further finds that PFBS exposure may cause dose additive adverse health effects in mixtures with PFHxS, PFNA, and/or HFPO–DA; that there is a substantial likelihood that PFBS co-occurs in mixtures with PFHxS, PFNA, and/or HFPO–DA in PWSs with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, regulation of PFBS in mixtures with PFHxS, PFNA, and/or HFPO–DA presents a meaningful opportunity for health risk reduction for persons served by PWSs. Therefore, PFBS will be regulated as part of a mixture with PFHxS, PFNA, and HFPO–DA.

A few commenters provided feedback on occurrence thresholds the agency should consider when evaluating the second statutory criterion for regulatory determinations. Particularly, these commenters recommended that the EPA should define a threshold for frequency and level of public health concern that warrants a specific regulatory determination. A few commenters cited other previous regulatory determinations where the agency made a determination not to regulate contaminants with similar or lower levels of occurrence suggesting that this should be the same for some or all of these four PFAS. Furthermore, some of these commenters stated that it would be arbitrary and capricious and conflict with the SDWA if the EPA did not use the level of adverse health effect (*i.e.,* the HRL) to represent the level at which a contaminant is considered a public health concern.

The EPA disagrees with these commenters and as demonstrated in the proposal and noted earlier in section III of this preamble, for this regulatory determination, as well as past determinations, the agency did compare available occurrence data relative to the contaminant HRL as a factor in informing the occurrence level of public health concern. However, the level of public health concern for purposes of the second criterion is a contaminant-specific analysis that include consideration of the HRL, as well as other factors and not solely based on the direct comparison to the HRL. There is not just one simple threshold used for public health concern for all contaminants. In the case of PFAS, this is particularly relevant given the dose-additivity of mixtures.

The EPA also disagrees with these commenters as SDWA does not define the occurrence level of public health

concern for contaminants, nor does it prescribe the level of adverse health effects that must be used for a regulatory determination. Ultimately, the overall decision to regulate a contaminant considers all three statutory criteria, including the comprehensive assessment of meaningful opportunity which is in the Administrator's sole discretion. In previous EPA regulatory determinations, the agency has considered the occurrence criteria unique to the contaminant it is evaluating and has made decisions not to regulate contaminants both where there was substantial likelihood of occurrence at frequency and/or at levels of public health concern and where there was limited or no substantial likelihood of occurrence at frequency and/or at levels of public health concern. Consistent with this past regulatory history and the Administrator's authority under the terms of the statute, the decision considers all three criteria and cannot be determined in the exact same manner for different contaminants. While the EPA may have made negative determinations for other contaminants demonstrating occurrence at different frequencies and levels of public health concern, the basis for those decisions was specific to those contaminants and does not apply to these PFAS or any other future contaminants for which the EPA would make regulatory determinations. Therefore, the statute does not require, and the EPA does not use a minimum or one-size-fits-all occurrence thresholds (for either frequency or precise level) for regulatory determinations.

As described in section VI of this preamble, many commenters supported the EPA's proposal to regulate mixtures of PFAS. Specific to occurrence, some of these commenters particularly expressed support for the EPA's preliminary determination that mixtures of these four PFAS meet the second statutory occurrence criterion under SDWA, citing that the agency has used the best available information to determine that there is a substantial likelihood that combinations of these PFAS will co-occur in mixtures at a frequency and level of public health concern. One commenter stated that the additional occurrence data presented by the EPA in the proposal for the Hazard Index PFAS supports the EPA's proposed determination that these PFAS should be regulated under the SDWA. Conversely, several other commenters stated that there was not supporting evidence for the co-occurrence of the four Hazard Index PFAS. The EPA disagrees; the extent to which Hazard Index PFAS chemicals co-occur in the non-targeted state dataset is discussed extensively in the record for this rule and made evident through the system level analysis in section VI.C. of this preamble. As also discussed elsewhere in the record for this rule, in both system level and sample level analyses where PFOA and/or PFOS were reported present and all four Hazard Index PFAS were monitored, two or more Hazard Index PFAS were reported present more than half of the time. Further, the odds ratios tables in Exhibit 11 provide a statistical examination of pairwise co-occurrence. The odds ratio is a statistic that quantifies the strength of association between two events. In the context described here, an ''event'' is the reported presence of a specific PFAS contaminant. The odds ratio between PFOA and PFHxS, for example, reflects the strength of association between PFHxS being reported present and PFOA being reported present. If an odds ratio is greater than 1, the two events are associated. The higher the odds ratio, the stronger the association. For every pair of PFAS chemicals included in the proposed regulation, the odds ratio was found to be statistically significantly greater than 1. This means there was a statistically significant increase in the odds of a PFAS being present if the other PFAS compound was detected (*e.g.,* if PFOA is detected, PFHxS is more likely to also be found). In most instances the odds appeared to increase in excess of a factor of ten. Thus, based on the large amount of available data, the chemicals are clearly demonstrated to co-occur rather than occur independently of one another, further supporting the agency's determination for combinations of mixtures of the four PFAS.

After considering the public comments and additional occurrence data evaluated as requested by public commenters, the EPA finds that PFHxS, PFNA, and HFPO–DA individually and mixtures of these three PFAS and PFBS, meet the second statutory criterion for regulatory determinations under section 1412(b)(1)(A) of SDWA that the contaminant is known to occur or co-occur or there is a substantial likelihood that the contaminant will occur or co-occur in PWSs with a frequency and at levels of public health concern (USEPA, 2024b).

D. Statutory Criterion 3—Meaningful Opportunity

The agency has determined that individual regulation of PFHxS, PFNA, and HFPO–DA and regulation of combinations of PFHxS, PFNA, HFPO–DA, and PFBS in mixtures presents a meaningful opportunity for health risk reduction for persons served by PWSs. As discussed in section III.C. of this preamble, the EPA evaluated this third statutory criterion similarly to previous regulatory determinations using the Protocol developed under Regulatory Determination 3 (USEPA, 2014b) and also used in the Regulatory Determination 4. This evaluation includes a comprehensive assessment of meaningful opportunity for each unique contaminant including the nature of the health effects, sensitive populations affected, including infants, children and pregnant and nursing women, number of systems potentially affected, and populations exposed at levels of public health concern, geographic distribution of occurrence, technologies to treat and measure the contaminant, among other factors. The agency further reiterates that, per the statute, this determination of meaningful opportunity is in the Administrator's sole discretion.

Accordingly, the EPA is making this determination of meaningful opportunity after evaluating health, occurrence, treatment, and other related information and factors including consideration of the following:

- PFHxS, PFNA, and HFPO–DA and combinations of these three PFAS and PFBS in mixtures may cause multiple adverse human health effects, often at very low concentrations, on several biological systems including the endocrine, cardiovascular, developmental, renal, hematological, reproductive, immune, and hepatic systems as well as are likely to produce dose-additive effects from co-exposures.
- The substantial likelihood that PFHxS, PFNA, and HFPO–DA individually occur or will occur and that mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS co-occur or will co-occur together at frequencies and levels of public health concern in PWSs as discussed in section III of this preamble above and in section VI of this preamble, and the corresponding significant populations served by these water systems which potentially include sensitive populations and lifestages, such as pregnant and lactating women, as well as children.
- PFHxS, PFNA, HFPO–DA and combinations of these three PFAS and PFBS in mixtures are expected to be persistent in the environment, with some (*e.g.,* PFHxS, PFNA) also demonstrated to be very persistent in the human body.
- Validated EPA-approved measurement methods are available to measure PFHxS, PFNA, HFPO–DA, and

PFBS. See section VII of this preamble for further discussion.

- Treatment technologies are available to remove PFHxS, PFNA, and HFPO–DA and combinations of these three PFAS and PFBS from drinking water. See section X of this preamble for further discussion.
- Even though PFBS is very likely to be below its corresponding individual HRL when it occurs in a mixture, the record indicates that there is a substantial likelihood that it co-occurs with the regulated PFAS throughout public water systems nationwide. See sections III.C.5 and VI.C. of this preamble for further discussion. According to the 2023 Interagency PFAS Report to Congress (United States OSTP, 2023), PFBS has been shown to affect the following health endpoints: body weight, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, hepatic, renal, ocular, endocrine, immunological, neurological, reproductive, and developmental. Thus, including PFBS as a mixture component represents a meaningful opportunity to reduce PFBS' contributions to the overall hazard of the mixture and resulting dose additive health concerns. This is particularly relevant where the exposures of the other three PFAS in the mixture are also below their respective HRLs but when the hazard contributions of each mixture component are summed, the total exceeds the mixture HRL. In this scenario, the inclusion of PFBS allows for a more accurate picture of the overall hazard of the mixture so that PFBS can be reduced along with associated dose additive health concerns. In short, hazard would be underestimated if PFBS was not included in the regulated mixture. The EPA also considered the situation where PFHxS, PFNA, or HFPO–DA exceed one or more of their corresponding HRLs and co-occur with PFBS below its corresponding HRL. Although the exceedance of the mixture HRL is driven by a PFAS other than PFBS, PFBS is contributing to the overall hazard of the mixture and resulting dose additive health concerns. Including PFBS in the regulated mixture offers a meaningful opportunity to reduce dose additive health concerns because, when PFBS and other Hazard Index PFAS are present, public water systems will be able to better design and optimize their treatment systems to remove PFBS and any other co-occurring Hazard Index PFAS. This optimization will be even more effective knowing both that PFBS is present in source waters and its measured concentrations.
- Regulating PFHxS, PFNA, and HFPO–DA and combinations of these three PFAS and PFBS in mixtures is anticipated to reduce the overall public health risk from other PFAS, including PFOA and PFOS, that co-occur and are co-removed. Their regulation is anticipated to provide public health protection at the majority of known PWSs with PFAS-impacted drinking water.
- There are achievable steps to manage drinking water that can be taken to reduce risk.

As described in sections III.C, VI.C, VI.D, and USEPA (2024b), data from both the UCMR 3 and state monitoring efforts demonstrates the substantial likelihood of individual occurrence of PFHxS, PFNA, and HFPO–DA and co-occurrence of mixture combinations of PFHxS, PFNA, HFPO–DA, and PFBS at frequencies and levels of public health concern. Under UCMR 3, 5.7 million and 526,000 people had reported detections (greater than or equal to their minimum reporting levels which were two to three times their HRLs of 10 ng/L), of PFHxS and PFNA, respectively. Additionally, based on the more recent available state monitoring data presented earlier in this section, a range of geographically diverse states monitored systems that reported individual detections of PFHxS, PFNA, and HFPO–DA and serve approximate populations of 26.5 million, 2.5 million, and 8.4 million, respectively. Of these same systems, detections above the EPA's HRLs for PFHxS, PFNA, and HFPO–DA were seen in systems that serve approximate populations of 4.3 million, 227,000, and 177,000 people, respectively. As discussed previously, if these monitored systems were extrapolated to the nation, the EPA estimates that thousands of additional systems serving millions of people could have detectable levels of these three PFAS and hundreds of these systems may show values above the EPA's HRLs. Lastly, in evaluating the available state data, the EPA has found that mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS occur with a Hazard Index greater than 1 in systems serving approximately 4.7 million people. The agency further notes that while it has demonstrated through sufficient data that these four PFAS co-occur in mixtures at a frequency and level of public health concern in PWSs, throughout the nation it is extremely likely that additional systems and associated populations served would also demonstrate a Hazard Index greater than 1 if data for all PWSs were evaluated.

Analytical methods are available to measure PFHxS, PFNA, HFPO–DA, and PFBS in drinking water. The EPA has published two multi-laboratory validated drinking water methods for individually measuring PFHxS, PFNA, HFPO–DA, and PFBS. Additional discussion on analytical methods can be found in section VII of this preamble.

The EPA's analysis, summarized in section X of this preamble, found there are available treatment technologies capable of reducing PFHxS, PFNA, HFPO–DA, and PFBS. These technologies include granular activated carbon (GAC), anion exchange (AIX) resins, reverse osmosis (RO), and nanofiltration (NF). These treatment technologies remove PFHxS, PFNA, HFPO–DA, and PFBS and their mixtures. They also have been documented to co-remove other PFAS (Sörengård et al., 2020; McCleaf et al., 2017; Mastropietro et al., 2021). Furthermore, as described in section VI of this preamble, PFHxS, PFNA, HFPO–DA, and PFBS also co-occur with PFAS for which the agency is not currently making a regulatory determination. Many of these other emergent co-occurring PFAS are likely to also pose hazards to public health and the environment (Mahoney et al., 2022). Therefore, based on the EPA's findings that PFHxS, PFNA, HFPO–DA, and PFBS have a substantial likelihood to co-occur in drinking water with other PFAS and treating for PFHxS, PFNA, HFPO–DA, and PFBS is anticipated to result in removing these and other PFAS, individual regulation of PFHxS, PFNA, and HFPO–DA and regulation of mixtures of these three PFAS and PFBS also presents a meaningful opportunity to reduce the overall public health risk from all other PFAS that co-occur and are co-removed with PFHxS, PFNA, HFPO–DA, and PFBS.

With the ability to monitor for PFAS, identify contaminated drinking water sources and contaminated finished drinking water, and reduce PFAS exposure through management of drinking water, the EPA has identified meaningful and achievable actions that can be taken to reduce the human health risk of PFAS.

1. Proposal

The EPA made a preliminary determination that regulation of PFHxS, PFNA, HFPO–DA, and PFBS, both individually and in a mixture, presents a meaningful opportunity for health risk reduction for persons served by PWSs. The EPA made this preliminary determination after evaluating health, occurrence, treatment, and other related information against the three SDWA statutory criteria including consideration of the factors previously

described in section III.D of this preamble above.

2. Summary of Major Public Comments and EPA Responses

The EPA received many comments on the agency's evaluation of the third statutory criterion under section 1412(b)(1)(A) of SDWA. Most commenters supported the EPA's evaluation under the preliminary determination that regulation of PFHxS, PFNA, HFPO–DA, PFBS and mixtures of these four contaminants presents a meaningful opportunity for health risk reduction and that the EPA had sufficiently justified this statutory criterion as well as the health and occurrence criterion. This included comments highlighting the extensive amount of work done by several states developing regulatory and non-regulatory levels for several PFAS compounds, including the PFAS for which the EPA is making regulatory determinations either individually or as a mixture. These commenters also noted the need for a consistent national standard for use in states where a state-specific standard has not yet been developed. Several commenters have also noted that although some states have developed or are in the process of developing their own state-level PFAS drinking water standards, regulatory standards currently vary across states. These commenters expressed concern that absence of a national drinking water standard has resulted in risk communication challenges with the public and disparities with PFAS exposure. Some commenters noted there are populations particularly sensitive or vulnerable to the health effects of these PFAS, including newborns, infants, and children. The EPA agrees with commenters that there is a need for a national PFAS drinking water regulation and that moving forward with a national-level regulation for PFHxS, PFNA, HFPO–DA, mixtures of these three PFAS and PFBS, as well as PFOA and PFOS, will provide improved national consistency in protecting public health and may reduce regulatory uncertainty for stakeholders across the country.

A few commenters expressed support for the EPA's evaluation of meaningful opportunity based on the treatment technologies which can remove the six PFAS for which the EPA is finalizing regulation. Furthermore, these commenters noted the meaningful opportunity to not only provide protection from the six regulated PFAS, but also other PFAS that will not be regulated as a part of this action.

Several commenters did not support the EPA's evaluation of the third statutory criterion, offering that in their opinion the EPA failed to justify that there is a meaningful opportunity for health risk reduction for the PFAS both individually and for their mixtures and stating that the EPA should consider other factors such as costs. A few of these commenters wrote that the EPA provided limited rationale and factors for its meaningful opportunity determination. The EPA disagrees with these commenters that the agency failed to justify that there is meaningful opportunity for health risk reduction or that the EPA provided limited rationale and factors in its meaningful opportunity evaluation for these contaminants individually and as mixtures. As described in the EPA's March 2023 proposal (USEPA, 2023f) and summarized previously, the EPA fully considered many factors both individually and within mixtures including individual contaminant and dose additive toxicity and health concerns, individual contaminant occurrence and co-occurrence of mixtures at frequencies and levels of public health concern, availability of similar treatment technologies to remove these four PFAS and analytical methods to measure them, and their individual and collective chemical and physical properties leading to their environmental persistence. Additionally, the EPA notes in this preamble, and as demonstrated through representative occurrence data, for the three contaminants individually and mixtures of the four, occurrence and co-occurrence is not only at a regional or local level, rather it covers multiple states throughout the country; therefore, a national level regulation is necessary to ensure all Americans served by PWSs are equally protected.

Some comments indicate that the health and occurrence information do not support that establishing drinking water standards presents a meaningful opportunity for health risk reduction. The agency disagrees with the commenters' assertion that the health and occurrence information are insufficient to justify a drinking water standard as supported in sections III.B. and III.C. of this preamble, and the agency finds that there is a meaningful opportunity for health risk reduction potential based upon multiple considerations including the population exposed to PFHxS, PFNA, HFPO–DA, and mixtures of these three PFAS and PFBS including sensitive populations and lifestages, such as newborns, infants and children.

Other comments assert that the EPA must evaluate the potential implementation challenges and cost considerations of regulation as part of the meaningful opportunity evaluation. The EPA disagrees with these commenters. The SDWA states that that the meaningful opportunity for overall health risk reduction for persons served by PWSs is in the sole judgement of the Administrator and does not require that the EPA consider costs for a regulatory determination. The SDWA does require that costs and benefits are presented and considered in the proposed rule's Health Risk Reduction Cost Analysis which the EPA did for the proposal and has updated as a part of the final rule within section XII.

A few other commenters provided that due to all of the additional human health exposure pathways other than drinking water for these PFAS, that regulation of drinking water would not represent a meaningful opportunity for overall health risk reduction. While the EPA recognizes that drinking water is one of several exposure routes, the EPA disagrees with these commenters. Removing the PFAS that have been found to occur or are substantially likely to occur from drinking water systems will result in a significant improvement in public health protection. The EPA also notes that through its *PFAS Strategic Roadmap* and associated actions, the agency is working expeditiously to address PFAS contamination in the environment and reduce human health PFAS exposure through all pathways. While beyond the scope of this rule, the EPA is making progress implementing many of the commitments in the Roadmap, including those that may significantly reduce PFAS source water concentrations.

E. The EPA's Final Determination Summary

The SDWA provides the EPA significant discretion when making a regulatory determination under section 1412(b)(1)(A). This decision to make a regulatory determination to individually regulate PFHxS, PFNA, and HFPO–DA and to regulate combinations of these three PFAS and PFBS in mixtures is based on consideration of the evidence supporting the factors individually and collectively.

The EPA's determination that PFHxS, PFNA, and HFPO–DA individually and mixtures of these three PFAS and PFBS ''may have an adverse effect on the health of persons'' is strongly supported by numerous studies. These studies demonstrate several adverse health effects, such as immune, thyroid, liver,

kidney and developmental effects, and increased cholesterol levels, may occur following exposure to individual PFAS, and dose-additive health effects can occur following exposure to multiple PFAS at doses that likely would not individually result in these adverse health effects, but may pose health risks when combined in mixtures. Importantly, the best available peer reviewed science documents that these PFAS may have multiple adverse human health effects even at relatively low levels individually and when combined in mixtures (see section III.B.6.e f of this preamble or further information on studies supporting the conclusion of dose additivity).

The EPA's determination there is a substantial likelihood that the contaminant will occur in PWS with a frequency and at levels of public health concern is supported by evidence documenting the measured occurrence of PFHxS, PFNA, and HFPO–DA, and co-occurrence of these three PFAS and PFBS above the HRL, the stability and persistence of the contaminant in humans and/or the environment, and the current or legacy production and use in commerce.

Finally, the EPA's determination that individual regulation of PFHxS, PFNA, and HFPO–DA and regulation of these three PFAS and PFBS in mixtures presents a meaningful opportunity for health risks reductions is strongly supported by numerous factors, including the potential adverse human health effects at low levels and potential for exposure and co-exposure of these PFAS on sensitive populations and lifestages such as lactating and pregnant women and children, their persistence, and the availability of both analytical methods and treatment technologies to remove these contaminants in drinking water.

After considering these factors individually and together, the EPA has determined that PFHxS, PFNA, and HFPO–DA individually and mixtures of these three PFAS and PFBS meet the statutory criteria for regulation under SDWA. The EPA has an extensive record of information to make this determination now and recognizes the public health burden of these PFAS as well as PFOA and PFOS. The EPA notes the public urgency to reduce PFAS concentrations in drinking water described in the public comments. A PFAS NPDWR provides a mechanism to reduce these PFAS expeditiously for these impacted communities. In addition to making this final regulatory determination, the EPA is exercising its discretion to concurrently finalize MCLGs and NPDWRs for these PFAS as individual contaminants and for the specified PFAS mixtures in part to allow utilities to consider these PFAS specifically as they design systems to remove PFAS and to ensure that they are reducing these PFAS in their drinking water to the extent feasible and as quickly as practicable.

IV. MCLG Derivation

Section 1412(a)(3) of the Safe Drinking Water Act (SDWA) requires the Administrator of the Environmental Protection Agency (EPA) to publish a final MCLG simultaneously with the NPDWR. The MCLG is set, as defined in section 1412(b)(4)(A), at ''the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.'' Consistent with SDWA section 1412(b)(3)(C)(i)(V), in developing the MCLG, the EPA considers ''the effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.'' Other factors considered in determining MCLGs can include health effects data on drinking water contaminants and potential sources of exposure other than drinking water. MCLGs are not regulatory levels and are not enforceable. The statute does not dictate that the MCLG take a particular form; however, it must represent a ''level'' that meets the MCLG statutory definition. Given that the MCL must be ''as close as feasible'' to the MCLG, and that the MCL is defined as the ''maximum permissible level of a contaminant in water which is delivered to any user of a public water system,'' the MCLG can take any form so long as it is a maximum level of a contaminant in water.

Due to their widespread use and persistence, many PFAS are known to co-occur in drinking water and the environment—meaning that these contaminants are often together and in different combinations as mixtures (see sections III.C and VI of this preamble for additional discussion on occurrence). PFAS exposure can disrupt signaling of multiple biological pathways resulting in common adverse effects on several biological systems and functions, including thyroid hormone levels, lipid synthesis and metabolism, development, immune function, and liver function. Additionally, the EPA's examination of health effects information found that exposure through drinking water to a mixture of PFAS can act in a dose-additive manner (see sections III.B and IV.B of this preamble for additional discussion on mixture toxicity). Dose additivity means that exposure to multiple PFAS, at doses that individually would not be anticipated to result in adverse health effects, may pose health risks when combined in a mixture.

A. MCLG Derivation for PFOA and PFOS

To establish an MCLG for individual contaminants, the EPA assesses the peer-reviewed science examining cancer and noncancer health effects associated with oral exposure to the contaminant. For known or likely linear carcinogenic contaminants, where there is a proportional relationship between dose and carcinogenicity at low concentrations or where there is insufficient information to determine that a carcinogen has a threshold dose below which no carcinogenic effects have been observed, the EPA has a long-standing practice of establishing the MCLG at zero (see USEPA, 1998a; USEPA, 2000c; USEPA, 2001; *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3). For nonlinear carcinogenic contaminants, contaminants that are designated as *Suggestive Human Carcinogens* (USEPA, 2005a), and non-carcinogenic contaminants, the EPA typically establishes the MCLG based on a noncancer RfD. An RfD is an estimate of a daily oral exposure to the human population (including sensitive populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime. A nonlinear carcinogen is a chemical agent for which the associated cancer response does not increase in direct proportion to the exposure level and for which there is scientific evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk.

1. Proposal

To support the proposed rule, the EPA published PFOA and PFOS draft toxicity assessments and the proposed MCLGs for public comment (USEPA, 2023g; USEPA, 2023h). Prior to conducting the systematic review for the PFOA and PFOS draft toxicity assessments, the EPA established the internal protocols for the systematic review steps of literature search, Population, Exposure, Comparator, and Outcomes (PECO) development, literature screen, and study quality evaluation. The EPA incorporated detailed, transparent, and complete protocols for all steps of the systematic

review process (USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j). Additionally, the EPA updated and expanded the protocols and methods based on SAB recommendations to improve the transparency of the process the EPA used to derive the MCLGs for PFOA and PFOS and to improve consistency with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f). The EPA followed this transparent systematic review process to evaluate the best available peer-reviewed science and to determine the weight of evidence for carcinogenicity and the cancer classifications for PFOA and PFOS according to agency guidance (USEPA, 2005a).

Based on the EPA's analysis of the best available data and following agency guidance, the EPA determined that both PFOA and PFOS are *Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals (USEPA, 2005a; USEPA, 2023g; USEPA, 2023h). The EPA also determined that a linear default extrapolation approach is appropriate for PFOA and PFOS as there is no evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk for either compound (USEPA, 2005a). Therefore, the EPA concluded that there is no known threshold for carcinogenicity. Based upon a consideration of the best available peer-reviewed science and the statute's directive that the MCLG be ''set at the level at which no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety,'' the EPA proposed MCLGs of zero for both PFOA and PFOS in drinking water. Setting the MCLG at zero under these conditions is also supported by long standing practice at the EPA's Office of Water for *Likely* or *Known Human Carcinogens* (see USEPA, 1998a; USEPA, 2000c; USEPA, 2001; USEPA, 2016b; *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3).

2. Summary of Major Public Comments and EPA Responses

The EPA requested comment on both the toxicity assessment conclusions and the proposed MCLG derivation for PFOA and PFOS. In this section the EPA focuses the summary of public comments and responses on comments related to the cancer classification determinations for PFOA and PFOS because that was the basis for the proposed MCLG derivations (USEPA, 2023g; USEPA, 2023h). The noncancer health effects that the EPA identified as hazards in the draft toxicity assessments (*i.e.,* decreased immune response in children, increased alanine aminotransferase (ALT), decreased birth weight and increased cholesterol) were not the basis for the proposed MCLG derivation. Importantly, an MCLG of zero is also protective of noncancer endpoints which were evaluated in the EPA's HRRCA (Health Risk Reduction and Cost Analysis). Comments related to the benefits the EPA quantified that are associated with noncancer health effects are described in section XII.

A few commenters agreed with the systematic review protocol the EPA used to evaluate the studies that supported the PFOA and PFOS cancer classification determinations in the draft toxicity assessments (USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j), with one commenter stating that the approach was ''thorough and well-reasoned.'' Commenters stated that the systematic review protocol was clear because the EPA had addressed all concerns highlighted during the peer review process.

One commenter stated that the EPA did not conduct a systematic review of the literature and did not follow the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) to develop the toxicity assessments for PFOA and PFOS. This commenter stated the EPA lacked ''a predefined protocol'' and that the ''systematic review methods lack[ed] transparency and consistency.'' The commenter took particular issue with the EPA's protocols for study quality evaluations, stating that they were inconsistent and not aligned with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f). The EPA disagrees with this commenter's claims. The EPA adopted the overall approach and steps in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021h) to develop PFOA- and PFOS-specific protocols that then formed the basis for performing study quality evaluations, evidence integration, and critical study selection (see appendix A in USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j). This predefined protocol was made available for public comment as appendix A of the toxicity assessments (USEPA, 2023i; USEPA, 2023j). Importantly, the EPA's Office of Water collaborated with the EPA's Office of Research and Development in conducting study quality evaluations, evidence integration, and selection of critical studies to ensure consistency with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021h).

A few commenters claimed that the EPA did not use the best available science when developing the toxicity assessments for PFOA and PFOS, asserting that the EPA did not follow its own guidance or data quality standards and that the EPA's systematic review process was flawed (see discussion above). The EPA disagrees with these commenters' claims. The EPA has followed statutory requirements to use the best available peer-reviewed science in two respects: by (1) considering relevant peer-reviewed literature identified by performing systematic searches of the scientific literature or identified through public comment and (2) relying on peer-reviewed, published EPA human health risk assessment methodology as well as systematic review best practices (USEPA, 2021h; USEPA, 2022f). The risk assessment guidance and best practices serve as the basis for the PFOA and PFOS health effects systematic review methods used to identify, evaluate, and quantify the available data. Not only did the EPA incorporate literature identified in previous assessments, as recommended by the SAB (USEPA, 2022i), but the EPA also conducted several updated systematic literature searches, the most recent of which was completed in February 2023. This approach ensured that the literature under review encompassed studies included in the 2016 *Health Effects Support Documents* (HESDs) (USEPA, 2016c; USEPA, 2016d) and recently available studies. The results of the most recent literature search provide further support for the conclusions made in the draft toxicity assessments for PFOA and PFOS (USEPA, 2023g; USEPA, 2023h) and are described in appendix A of the final toxicity assessments (USEPA, 2024h; USEPA, 2024i).

As described above, the PFOA and PFOS systematic review protocol is consistent with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and also considers PFOA- and PFOS-specific protocol updates outlined in the *Systematic Review Protocol for the PFBA, PFHxA, PFHxS, PFNA, and PFDA (anionic and acid forms) IRIS Assessments* (USEPA, 2021h). The EPA additionally followed human health risk assessment methods for developing toxicity values (*e.g.,* USEPA, 2002a), conducting benchmark dose (BMD) modeling (USEPA, 2012), and other analyses. In the PFOA and PFOS toxicity assessments and the appendices, the EPA clearly describes

the methods used and how those methods and decisions are consistent with the EPA practices and recommendations (*i.e.,* through quotes and citations) described in various guidance documents.

One commenter stated that the EPA did not use the best available peer-reviewed science because the assessments did not follow methodological or statistical guidance. Specifically, this commenter stated the EPA did not follow *A Review of the Reference Dose and Reference Concentration Processes* (USEPA, 2002a) when selecting uncertainty factors and claimed the EPA did not follow guidance on data quality (USEPA, 2003; USEPA, 2006b; USEPA, 2014b). The commenter stated they believed the assessments contained flaws including exclusion of covariates in modeling, reliance on peer-reviewed studies published by non-EPA employees, and an inability to replicate results. The EPA disagrees with these comments. Regarding data quality control, data quality objectives are an integral part of the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and many of the concepts outlined in data quality guidance recommended by the commenter (USEPA, 2003; USEPA, 2006b; USEPA, 2014b) are addressed through the EPA's use of the *ORD Handbook* (USEPA, 2022f). Furthermore, this work was conducted under a programmatic quality assurance project plan (QAPP) which ensures that all EPA data quality guidance is followed, including those cited by the commenter. Additionally, by developing and implementing a systematic review protocol consistent with the *ORD Handbook* (USEPA, 2022f), the EPA reduced potential confirmation bias, a concern raised by another commenter, by conducting multiple independent evaluations of studies, relying on a data-driven, weight of evidence approach, and by incorporating expertise from across the agency.

In many cases the commenters have misinterpreted the methods and decisions the EPA used to analyze the data or misinterpreted the guidance itself. For example, one commenter mistakenly suggested that the EPA did not consider covariates in its analyses of epidemiological studies; the EPA described which covariates were considered in each analysis in several sections of the draft toxicity assessments and appendices (USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j), including in descriptions of the studies in section 3 and modeling of the studies in appendix E. The EPA also notes that the primary studies that provide the data describe covariate adjustments in their published analyses.

A couple of commenters suggested that the toxicity assessments for PFOA and PFOS were not adequately peer-reviewed because changes were made post peer review (*i.e.,* after publication of the final report by the SAB PFAS Review Panel (USEPA, 2022i)), the most significant of which was the updated cancer classification for PFOS, but also included the addition of figures and mechanistic syntheses. The EPA disagrees with this assertion. The toxicity assessments, including the conclusions that are material to the derivation of the MCLGs, were peer-reviewed by the SAB PFAS review panel (USEPA, 2022i). Notably, this panel ''agreed with many of the conclusions presented in the assessments, framework and analysis'' (USEPA, 2022i). The only assessment conclusion that changed and impacted MCLG derivation between SAB review and rule proposal was that the cancer classification for PFOS of *Suggestive Evidence of Carcinogenicity* was updated to *Likely to be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). This conclusion for PFOS was based on a reevaluation of the available data in response to multiple comments from the SAB PFAS review panel stating that ''[s]everal new studies have been published that warrant further evaluation to determine whether the 'likely' designation is appropriate'' for PFOS and that the EPA's ''interpretation of the hepatocellular carcinoma data from the Butenhoff et al. (2012) study in the 2016 HESD is overly conservative in dismissing the appearance of a dose-response relationship for this endpoint, particularly in females'' (USEPA, 2022i). In responding to the SAB's recommendation that the EPA provide an ''explicit description of why the available data for PFOS do not meet the EPA *Guidelines for Carcinogen Risk Assessment* (2005) criterion for the higher designation as 'likely carcinogenic,' '' and taking into consideration recently published peer-reviewed epidemiological studies demonstrating concordance in humans identified through the final updated literature search recommended by the SAB, the EPA determined that PFOS meets the criterion for the higher designation of *Likely to Be Carcinogenic to Humans* (USEPA, 2005a). This decision was described in sections 3.5.5 and 6.4 of the draft assessment (USEPA, 2023h). Additional discussion regarding the PFOS cancer descriptor decision is provided here.

One commenter stated that the EPA addressed the SAB's concerns regarding the systematic review protocol in the documents supporting the proposed rulemaking. A few commenters reiterated the importance of the SAB's recommendations, including to more thoroughly describe systematic review methods used in the assessment (*e.g.,* study inclusion and exclusion criteria), incorporate additional epidemiological studies, provide rationale for critical study selection, and derive candidate toxicity values from both human and animal data. In contrast, a few commenters claimed that the EPA did not adequately consider several recommendations made by the SAB PFAS Review Panel in their final report (USEPA, 2022i), including that the EPA did not incorporate studies from the 2016 HESDs (USEPA, 2016c; USEPA, 2016d) or develop multiple cancer slope factors (CSFs). One commenter requested clarification on whether the EPA had implemented the feedback from the SAB.

The EPA disagrees with the comments that the agency did not ''meaningfully implement'' SAB feedback. The EPA agrees with commenters that highlighted the importance of the SAB's suggestions, and notes that the EPA addressed the SAB's recommendations to more thoroughly explain the systematic review protocol and expand the systematic review protocol beyond study quality evaluation and data extraction in the draft toxicity assessments published at the time of rule proposal (USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j). As outlined in the *EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation* (USEPA, 2023k), the EPA considered all of the comments and recommendations from the SAB and made substantial improvements to address the reported concerns prior to publishing the public comment draft assessments (USEPA, 2023g; USEPA, 2023h). The EPA published a response to SAB comments document that detailed how the agency considered and responded to the SAB PFAS Review Panel's comments at the time of rule proposal (USEPA, 2023k). The resulting draft toxicity assessments and protocol released for public comment along with the proposed rule reflect improvements including thorough and detailed descriptions of the methods used during assessment development, inclusion of

epidemiological studies from the 2016 HESDs for PFOA and PFOS in the systematic review (USEPA, 2016c; USEPA, 2016d), updates to the literature, implementation of an evidence integration framework, expansion of rationale for critical study and model selections, development of toxicity values from both animal toxicological and epidemiological data, when warranted, and many other actions. The EPA appreciated the SAB's engagement, extensive review, and comments on the *Proposed Approaches* documents (USEPA, 2021i; USEPA, 2021j). Furthermore, the EPA provided its consideration of every recommendation the SAB provided when updating and finalizing the assessments for PFOA and PFOS at the time of rule proposal (USEPA, 2023k).

Many commenters agreed that that available data indicate that exposure to either PFOA or PFOS is associated with cancer in humans and supported the EPA's determination that PFOA and PFOS are *Likely to be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). Multiple commenters agreed that studies published since the 2016 HESDs (USEPA, 2016c; USEPA, 2016d) have strengthened this conclusion. In particular, one commenter supported the EPA's conclusions regarding the human relevance of hepatic and pancreatic tumors observed in rats administered PFOS, citing their own independent health assessment conclusion that ''several lines of evidence do not support a conclusion that liver effects due to PFOS exposure are PPARα-dependent'' and therefore, may be relevant to humans (NJDWQI, 2018).

Several commenters disagreed with the EPA's determinations that PFOA and PFOS are each *Likely to be Carcinogenic to Humans.* Two commenters claimed that the tumor types observed in rats (*e.g.,* hepatic tumors) after PFOA or PFOS administration are not relevant to humans. Some commenters also stated that the human data do not support an association between PFOS exposure and cancer. One commenter specifically claimed that Shearer et al. (2021) does not provide sufficient evidence for changing PFOS's cancer classification from *Suggestive Evidence of Carcinogenicity* to *Likely to be Carcinogenic to Humans* because it did not report associations between PFOS exposure and risk of renal cell carcinoma (RCC). Two commenters stated that the EPA's discussion using structural similarities between PFOA and PFOS to support evidence of the carcinogenicity of PFOS was inconsistent with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). A few commenters additionally questioned or disagreed with the determination that PFOA is *Likely to be Carcinogenic to Humans* because of uncertainties in the epidemiological database and a lack of evidence indicating that PFOA is genotoxic.

The EPA disagrees with these comments. With respect to the human relevance of the animal tumors observed in rats after chronic oral exposure to either PFOA or PFOS, the EPA considered all hypothesized modes of action (MOAs) and underlying carcinogenic mechanisms in its cancer assessments, including those that some commenters have argued are irrelevant to humans (*e.g.,* peroxisome proliferator-activated receptor α (PPARα) activation), the discussion for which is available in section 3.5.4.2 of the toxicity assessments for PFOA and PFOS (USEPA, 2024c; USEPA, 2024d). After review of the available mechanistic literature for PFOA and PFOS, the EPA concluded that there are multiple plausible mechanisms, including some that are independent of PPARα, that may contribute to the observed carcinogenicity of either PFOA or PFOS in rats. Further confirmatory support for the EPA's conclusions regarding multiple plausible mechanisms of carcinogenicity comes from literature reviews published by state and global health agencies which concluded that the liver tumors associated with PFOA and/or PFOS exposure may not entirely depend on PPARα activation and therefore may be relevant to humans (CalEPA, 2021; IARC, 2016; NJDWQI, 2017; NJDWQI, 2018).

Additionally, the EPA did not rely on results reported by Shearer et al. (2021) as a rationale for updating the cancer classification for PFOS to *Likely to be Carcinogenic to Humans* (USEPA, 2005a) and acknowledges uncertainties in the results from this study, including that the effect in the third PFOS exposure quartile was null, the effects were attenuated (*i.e.,* reduced in magnitude) when adjusted for exposure to other PFAS, and there was no association when exposure to PFOS was considered as a continuous variable, rather than when PFOS exposure levels were stratified by quartiles (USEPA, 2023h). As described in sections 3.5.5 and 6.4 of the draft PFOS toxicity assessment, the available information exceeds the characteristics for the classification of *Suggestive Evidence of Carcinogenic Potential* (USEPA, 2005a) because there is statistically significant evidence of multi-sex and multi-site tumorigenesis from a *high* confidence animal toxicological study, as well as mixed but plausible evidence of carcinogenicity in humans and mechanistic data showing potential human relevance of the observed tumor data in animals (USEPA, 2023h). The EPA notes that the recently published studies reporting associations between PFOS exposure and hepatocellular carcinoma in humans (Goodrich et al., 2022; Cao et al., 2022) further strengthen the epidemiological database and support the cancer classification of *Likely to be Carcinogenic to Humans* for PFOS.

Regarding commenters' claims that the EPA used the structural similarities between PFOA and PFOS as supporting evidence of the carcinogenic potential of PFOS, the EPA did not rely on structural similarities to draw conclusions about the cancer classification (see rationale listed above) but instead used this information as supplemental support for the *Likely* classification. The EPA originally included this supplemental line of evidence because the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a) explicitly states that ''[a]nalogue effects are instructive in investigating carcinogenic potential of an agent as well as in identifying potential target organs, exposures associated with effects, and potential functional class effects or modes of action.'' PFOA and PFOS differ in their chemical structure by a single functional group; nevertheless, since a full structure-activity relationship analysis was not conducted, the EPA removed discussion on this supplemental line of evidence from the final toxicity assessment for PFOS (USEPA, 2024d).

Further, the EPA disagrees with comments stating that the epidemiological database for PFOA is too uncertain to support a classification of *Likely to be Carcinogenic to Humans* (USEPA, 2005a). As described in both the draft (USEPA, 2023g) and final toxicity assessments for PFOA (USEPA, 2024c), as well as the *Maximum Contaminant Level Goals for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS)* document (USEPA, 2024j) the available data support an increased risk of both kidney and testicular cancers associated with PFOA exposure. There is also evidence that PFOA exposure may be associated with an increased breast cancer risk, based on studies in populations with specific polymorphisms and for specific types of breast tumors. Taken together, these results provide consistent and plausible

evidence of PFOA carcinogenicity in humans. Additionally, the EPA notes that while genotoxicity is one potential MOA leading to carcinogenicity, there is no requirement that a chemical be genotoxic for the EPA to classify it as either *Carcinogenic to Humans, Likely to be Carcinogenic to Humans,* or *Suggestive Evidence of Carcinogenic Potential* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). Importantly, the SAB PFAS Review Panel supported the *Likely to be Carcinogenic to Humans* designation for PFOA in its final report (USEPA, 2022i).

Many commenters supported the EPA's proposed MCLGs of zero for both PFOA and PFOS, citing well-documented health effects, including cancer, resulting from exposure to either PFOA or PFOS as rationale for their support of the proposed rulemaking. Several commenters also agreed with the EPA's long-standing practice of establishing the MCLG at zero (see USEPA, 1998a; USEPA, 2000c; USEPA, 2001; *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3) for known or likely linear carcinogenic contaminants, with one commenter stating that it is ''appropriate based on the weight of evidence for carcinogenicity and other adverse health impacts of PFOA and PFOS at very low exposures.''

Two commenters disagreed with MCLGs of zero for PFOA and PFOS, with one commenter claiming that the EPA's determinations were ''not consistent with the evidence the EPA presents nor with its own guidance'' (*i.e.,* the EPA's cancer assessment was not consistent with assessment approaches recommended in the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a)). The EPA disagrees with these commenters' assertions because there is sufficient weight of evidence for carcinogenic risk of both PFOA and PFOS exposures supporting a classification of *Likely to be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a) from the available epidemiological and animal toxicological studies. Consistent with the guidelines, the EPA provided a narrative to ''explain the case for choosing one descriptor and discuss the arguments for considering but not choosing another'' (USEPA, 2005a) in the draft and final toxicity assessments (USEPA, 2024c; USEPA, 2024d; USEPA, 2023g; USEPA, 2023h).

3. Final Rule

Based on the best available peer-reviewed science and consistent with agency guidance (USEPA, 2005a), the EPA has determined that both PFOA and PFOS are *Likely to be Carcinogenic to Humans.* Therefore, following established agency practice regarding contaminants with this classification and consistent with the statutory directive to set an MCLG ''at the level at which no known or anticipated adverse effects on the health of persons occur and which allows for an adequate margin of safety,'' the EPA set individual MCLGs for both PFOA and PFOS at zero. As described above, the EPA used the best available peer-reviewed science, followed agency guidance and current human health risk assessment methodology, including the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a), and adequately peer-reviewed (USEPA, 2022i) the science underlying the MCLG derivation for both PFOA and PFOS (USEPA, 2024c; USEPA, 2024d; USEPA, 2024j).

Consistent with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a), the EPA reviewed the weight of evidence and determined that PFOA and PFOS are each designated as *Likely to Be Carcinogenic to Humans,* because ''the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans.'' For PFOA, this determination was based on the evidence of kidney and testicular cancer in humans and Leydig cell tumors, pancreatic acinar cell tumors, and hepatocellular tumors in rats as described in USEPA (2024c). For PFOS, this determination was based on the evidence of hepatocellular tumors in male and female rats, which is further supported by recent evidence of hepatocellular carcinoma in humans (Goodrich et al., 2022; Cao et al., 2022), pancreatic islet cell carcinomas in male rats, and mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans (USEPA, 2024d). The EPA has updated and finalized the toxicity assessment for PFOS to reflect the new epidemiological evidence (USEPA, 2024d; USEPA, 2024i).

Consistent with the statutory definition of MCLG, the EPA establishes MCLGs of zero for carcinogens classified as either *Carcinogenic to Humans* or *Likely to be Carcinogenic to Humans* where there is a proportional relationship between dose and carcinogenicity at low concentrations or where there is insufficient information to determine that a carcinogen has a threshold dose below which no carcinogenic effects have been observed. In these situations, the EPA takes the health protective approach of assuming that carcinogenic effects should therefore be extrapolated linearly to zero. This is called the linear default extrapolation approach. This approach ensures that the MCLG is set at a level where there are no known or anticipated adverse health effects, allowing for an adequate margin of safety. Here, the EPA has determined that PFOA and PFOS are *Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals (USEPA, 2024c; USEPA, 2024d). The EPA has also determined that a linear default extrapolation approach is appropriate as there is no evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk (USEPA, 2005a). Based on this lack of evidence, the EPA concluded that there is no known threshold for carcinogenicity. Based upon a consideration of the best available peer-reviewed science and statutory directive to set the MCLG ''at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety,'' the EPA has finalized MCLGs of zero for PFOA and PFOS in drinking water.

While not a basis for the EPA's MCLG, the EPA notes that its toxicity assessments indicate either PFOA or PFOS exposure are also associated with multiple non-cancer adverse health effects. The PFOA and PFOS candidate non-cancer RfDs based on human epidemiology studies for various health outcomes (*i.e.,* developmental, cardiovascular, immune, and hepatic) range from 2×10^{-7} to 3×10^{-8} mg/kg/day (USEPA, 2024c; USEPA, 2024d; USEPA, 2024h; USEPA, 2024i).

B. MCLG Derivation for Additional PFAS

Section 1412(b)(4)(A) requires the EPA to set the MCLG at a ''level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.'' In this action, the EPA is setting MCLGs (and MCLs) for five individual PFAS (section IV.C of this preamble) as well as for mixtures of three of these PFAS plus PFBS. In the context of this NPDWR, the Hazard Index is a method which determines when a mixture of two or more of four PFAS—PFHxS, PFNA, HFPO–DA, and PFBS—exceeds the level of health concern with a margin of safety and thus the Hazard Index (equal to 1) is the MCLG for any mixture of those four PFAS. Based on the scientific record, each PFAS within the mixture has a HBWC, which is set at the level below which adverse effects

are not likely to occur and allows for an adequate a margin of safety. See USEPA, 2024f and section IV.B. of this preamble. The scientific record also shows that PFHxS, PFNA, HFPO–DA, and PFBS elicit the same or similar profiles of adverse health effects in several biological organs and systems, but with differing potencies for effect(s) (see USEPA, 2022i and 2024a; and section IV.B of this preamble). As a result, as discussed elsewhere in the preamble, PFAS that elicit similar observed adverse health effects following individual exposure should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise (USEPA, 2024a). See USEPA, 2024a and section II and IV.B of this preamble. This means that where drinking water contains any combination of two or more of these PFAS, the hazard associated with each PFAS in the mixture must be added up to determine whether the mixture exceeds a level of public health concern.

The Hazard Index is the method for calculating this level (*i.e.,* the mixture MCLG) and reflects both the measured amount of each of the four PFAS in the mixture and the toxicity (represented by the HBWC) of each of the four PFAS. The PFAS mixture Hazard Index is an approach to determine whether any mixture of two or more of these four PFAS in drinking water exceeds a level of health concern by first calculating the ratio of the measured concentration of each of the four PFAS divided by its toxicity (the HBWC). This results in the ''hazard quotient'' (HQ) for each of the four PFAS. Because the health effects of these PFAS present dose additive concerns (USEPA, 2024a), the four HQs are added together, and if the result exceeds 1, then the hazard from the combined amounts of the four PFAS in drinking water exceeds a level of public health concern.

1. MCLG Derivation for a PFAS Mixture

a. Proposal

The EPA proposed a Hazard Index MCLG to protect public health from exposure to mixtures of any combination of PFHxS, PFNA, HFPO–DA, and/or PFBS, four PFAS that elicit a shared set of adverse effects and co-occur in drinking water. The Hazard Index is an approach based on dose additivity that has been validated and used by the EPA to assess chemical mixtures in several contexts (USEPA, 1986; USEPA, 2000a; USEPA, 2022i). The EPA's proposal was based on the agency's finding that the Hazard Index approach is the most practical approach for establishing an MCLG for PFAS mixtures that meets the statutory requirements outlined in section 1412(b)(1)(A) of SDWA. This is because the Hazard Index assesses the exposure level of each component PFAS relative to its HBWC, which is based on the most sensitive known adverse health effect (based on the weight of evidence) and considers sensitive population(s) and life stage(s) as well as potential exposure sources beyond drinking water. Furthermore, the Hazard Index accounts for dose additive health concerns by summing the hazard contribution from each mixture component to ensure that the mixture is not exceeding the level below which there are no known or anticipated adverse health effects and allows for an adequate margin of safety.

The proposal defined a mixture as containing one or more of the four PFAS and therefore covered each contaminant individually if only one of the four PFAS occurred. Thus, the Hazard Index as proposed ensures that the level of exposure to an individual PFAS remains below that which could impact human health because the exposure for that measured PFAS is divided by its corresponding HBWC. For example, if the mixture only included PFNA, then under the Hazard Index approach as proposed any measured concentrations over 10.0 ng/L divided over the 10.0 ng/L HBWC would be greater than the 1.0 Hazard Index MCLG. The proposed Hazard Index MCLG was 1.0 and the HBWCs of each mixture component were as follows: 9.0 ng/L [3] for PFHxS; 10.0 ng/L for HFPO–DA; 10.0 ng/L for PFNA; and 2000.0 ng/L for PFBS (USEPA, 2023e).

b. Summary of Major Public Comments and EPA Responses

Many commenters supported the EPA's proposal to regulate a mixture of PFAS and agreed with the EPA's scientific conclusions about PFAS dose additivity and the agency's use of the Hazard Index approach to develop an MCLG for a mixture of PFHxS, PFNA, HFPO–DA, and/or PFBS. Many commenters opposed the EPA's conclusion about dose additivity and the use of the Hazard Index approach to regulate co-occurring PFAS. A few commenters opposed the EPA's use of shared or similar health endpoints/outcomes rather than a shared MOA as a basis for assessing risks of PFAS mixtures. A few commenters agreed with the EPA's decision to regulate these PFAS as a mixture (that some commenters referred to as a ''group'') and supported the EPA's conclusion about dose additivity but questioned the EPA's use of the Hazard Index and suggested alternative approaches such as development of individual MCLGs or a target organ-specific Hazard Index (TOSHI). Some commenters claimed that the EPA did not appropriately seek review from the SAB, particularly on the application of the Hazard Index as an approach to regulate PFAS under SDWA. Comments on the number of significant digits applied in the HBWCs and the Hazard Index were varied. For a discussion of comments and the EPA responses on dose additivity and similarity of toxic effects, see section III.B of this preamble. Commenters referred to the HRLs and the HBWCs interchangeably; see section III of this preamble for comments on HBWCs and the EPA's responses. Responses to the other topics raised are discussed in the following paragraphs.

The EPA disagrees with commenters that the agency did not seek adequate consultation from the EPA SAB in the development of the NPDWR. SDWA section 1412(e) requires that the EPA ''request comments'' from the SAB ''prior to proposal'' of the MCLG and NPDWR. Consistent with this statutory provision, the EPA consulted with the SAB from 2021–2022. As discussed in the proposed rule, the SAB PFAS Review Panel met virtually via a video meeting platform on December 16, 2021, and then had three (3) subsequent meetings on January 4, 6 and 7, 2022 to deliberate on the agency's charge questions, which included a question specifically focused on the utility and scientific defensibility of the Hazard Index approach in the context of mixtures risk assessment in drinking water. Another virtual meeting was held on May 3, 2022, to discuss the SAB PFAS Review Panel's draft report. Oral and written public comments were considered throughout the advisory process. The SAB provided numerous recommendations to the EPA which can be found in the SAB's final report (USEPA, 2022i). The EPA addressed the SAB's recommendations and described the EPA's responses to SAB recommendations in its *EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation* (USEPA, 2023k) and also in the EPA's Response to Comments document in response to public comments on the proposed PFAS

[3] Some commenters noted an error in the HBWC calculation for PFHxS which was reported as 9.0 ng/L in the proposal. The agency has corrected the value in this NPDWR and within the requirements under 40 CFR part 141 subpart Z. The correct HRL/HBWC for PFHxS is 10 ng/L.

NPDWR (USEPA, 2024k). Further discussion on the EPA consultations and stakeholder engagement activities can be found in section XIII of this preamble.

The agency also disagrees with commenters who contend that the EPA must seek advice from the SAB on all aspects of the NPDWR. The statute does not dictate on which scientific issues the EPA must request comment from the SAB. In this case, the EPA sought comments on four documents: *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water* (USEPA, 2021i); *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanesulfonic Acid (PFOS) in Drinking Water* (USEPA, 2021j); *Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water* (USEPA, 2021k); and *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2021e).

The approach of the EPA's *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2024a) and this rule is to evaluate risks from exposure to mixtures of PFAS that elicit the same or similar adverse health effects (but with differing potencies for effect(s)) rather than similarity in MOA. This is consistent with the EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000a) and expert opinion from the NAS National Research Council (NRC, 2008). MOA, which describes key changes in cellular or molecular events that may cause functional or structural changes that lead to adverse health effects, can be a useful metric by which risk can be assessed. It is considered a key determinant of chemical toxicity, and chemicals can often be classified by their type of toxicity pathway(s) or MOAs. However, because PFAS are an emerging chemical class, MOA data can be limited or entirely lacking for many PFAS. Therefore, the EPA's approach for assessing risks of PFAS mixtures is based on the conclusion that PFAS that share one or more adverse outcomes produce dose-additive effects from co-exposures. This evidence-based determination supports a health-protective approach that meets the statute's directive to set the MCLG at a level at which there are no known or anticipated adverse health effects and which allows for an adequate margin of safety (1412(b)(4)(A)). The EPA's evidence-based determination regarding dose additivity, based on similarity of adverse health effects rather than MOA, and use of the Hazard Index approach to assess risks of exposure to PFAS mixtures were supported by the SAB in its review of the *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2022i). For a detailed description of the evidence supporting dose additivity as the default approach for assessing mixtures of PFAS, see the final *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2024a).

A few commenters supported the EPA's approach to assessing risks of PFAS mixtures based on similarity of toxicity effect rather than similarity in MOA. A few commenters opposed the EPA's use of same or similar adverse health effects/outcomes rather than MOA as a basis for the approach to assessing risks of PFAS mixtures and suggested that the agency is not following its own chemical mixtures guidance (USEPA, 2000a). The EPA disagrees with these commenters' assertions. The EPA's approach, to evaluate health risks of exposure to mixtures of these four PFAS based on shared or similar adverse health effects of the mixture components rather than a common MOA, is consistent with the EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000a). Although a conclusion about dose additivity can be based on mixture components sharing a common MOA, dose additivity can also be based on ''toxicological similarity, but for specific conditions (endpoint, route, duration)'' (see the EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures,* USEPA, 2000a). The EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* indicates that although basing a conclusion about dose additivity on a common MOA across mixture components is optimal, there is flexibility in the level of biological organization at which similarity among mixture components can be determined.

The EPA directly asked the SAB for feedback on this issue during its 2021 review of the EPA's draft *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS.* Specifically, the EPA asked the SAB, ''If common toxicity endpoint/health effect is not considered an optimal similarity domain for those PFAS with limited or no available MOA-type data, please provide specific alternative methodologies for integrating such chemicals into a component-based mixture evaluation(s)'' (USEPA, 2022i). The SAB strongly supported the EPA's approach of using a similar toxicity endpoint/health effect instead of a common MOA as a default approach for evaluating mixtures of PFAS using dose additivity and did not offer an alternative methodology. For example, the SAB panel stated that:

> The Panel agreed with use of a similar toxicity endpoint/health effect instead of a common MOA as a default approach for evaluating mixtures of PFAS. This approach makes sense because multiple physiological systems and multiple MOAs can contribute to a common health outcome. Human function is based on an integrated system of systems and not on single molecular changes as the sole drivers of any health outcome. The Panel concluded that rather than the common MOA, as presented in the EPA draft mixtures document, common physiological outcomes should be the defining position (USEPA, 2022i).

The SAB panel also stated:

> Furthermore, many PFAS, including the four used in the examples in the draft EPA mixtures document and others, elicit effects on multiple biological pathways that have common adverse outcomes in several biological systems (*e.g.,* hepatic, thyroid, lipid synthesis and metabolism, developmental and immune toxicities) (USEPA, 2022i).

Some commenters expressed support for the EPA's proposed Hazard Index approach to regulating a mixture of one or more of the four PFAS in drinking water. The commenters also stated that occurrence and co-occurrence of these four PFAS in PWSs, as well as individual and dose-additive effects of these PFAS, justify the general Hazard Index approach. The EPA agrees that the general Hazard Index approach is the most scientifically sound and health-protective approach to deriving a PFAS mixtures MCLG which considers both their dose additive health concerns and co-occurrence in drinking water (see additional discussion in the following paragraphs).

Some commenters opposed the EPA's use of a general Hazard Index as opposed to a target organ-specific Hazard Index (TOSHI) and suggested the use of a TOSHI instead. As discussed in this section, the EPA disagrees with these comments because the use of the general Hazard Index approach to develop an MCLG for a mixture of PFHxS, PFNA, HFPO–DA, and/or PFBS is scientifically sound, supported by external peer review (SAB), and consistent with the EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000a).

The EPA considered the two main types of Hazard Index approaches: (1)

the general Hazard Index, which allows for component chemicals in the mixture to have different health effects or endpoints as the basis for their toxicity reference values (*e.g.,* RfDs, minimal risk levels), and (2) the TOSHI, which relies on toxicity reference values based on the same specific target organ or system effects (*e.g.,* effects on the liver or thyroid; effects on developmental or reproductive systems) (USEPA, 2000a). The general Hazard Index approach uses the most health-protective RfD (or minimal risk levels) available for each mixture component, irrespective of whether the RfDs for all mixture components are based on effects in the same target organs or systems. These ''overall'' RfDs (as they are sometimes called) are protective of all other adverse health effects because they are based on the most sensitive known endpoints as supported by the weight of the evidence. As a result, this approach is protective of all types of toxicity/adverse effects, and thus ensures that the MCLG is the level at and below which there are no known or anticipated adverse human health effects with an adequate margin of safety with respect to certain PFAS mixtures in drinking water. The TOSHI produces a less health protective indicator of risk than the general Hazard Index because the basis for the component chemical toxicity reference values has been limited to a specific target organ or system effect, which may occur at higher exposure levels than other effects (*i.e.,* be a less sensitive endpoint). Additionally, since a TOSHI relies on toxicity reference values aggregated for the same specific target organ or system endpoint/effect, an absence or lack of data on the specific target organ or system endpoint/effect for a mixture component may result in that component not being adequately accounted for in this approach (thus, underestimating health risk of the mixture). A TOSHI can only be derived for those PFAS for which the same target organ or system endpoint/effect-specific RfDs have been calculated. Many PFAS have data gaps in epidemiological or animal toxicological dose-response information for multiple types of health effects, thus limiting derivation of target organ-specific toxicity reference values; target organ-specific toxicity reference values are not currently available for PFHxS, PFNA, HFPO–DA, and PFBS. The EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* recognizes the potential for organ- or system-specific data gaps and supports use of overall RfDs in a general Hazard Index approach, stating, ''The target organ toxicity dose (TTD) is not a commonly evaluated measure and currently there is no official EPA activity deriving these values, as there is for the RfD and RfC'' . . . ''Because of their much wider availability than TTDs, standardized development process including peer review, and official stature, the RfD and RfC are recommended for use in the default procedure for the HI'' (USEPA, 2000a). The EPA determined that the general Hazard Index approach is the most scientifically defensible and health protective approach for considering PFAS mixtures in this rule because it is protective of all adverse health effects rather than just those associated with a specific organ or system, consistent with the statutory definition of MCLG.

The EPA directly asked the SAB about the utility and scientific defensibility of the general Hazard Index approach (in addition to other methods, including TOSHI) during the 2021 review of the EPA's draft *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS.* Specifically, the EPA asked the SAB to ''Please provide specific feedback on whether the HI approach is a reasonable methodology for indicating potential risk associated with mixtures of PFAS. If not, please provide an alternative;'' and ''Please provide specific feedback on whether the proposed HI methodologies in the framework are scientifically supported for PFAS mixture risk assessment'' (USEPA, 2022i). In its report (USEPA, 2022i), the SAB stated its support for the general Hazard Index approach:

> In general, the screening level Hazard Index (HI) approach, in which Reference Values (RfVs) for the mixture components are used regardless of the effect on which the RfVs are based, is appropriate for initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated. Toxicological studies to inform human health risk assessment are lacking for most members of the large class of PFAS, and mixtures of PFAS that commonly occur in environmental media, overall. For these reasons, the HI methodology is a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media. The HI is an approach based on dose additivity (DA) that has been validated and used by the EPA. The HI does not provide quantitative risk estimates (*i.e.,* probabilities) for mixtures, nor does it provide an estimate of the magnitude of a specific toxicity. This approach is mathematically straightforward and may readily identify mixtures of potential toxicological concern, as well as identify chemicals that drive the toxicity within a given mixture.

A few commenters stated that it is inappropriate to use the general Hazard Index in the context of a drinking water rule because it is a screening tool. The EPA guidance (*e.g., Risk Assessment Guidance for Superfund* [RAGS], USEPA, 1991b) and the SAB does characterize the general Hazard Index as appropriate for screening, but the SAB did not say that the methodology's use was limited to screening, nor that the agency would or should be prohibited from considering its use in any regulatory or nonregulatory application. The general Hazard Index is a well-established methodology that has been used for several decades in at least one other regulatory context to account for dose additivity in mixtures. The EPA routinely uses the Hazard Index approach to consider the risks from multiple contaminants of concern in the Remedial Investigations and Feasibility Studies for cleanup sites on the Superfund National Priorities List under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Noncarcinogenic effects are summed to provide a Hazard Index that is compared to an acceptable index, generally 1. This procedure assumes dose additivity in the absence of information on a specific mixture. These assessments of hazards from multiple chemical exposures are important factors to help inform the selection of remedies that are ultimately captured in the Superfund Records of Decision. Moreover, the EPA has determined that in the context of SDWA, the Hazard Index is also an appropriate methodology for determining the level at and below which there are no known or anticipated adverse human health effects with an adequate margin of safety with respect to certain PFAS mixtures in drinking water. The Hazard Index approach is the most practical approach for establishing an MCLG for PFAS mixtures that meets the statutory requirements outlined in section 1412(b)(1)(A) of SDWA. This is because the Hazard Index assesses the exposure level of each component PFAS relative to its HBWC, which is based on the most sensitive known adverse health effect (based on the weight of evidence) and considers sensitive population(s) and life stage(s) as well as potential exposure sources beyond drinking water. Furthermore, the Hazard Index accounts for dose additive health concerns by summing the hazard contribution from each mixture component to ensure that the mixture is not exceeding the level below which there are no known or anticipated adverse health effects and allows for an

adequate margin of safety. In addition, given the temporal and spatial variability of PFAS occurrence in drinking water across the nation (USEPA, 2024b), this methodology allows the EPA to regulate these chemicals in drinking water by taking into account site-specific data at each PWS. Component PFAS HQs (hazard quotients) are expected to differ across time and space depending on the actual measured concentrations of each of the four PFAS at each PWS. This approach thus allows for flexibility beyond a one-size-fits-all approach and is tailored to address risk at each PWS. The EPA has made a final regulatory determination for mixtures of two or more of these PFAS. The EPA's application of the Hazard Index approach to regulate such mixtures accounts for the dose additivity that was the basis for the EPA's final determination to regulate such mixtures.

A Hazard Index greater than 1 is generally regarded as an indicator of adverse health risks associated with a specific level of exposure to the mixture; a Hazard Index less than or equal to 1 is generally regarded as not being associated with any appreciable risk (USEPA, 1986; USEPA,1991b; USEPA, 2000a). Thus, in the case of this drinking water rule, a Hazard Index greater than 1 indicates that occurrence of two or more of these four component PFAS in a mixture in drinking water exceeds the health protective level(s) (*i.e.,* HBWC(s)), indicating health risks.

The EPA proposed a Hazard Index MCLG of 1.0, expressed with two significant digits. The EPA's proposal expressed the HBWCs to the tenths place, as follows: 9.0 ng/L for PFHxS, 10.0 ng/L for HFPO–DA; 10.0 ng/L for PFNA; and 2000.0 ng/L for PFBS. The EPA's draft Hazard Index MCLG document expressed all of the HBWCs with one significant digit (9, 10, 10, 2000 ng/L, respectively) (USEPA, 2023e). A few commenters supported the use of two significant digits for the HBWCs, individual HQs, and the Hazard Index MCLG and stated that the use of two significant digits would not be expected to result in issues related to analytical methods precision. One commenter supported using all digits of precision in calculations but rounding to two significant digits for the final reported value of the Hazard Index, noting that the number of significant digits used only affects rounding during steps prior to the point at which a Hazard Index MCL is reached. Commenters noted the importance of clearly communicating the number of significant digits to be used in the documents, and that the choice of the number of significant digits could impact implementation of an MCL based on the Hazard Index. For example, a Hazard Index of 1 (*i.e.,* using one significant digit) would not be exceeded unless the value is calculated to be at 1.5 or above. Alternatively, a Hazard Index of 1.0 (reporting with more than one significant digit) would be exceeded when the Hazard Index is calculated to be 1.05 or above. For additional discussion on significant digit usage, please see sections V and VIII.

A few commenters did not support more than a single significant digit for the HBWCs and Hazard Index MCLG, with some stating that using two or more significant digits for the Hazard Index contradicts the EPA chemical mixtures guidance (USEPA, 2000a) and the RAGS (USEPA, 1991b). The EPA agrees that one (1) significant digit is appropriate for the HBWCs and the Hazard Index MCLG (*i.e.,* 1 rather than 1.0, as in the proposal) because although there is sufficient analytical precision for two significant digits at these concentrations, the RfVs (RfDs and minimal risk levels) used to derive the HBWCs have one significant digit. According to the EPA chemical mixtures guidance (USEPA, 2000a), ''Because the RfDs (and by inference the TTDs) are described as having precision no better than an order of magnitude, the HI should be rounded to no more than one significant digit.'' This approach of using a Hazard Index of 1 is consistent with agency chemical mixtures guidance (USEPA, 1986; USEPA, 2000a) and RAGS (USEPA, 1991b; USEPA, 2018c). The EPA's *Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual* states, ''For noncarcinogenic effects, a concentration is calculated that corresponds to an HI of 1, which is the level of exposure to a chemical from all significant exposure pathways in a given medium below which it is unlikely for even sensitive populations to experience adverse health effects,'' and ''The total risk for noncarcinogenic effects is set at an HI of 1 for each chemical in a particular medium'' (USEPA, 1991b). Finally, ''Cancer risk values and hazard index (HI) values may express more than one significant figure, but for decision-making purposes one significant figure should be used'' (USEPA, 2018c).

c. Final Rule

The EPA has made a final determination to regulate mixtures containing two or more of PFHxS, PFNA, HFPO–DA, and/or PFBS. For the final determination, the EPA's evaluation utilized an HRL as part of a general Hazard Index approach (for additional discussion on the EPA's *Final Regulatory Determinations,* please see section III of this preamble). The EPA's proposal included individual preliminary regulatory determinations for PFHxS, PFNA, HFPO–DA, and PFBS and a mixture regulatory determination for mixtures of those PFAS. The EPA's proposal addressed these regulatory determinations through the Hazard Index MCLG and MCL that would apply to a mixture containing one or more of PFHxS, PFNA, HFPO–DA, and PFBS. If two or more of these PFAS were present then the MCLG and MCL would account for dose additivity of all of the contaminants present, but if only one of the contaminants were present then the Hazard Index would operate as an individual MCLG and MCL. In this final rule, the EPA is promulgating individual MCLGs and MCLs to address the individual final regulatory determinations (PFHxS, PFNA, and HFPO–DA) and is promulgating a Hazard Index MCLG and MCL to address the final mixtures regulatory determination for two or more Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) present.

The EPA used the same general Hazard Index approach for the mixture MCLG. In the general Hazard Index approach, individual PFAS HQs are calculated by dividing the measured concentration of each component PFAS in water (*e.g.,* expressed as ng/L) by the corresponding HBWC for each component PFAS (*e.g.,* expressed as ng/L), as shown in the following equation (and described in USEPA, 2024f). For purposes of this NPDWR, the EPA is using the term ''health-based water concentration'' or ''HBWC'' given its role in calculating the Hazard Index (see the Executive Summary of this preamble). The EPA notes that the Hazard Index MCLG applies to the entire mixture but the EPA's technical justification for the HBWCs for the mixture components is the same as for the individual MCLGs provided in this rule. In this final rule, component PFAS HQs are summed across the PFAS mixture to yield the Hazard Index MCLG. The final PFAS mixture Hazard Index MCLG is set at 1 (one significant digit). A Hazard Index greater than 1 (rounded to one significant digit) indicates that exposure (*i.e.,* PFAS occurrence in drinking water) exceeds the health protective level (*i.e.,* HBWC) for two or more of the individual PFAS mixture components, and thus indicates health risks. The Hazard Index MCLG ensures that even when the individual

components are below a level of concern, the components when added together in the mixture do not result in a mixture that itself exceeds a level of concern. A Hazard Index less than or equal to 1 indicates that occurrence of these four PFAS in drinking water does not exceed the health protective level and is therefore generally regarded as unlikely to result in any appreciable risk (USEPA, 1986; USEPA, 1991b; USEPA, 2000a). For more details, please see USEPA (2024a; USEPA, 2024f). The final Hazard Index MCLG for a mixture of PFHxS, PFNA, HFPO–DA, and/or PFBS is derived as follows:

$$HI\ MCLG\ = \left(\frac{[HFPO\text{-}DA_{water}]}{[HFPO\text{-}DA_{HBWC}]}\right) + \left(\frac{[PFBS_{water}]}{[PFBS_{HBWC}]}\right) + \left(\frac{[PFNA_{water}]}{[PFNA_{HBWC}]}\right) + \left(\frac{[PFHxS_{water}]}{[PFHxS_{HBWC}]}\right) = 1$$

$$HI\ MCLG\ = \left(\frac{[HFPO\text{-}DA_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[PFBS_{ng/L}]}{[2000\ ng/L]}\right) + \left(\frac{[PFNA_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[PFHxS_{ng/L}]}{[10\ ng/L]}\right) = 1$$

Where

[$PFAS_{water}$] = the measured component PFAS concentration in water and

[$PFAS_{HBWC}$] = the HBWC of a component PFAS.

2. MCLG Derivation for PFHxS, PFNA, and HFPO–DA

a. Proposal

As described in section IV.B.1.a of this preamble, in March 2023, the EPA proposed a Hazard Index MCLG to protect public health from exposure to mixtures of PFHxS, PFNA, HFPO–DA, and PFBS, four PFAS that affect many similar health endpoints/outcomes and that occur and co-occur in drinking water. At that time, the EPA also considered setting individual MCLGs for these PFAS either instead of or in addition to using a mixtures-based approach for PFHxS, PFNA, HFPO–DA, and PFBS. The EPA ultimately proposed the Hazard Index approach for establishing an MCLG for a mixture of these four PFAS.

b. Summary of Major Public Comments and EPA Responses

Several commenters favored finalization of individual MCLGs (and MCLs) for some or all of the PFAS included in the proposed Hazard Index, with or without a Hazard Index approach to address mixtures of these PFAS. Specifically, commenters supported establishing individual MCLGs for PFHxS, PFNA, HFPO–DA, and PFBS because they questioned the EPA's scientific conclusions regarding PFAS dose additivity and raised concerns about potential risk communication issues and confusion about the EPA's use of the Hazard Index to establish drinking water standards (for additional discussion on MCLs, please see section V of this preamble). The EPA agrees with commenters who favored finalization of individual MCLGs for some of the PFAS included in the Hazard Index, and to do so in addition to the Hazard Index MCLG being finalized for the mixture of the four PFAS. The EPA believes this provides clarity for purposes of implementation of the rule. The EPA is finalizing individual MCLGs for PFHxS, PFNA, and HFPO–DA (for additional discussion on the final regulatory determinations, please see section III of this preamble). Regarding risk communication and potential confusion about the use of the Hazard Index, the EPA acknowledges that effective risk communication is important, and the agency will develop communication materials to facilitate understanding of all aspects of this NPDWR, including the Hazard Index MCL (for additional discussion on MCLs, please see section V of this preamble). The EPA has provided language for consumer notifications as part of CCR (see section IX of this preamble).

One commenter stated that developing individual MCLGs (and MCLs) in addition to the Hazard Index mixture MCLG (and MCL) would have no practical impact, since an exceedance of an HBWC for an individual PFAS within a mixture would result in an exceedance of the Hazard Index even if none of the other PFAS included in the Hazard Index are detected. The EPA clarifies the final rule promulgates individual MCLs for PFHxS, PFNA and HFPO–DA as well as a mixture Hazard Index MCL for two or more of these PFAS and PFBS. There may be a practical impact of these individual MCLs (for PFHxS, PFNA and HFPO–DA) where one of these three PFAS occur in isolation (*i.e.,* without one of the other four Hazard Index PFAS present) above their individual MCLs. The EPA notes that this regulatory structure is consistent with the intended effect of the proposed regulation, where as proposed, a single PFAS above its HBWC would have caused an exceedance of the MCL. Based on public comment, the EPA has restructured the rule such that two or more of these regulated PFAS would be necessary to cause an exceedance of the Hazard Index and instead will regulate individual exceedances of PFNA, PFHxS, and HFPO–DA as individual MCLs to improve risk communication. Risk communication is an important focus for water systems and the EPA believes that finalizing individual MCLs for PFHxS, PFNA, and HFPO–DA can support risk communication as utilities and the public may be more familiar with this regulatory framework. Additionally, the final individual MCLs for PFHxS, PFNA and HFPO–DA will address and communicate health concerns for these compounds where they occur in isolation. At the same time, since those individual MCLs do not address additional risks from co-occurring PFAS, the EPA is finalizing a Hazard Index MCL that provides a framework to address and communicate dose additive health concerns associated with mixtures of PFHxS, PFNA, HFPO–DA, and PFBS that co-occur in drinking water. For the EPA's discussion on the practical impact of the establishment of stand-alone standards in lieu of or in addition to the Hazard Index MCL, please see sections V and IX.A of this preamble. The EPA's discussion on the practical impact of the establishment of stand-alone standards in lieu of or in addition to the Hazard Index MCL, please see sections V and IX.A of this preamble.

A few commenters questioned why the EPA is developing an NPDWR for contaminants that do not have EPA Drinking Water Health Advisories (PFHxS, PFNA), and stated that the EPA should wait to propose an NPDWR for PFHxS and PFNA until after Health Advisories are finalized for these PFAS. The EPA disagrees with this comment. Health Advisories are not a pre-requisite for an NPDWR under SDWA and there is nothing in the statute or the EPA's historical regulatory practice that suggests that the agency must or should

delay regulation of a contaminant in order to develop a health advisory first.

c. Final Rule

As described in section III of this preamble, the EPA has made a final determination to individually regulate PFHxS, PFNA, and HFPO–DA.

The EPA is finalizing individual MCLGs for PFHxS, PFNA, and HFPO–DA as follows: PFHxS MCLG = 10 ng/L; HFPO–DA MCLG = 10 ng/L; and PFNA MCLG = 10 ng/L. The technical basis for why each of these levels satisfies the statutory definition for MCLG is described in section III of this preamble (and is the same technical basis the EPA used to explain the levels identified as the HBWCs). These MCLGs are expressed with one significant digit and are based on an analysis of each chemical's toxicity (*i.e.,* RfD/minimal risk level) and appropriate exposure factors (*i.e.,* DWI–BW, RSC) (USEPA, 2024f).

The EPA is deferring its individual regulatory determination for PFBS and not finalizing an individual MCLG for PFBS at this time (please see section III of this preamble, *Final Regulatory Determinations for Additional PFAS,* for further information).

V. Maximum Contaminant Levels

Under current law and as described in the proposed rule (USEPA, 2023f), the Environmental Protection Agency (EPA) establishes drinking water standards through a multi-step process. *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3. First, the agency establishes a non-enforceable Maximum Contaminant Level Goals (MCLG) for the contaminant in drinking water at a level which no known or anticipated adverse effects to the health of persons will occur and which allow for an adequate margin of safety. Second, the agency generally sets an enforceable Maximum Contaminant Level (MCL) as close to that public health goal as feasible, taking costs into consideration.

In this second step, consistent with the definition of ''feasible'' in section 1412(b)(4)(D), the EPA evaluates the availability and performance of Best Available Technologies (BATs) for treating water to minimize the presence of the contaminant consistent with the MCLG (see section X for additional discussion on BATs) as well as the costs of applying those BATs to large metropolitan water systems when treating to that level (1412(b)(4)(E) and (5)).[4] The definition of ''feasible'' means *feasible* with the use of the best technology . . . ''which includes consideration of the analytical limits of best available treatment and testing technology.'' *see* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3; *see also* section 1401(1)(C)(i) stating that a NPDWR includes an MCL only ''if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems.'' In addition, the MCL represents ''the maximum permissible level of a contaminant in water which is delivered to any user of a public water system,'' section 1401(3). Thus, in setting the MCL level, the EPA also identifies the level at which it is technologically feasible to measure the contaminant in the public water system. To identify this level, the EPA considers (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (known as the practical quantitation levels (PQLs)). The ability of laboratories to measure the level of the contaminant with sufficient precision and accuracy using approved methods is essential to ensure that any public water system nationwide can monitor, determine compliance, and deliver water that does not exceed the maximum permissible level of a contaminant in water to any of its consumers. (See section VII of this preamble for additional discussion on analytical methods and PQLs for the per- and polyfluoroalkyl substances (PFAS) regulated in this rule.)

In practice this means that where the MCLG is zero, the EPA typically sets MCLs at the PQLs when treatment is otherwise feasible, based on cost and treatment availability, because the PQL is the limiting factor. Conversely, for contaminants where the MCLG is higher than the PQL, the EPA generally sets the MCL at the MCLG when treatment is otherwise feasible, based on costs and treatment availability, because the PQL is not a limiting factor.

The Safe Drinking Water Act (SDWA) defines an MCL as ''the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.'' Like the MCLG, SDWA does not dictate that the MCL take a particular form; however, given this definition, an MCL establishes a ''maximum permissible level of a contaminant in water'' and as a practical matter the identified ''level'' must be capable of being validated so that it can be determined whether that public water systems are delivering water to any user meeting or exceeding that ''level.''

A. PFOA and PFOS

1. Proposal

In the March 2023 proposal, the EPA proposed individually enforceable MCLs for PFOA and PFOS at the PQL which is 4.0 ng/L (USEPA, 2023f). Section 1412(b)(4)(E) of SDWA requires that the agency ''list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL],'' which are referred to as Best Available Technologies (BATs). The EPA found multiple treatment technologies to be effective and available to treat PFOA and PFOS to at or below the proposed standards (please see and section X (10) of this preamble and USEPA, 2024l for additional discussion on feasible treatment technologies including BAT/SSCT identification and evaluation). In addition, the EPA found that there are analytical methods available to reliably quantify PFOA and PFOS at the PQL. The EPA requested comment on regulatory alternatives for both compounds at 5.0 ng/L and 10.0 ng/L. The EPA also requested comment on whether setting the MCL at the PQL for PFOA and PFOS is implementable and feasible.

2. Summary of Major Public Comments and EPA Responses

The EPA received many comments that strongly support the proposed MCLs of 4.0 ng/L and the agency's determination that the standards are as close as feasible to the MCLG. These commenters request the agency to finalize the standards as expeditiously as possible. Consistent with these comments, through this action, the agency is establishing drinking water standards for PFOA and PFOS (and four other PFAS) to provide health protection against these contaminants found in drinking water.

Many commenters assert that implementation of the PFOA and PFOS standards would be challenging because the MCLs are set at the PQLs for each compound, and some commenters recommended alternative standards (*e.g.,* 5.0 ng/L or 10.0 ng/L). These commenters contend that by setting the

[4] Based on legislative history, the EPA interprets ''taking cost into consideration'' in section 1412(b)(4)(D) to be limited to ''what may be reasonably be afforded by large metropolitan or regional public water systems.'' H.R. Rep. No 93–1185 (1974), *reprinted in* 1974 U.S.C.C.A.N. 6454, 6470–71.

MCLs at the PQLs, utilities would not be able to reliably measure when the concentration of contaminants in their drinking water is approaching the MCLs. Some of these commenters suggest that having a buffer between the PQLs and the MCLs may allow utilities to manage treatment technology performance more efficiently because utilities generally aim to achieve lower than the MCLs to avoid a violation and that this buffer would provide some level of operational certainty for systems treating for PFAS. The EPA disagrees that the PFOA and PFOS standards are not implementable because the MCLs are set at their respective PQLs.

As the agency noted in the proposed rule preamble, the EPA has promulgated, and both the EPA and water systems have successfully implemented, several NPDWRs with MCLs equal to the contaminant PQLs. As examples, in 1987, the EPA finalized the Phase I Volatile Organic Compounds (VOC) rule (USEPA, 1987), where the agency set the MCL at the PQL for benzene, carbon tetrachloride, trichloroethylene, vinyl chloride, and 1,2-dichloroethane (52 FR 25690). Other examples where MCLs were set at the PQL include benzo(a)pyrene, di(2-ethylhexyl) phthalate, dioxin, dichloromethane, hexachlorobenzene, and PCBs (see USEPA, 1991c and USEPA, 1992). Some commenters at the time stated they believed implementation would be challenging because the MCLs were set at the PQL in these examples; however, the EPA notes that those rules have been implemented successfully despite commenters initial concerns. The agency does not agree with commenters that operational flexibility (*i.e.,* the inclusion of a 'buffer' between the PQL and MCL) is relevant for purposes of setting an MCL. That is because the PQL is the lowest level that can be reliably achieved within specified limits of precision and accuracy and is therefore the metric by which the agency uses to evaluate the most feasible MCL pursuant to SDWA requirements. Considerations for operational flexibility may be relevant to other parts of the rule, such as determining monitoring and compliance with the rule. First, for purposes of determining compliance with the MCL, water systems must calculate the running annual average (RAA) of results, which could allow some results to exceed 4.0 ng/L for single measurements if the overall annual average is below the MCL. In other words, there is a buffer built into determining compliance with the MCL. Second, when calculating the RAA, zero will be used for results less than the PQL which provides an additional analytic buffer for utilities in their compliance calculations. This monitoring and compliance framework allows for temporal fluctuations in concentrations that may occur because of unexpected events such as premature PFOA and PFOS breakthrough or temporary elevated source water concentrations. Thus, periodic occurrences of PFOA or PFOS that are slightly above the PQLs do not necessarily result in a violation of the MCL if other quarterly samples are below the PQL. The agency notes that in general, PQLs are set above the limit of detection; for PFAS specifically, all the PQLs are well above their limits of detection. The PQL is also different than detection limits because the PQL is set considering a level of precision, accuracy, and quantitation. Systems may be able to use sample results below the PQL to understand whether PFOA and PFOS are present. While the EPA has determined that results below the PQL are insufficiently precise for determining compliance with the MCL, results below the PQL can be used to determine analyte presence or absence in managing a system's treatment operations and to determine monitoring frequency. See discussion in section VII of this preamble for further discussion of the PQL, results below the PQL, and how those results provide useful information.

Some commenters contend that the PQLs for PFOA and PFOS are not set at an appropriate level (*e.g.,* the PQLs are either too high or too low for laboratories to meet). Specifically, these commenters question whether enough laboratories have the ability to analyze samples at 4.0 ng/L and, as a result, contend it is not a ''reasonable quantitation level.'' The EPA disagrees with commenters who suggest the PQLs for PFOA and PFOS are not set at an appropriate level or that they should be either higher or lower levels than that proposed. As discussed above and in the March 2023 proposal, the EPA derives PQLs that reflect the level of contaminants that laboratories can reliably quantify within specific limits of precision and accuracy during routine laboratory operating conditions. The ability to reliably measure is an important consideration for feasibility to ensure that water systems nationwide can monitor and dependably comply with the MCLs and deliver drinking water that does not exceed the maximum permissible level. In the rule proposal (USEPA, 2023f), the EPA explained that the minimum reporting levels under UCMR 5 reflect ''a minimum quantitation level that, with 95 percent confidence, can be achieved by capable lab analysts at 75 percent or more of the laboratories using a specified analytical method'' (USEPA, 2022k). The PQLs for the regulated PFAS are based on the UCMR 5 minimum reporting levels. The EPA calculated the UCMR 5 minimum reporting levels using quantitation-limit data from multiple laboratories participating in multi-lab method validation studies conducted in the 2017–2019 timeframe, prior to the UCMR 5 Laboratory Approval Program (see appendix B of USEPA, 2020b). The calculations account for differences in the capability of laboratories across the country. Laboratories approved to analyze UCMR samples must demonstrate that they can consistently make precise measurements of PFOA and PFOS at or below the established minimum reporting levels. Therefore, the EPA finds that the UCMR 5 minimum reporting levels are appropriate for using as PQLs for this rule: the EPA estimates that laboratories across the nation can precisely and accurately measure PFOA and PFOS at this quantitation level. After reviewing data from laboratories that participated in the minimum reporting level setting study under UCMR 5 and in consideration of public comment, the EPA finds that the minimum reporting levels set in UCMR 5 of 4.0 ng/L for PFOA and PFOS, that are also the PQLs, are as close as feasible to the MCLG. While lower quantitation levels may be achievable for some laboratories, it has not been demonstrated that these lower quantitation levels can be achieved for ''at 75 percent or more of the laboratories using a specified analytical method'' across laboratories nationwide. Moreover, though the EPA is confident of sufficient laboratory capacity to implement this PFAS National Primary Drinking Water Regulation (NPDWR) as finalized, a lower PQL could potentially limit the number of laboratories available to support analytical monitoring that would be otherwise available to support analytical monitoring with PFOA and PFOS PQLs of 4.0 ng/L.

In the proposal, the EPA discussed how utilities may be able to use sample results below the PQL to determine analyte presence or absence in managing their treatment operations; however, a few commenters contend that this is not practical to determine compliance with the MCL as these values are less precise and violations may result in expensive capital

improvements. Commenters are conflating two different issues. While commenters are referring to quantitation of a sampling result for compliance with the rule, the EPA's discussion on results below the PQL refers to determining simple presence or absence of a contaminant for other purposes. Sampling results below the PQL may not have the same precision as a sampling result at or above the PQL but they are useful for operational purposes such as understanding that PFOA and PFOS may be present, which can inform treatment decisions and monitoring frequency. For example, a utility may use sampling results below 4.0 ng/L as a warning that they are nearing the PFOA and PFOS MCLs of 4.0 ng/L prior to an exceedance. Then, the utility can make informed treatment decisions about managing their system (*e.g.,* replacing GAC). Additionally, the EPA evaluated data submitted as part of the UCMR 5 Laboratory Approval Program (LAP) and found that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a minimum reporting level confirmation at 2 ng/L (one-half the proposed MCL) or less for Method 533 (USEPA, 2022j). This suggests that the majority of laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide useful screening measurement results below the PQL. Further, as discussed in section VII of this preamble, all labs are required per the approved methods to demonstrate whether laboratory reagent blank (LRB) quality control (QC) samples have background concentrations of less than one-third the minimum reporting level (*i.e.,* the minimum concentration that can be reported as a quantitated value for a method analyte in a sample following analysis). Therefore, for a laboratory to be compliant with the methods, they must be able to detect, not necessarily quantify, analytes at or above ⅓ the minimum reporting level.

The EPA agrees with commenters that it is inappropriate to make potentially costly compliance decisions based on measurements below the PQL because they do not have the same level of precision and accuracy as results at or above the PQL. As previously discussed, for MCL compliance purposes, results less than the PQL will be recorded as zero. For additional details on monitoring and compliance requirements, please see section VIII of this preamble.

Some commenters argue that the EPA did not sufficiently consider cost in the agency's feasibility analysis of the proposed MCLs and therefore disagreed with the EPA that the standards are feasible. In particular, these commenters suggest that the agency did not adequately consider costs associated with implementation (*e.g.,* costs for labor, materials, and construction of capital improvements) and compliance (*e.g.,* costs to monitor) with the proposed MCLs. Based on these factors, many of these commenters suggest either raising the MCLs or re-proposing the standard in its entirety. The EPA did consider these costs and therefore disagrees with commenters' assertions that the agency did not consider these issues in establishing the proposed MCLs for PFOA and PFOS (USEPA, 2024g; USEPA, 2024l; USEPA, 2024m). The EPA considers whether these costs are reasonable based on large metropolitan drinking water systems. H.R. Rep. No 93–1185 (1978), *reprinted in* 1974 U.S.C.C.A.N. 6454, 6470–71. The EPA considered costs of treatment technologies that have been demonstrated under field conditions to be effective at removing PFOA and PFOS and determined that the costs of complying with an MCL at the PQL of 4.0 are reasonable for large metropolitan water systems at a system and national level (USEPA, 2024e; USEPA, 2024g). To designate technologies as BATs, the EPA evaluated each technology against six BAT criteria, including whether there is a reasonable cost basis for large and medium water systems. The EPA evaluated whether the technologies are currently being used by systems, whether there were treatment studies available with sufficient information on design assumptions to allow cost modeling, and whether additional research was needed (USEPA, 2024l). In considering the results of this information, the EPA determined that these costs are reasonable to large metropolitan water systems.

Pursuant to SDWA section 1412(b)(4)(E)(ii), the agency also evaluated ''technolog[ies], treatment technique[s], or other means that is affordable'' for small public water systems. In this evaluation, the agency determined that the costs of small system compliance technologies (SSCTs) to reach 4.0 ng/L are affordable for households served by small drinking water systems. Additionally, the EPA notes that SDWA section 1412(b)(4)(D) states that ''granular activated carbon is feasible for the control of synthetic organic chemicals'' which the agency lists as a BAT for this rule (section X). All PFAS, including PFOA and PFOS, are SOCs, and therefore, GAC is BAT as defined by the statute. For additional discussion on BATs and SSCTs, please see section X of this preamble.

Some commenters disagreed with the EPA's determination that the rule is feasible under SDWA asserting that there is insufficient laboratory capacity and other analytic challenges to measure samples at these thresholds. As described above in the agency's approach toward evaluating feasibility, the EPA assesses (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (*i.e.,* the PQLs). This framework inherently considers both the capacity and capability of labs available to meet the requirements of the NPDWR. Based on the EPA's analysis of these factors, the EPA disagrees with commenter assertions that there is insufficient laboratory capacity at this time to support implementation of the NPDWR. Currently, there are 53 laboratories for PFAS methods (Method 533 or 537.1) in the EPA's Unregulated Contaminant Monitoring Rule (UCMR) 5 Laboratory Approval Program, more than double the participation in UCMR 3 (21 laboratories), with several laboratory requests to participate after the lab approval closing date. At a minimum, these 53 labs alone have already demonstrated sufficient capacity for current UCMR 5 monitoring, which requires monitoring for all systems serving above 3,300 or more persons and 800 systems serving less than 3,300 persons over a three-year period. The 21 laboratories participating in UCMR 3 provided more than sufficient capacity for that monitoring effort, which required monitoring for all systems serving greater than 10,000 persons and 800 systems serving less than 10,000. Further, a recent review of state certification and third-party accreditation of laboratories for PFAS methods found an additional 25 laboratories outside the UCMR 5 LAP with a certification or accreditation for EPA Method 533 or 537.1. Additionally, as has happened with previous drinking water regulations, the EPA anticipates laboratory capacity to grow once the rule is finalized to include an even larger laboratory community, as the opportunity for increased revenue by laboratories would be realized by filling the analytical needs of the utilities (USEPA, 1987; USEPA, 1991c; USEPA, 1991d; USEPA, 1992; USEPA, 2001). Finally, with the use of a reduced monitoring schedule to once every three years for eligible systems, and the

ability for systems that are reliably and consistently below the MCLs of 4.0 ng/L to only monitor once per year, the EPA anticipates that the vast majority of utilities may be able to take advantage of reduced or annual monitoring, and will not require a more frequent monitoring schedule, thus easing the burden of laboratory capacity as well.

The EPA also disagrees with commenter assertions that there is insufficient laboratory capability at this time. As discussed above and in the proposed rule preamble, the EPA proposed a PQL of 4.0 ng/L for both PFOA and PFOS based on current analytical capability and from the minimum reporting levels generated for the UCMR 5 program. The EPA evaluated data submitted as part of the UCMR 5 LAP and found that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a minimum reporting level confirmation at 2 ng/L (one-half the proposed MCL) or less for Method 533. The MCLs for PFOA and PFOS were also set at 4.0 ng/L as a result of the analytical capability assessment under the minimum reporting level setting study for UCMR 5, as well as consideration of other factors (*e.g.,* treatment, costs) as required under SDWA. For UCMR 5, all UCMR-approved laboratories were able to meet or exceed the PFOS and PFOA UCMR minimum reporting levels, set at 4 ng/L, the proposed MCL for both. The UCMR 5 minimum reporting levels of 4 ng/L for PFOS and PFOA are based on a multi-laboratory minimum reporting level calculation using lowest concentration minimum reporting level (LCMRL) data. The LCMRL and minimum reporting level have a level of confidence associated with analytical results. More specifically, the LCMRL calculation is a statistical procedure for determining the lowest true concentration for which future analyte recovery is predicted with 99% confidence to fall between 50 and 150% recovery (Martin et al., 2007). The multi-laboratory minimum reporting level is a statistical calculation based on the incorporation of LCMRL data collected from multiple laboratories into a 95% one-sided confidence interval on the 75th percentile of the predicted distribution referred to as the 95–75 upper tolerance limit. This means that 75% of participating laboratories will be able to set a minimum reporting level with a 95% confidence interval. The quantitation level of 4 ng/L has been demonstrated to be achieved with precision and accuracy across laboratories nationwide, which is important to ensure that systems can dependably comply with the MCL and deliver drinking water that does not exceed the maximum permissible level. The agency anticipates that these quantitation levels for labs will continue to improve over time, as technology advances and as laboratories gain experience with the PFAS Methods. The EPA's expectation is supported by the record borne out by the significant improvements in analytical capabilities for measuring certain PFAS, including PFOA and PFOS, between UCMR 3 and UCMR 5. For example, the minimum reporting levels calculated for UCMR 3 (2012–2016) were 40 ng/L and 20 ng/L for PFOS and PFOA, respectively, the minimum reporting levels calculated for UCMR 5 (2022–2025) were 4 ng/L each for PFOA and PFOS.

Some commenters recommend a different regulatory framework than what the EPA proposed to alleviate perceived implementation concerns (*e.g.,* reduce the potential of inundating laboratories or providing more time to plan and identify opportunities for source water reduction). For example, a few commenters suggest a phased-in MCL, where systems demonstrating higher concentrations are addressed first in the NPDWR, or MCL approaches where interim targets are set for compliance. Upon consideration of information submitted by commenters, particularly issues related to supply chain complications that are directly or indirectly related to the COVID–19 pandemic residual challenges, the EPA has determined that a significant number of systems subject to the rule will require an additional 2 years to complete the capital improvements necessary to comply with the MCLs for PFAS regulated under this action. Thus, the EPA also disagrees with recommendations to create a phased schedule for rule implementation based on the concentrations of PFAS detected because the EPA has granted a two-year extension for MCL compliance to all systems. For additional discussion on this extension and the EPA responses to public comment on this issue, please see section XI.D.

Some commenters argue for a lower PFOA and PFOS MCL due to the underlying health effects of these contaminants. These commenters suggest the EPA establish MCLs lower than the agency's proposed standard of 4.0 ng/L due to the capability of some laboratories to quantitate lower concentrations. Some of these commenters also argue that since PFOA and PFOS are likely human carcinogens, the EPA should consider an MCL at zero. While the EPA agrees with the health concerns posed by PFAS that are the basis for the proposed health based MCLGs for these contaminants, the agency disagrees with commenters on these alternative MCL thresholds given the EPA's consideration of feasibility as required by SDWA. These commenters did not provide evidence demonstrating the feasibility of achieving lower MCL thresholds (including an MCL at zero) consistent with SDWA requirements in establishing an MCL. For example, commenters did not provide evidence to support a lower PQL that can be consistently achieved by laboratories across the country. They also did not provide arguments supporting why the EPA should accept less than 75% of participating laboratories will be able to set a minimum reporting level with a 95% confidence interval. Thus, the agency is finalizing the MCLs for PFOA and PFOS at 4.0 ng/L (at the PQL) as this is the closest level to the MCLG that is feasible due to the ability of labs using approved analytical methods to determine with sufficient precision and accuracy whether such a level is actually being achieved. The record supports the EPA's determination that the lowest feasible MCL for PFOA and PFOS at this time is 4.0 ng/L.

A few commenters suggest the EPA did not appropriately consider disposal concerns for spent treatment media as part of the agency's feasibility determination. These commenters state that they believe disposal options are currently limited for liquid brine, reject waters resulting from RO, or solid waste from GAC treatment and that disposal capacity will be further limited should the EPA designate PFAS waste as hazardous. These commenters contend that these limitations increase operating expenses for utilities and should be factored in the establishment of the PFOA and PFOS MCLs. The EPA disagrees with these commenters that the agency did not adequately consider disposal of spent treatment media in the rule. First, disposal options for PFAS are currently available. These destruction and disposal options include landfills, thermal treatment, and underground injection. Systems are currently disposing of spent media, such as activated carbon, through thermal treatment, to include reactivation, and at landfills. While precautions should be taken to minimize PFAS release to the environment from spent media, guidance exists that explains the many disposal options with relevant precautions. See section X for further discussion. Furthermore, the EPA has provided guidance for pretreatment and wastewater disposal to manage PFAS

that enters the sanitary sewer system and must be managed by publicly owned treatment works (POTWs) (USEPA, 2022d; USEPA, 2022e). As discussed in the proposed rule (USEPA, 2023f), the EPA assessed the availability of studies of full-scale treatment of residuals that fully characterize residual waste streams and disposal options. Although the EPA anticipates that designating chemicals as hazardous substances under CERCLA generally should not result in limits on the disposal of PFAS drinking water treatment residuals, the EPA has estimated the treatment costs for systems both with the use of hazardous waste disposal and non-hazardous disposal options to assess the effects of potentially increased disposal costs. Specifically, the EPA assessed the potential impact on public water system (PWS) treatment costs associated with hazardous residual management requirements in a sensitivity analysis. The EPA's sensitivity analysis demonstrates that potential hazardous waste disposal requirements may increase PWS treatment costs marginally; however, the increase in PWS costs is not significant enough to change the agency's feasibility determination nor the determination made at proposal that benefits of the rulemaking justify the costs. These estimates are discussed in greater detail in the HRRCA section of this final rule and in appendix N of the *Economic Analysis* (EA) (USEPA, 2024e). For the discussion on management of treatment residuals and additional responses to stakeholder concerns on this topic, please see section X of this preamble. While beyond the scope of this rule, the EPA further notes that the agency is proposing to amend its regulations under the Resource Conservation and Recovery Act (RCRA) by adding nine specific per-and polyfluoroalkyl substances (PFAS), their salts, and their structural isomers, to the list of hazardous constituents at 40 CFR part 261, appendix VIII (89 FR 8606). The scope of the proposal is limited and does not contain any requirements that would impact disposal of spent drinking water treatment residuals. This is because listing these PFAS as RCRA hazardous constituents does not make them, or the wastes containing them, RCRA hazardous wastes. The principal impact of the proposed rule, if finalized, will be on the RCRA Corrective Action Program. Specifically, when corrective action requirements are imposed at a RCRA treatment, storage, and disposal facility (TSDF), these specific PFAS would be among the hazardous constituents expressly identified for consideration in RCRA facility assessments and, where necessary, further investigation and cleanup through the RCRA corrective action process.

Some commenters suggest that the EPA failed to consider the costs and impacts of the proposed MCLs in non-drinking water contexts, such as its potential uses as CERCLA clean-up standards. As required by SDWA, this rule and analyses supporting the rulemaking only includes costs that ''are likely to occur solely as a result of compliance with the [MCL].'' (SDWA section 1412(b)(3)(C)(i)(III)) Thus, the EPA's cost analyses focused on the compliance costs of meeting the MCL to public water systems that are directly subject to this regulation. The same provision expressly directs the EPA to exclude ''costs resulting from compliance with other proposed or promulgated regulations.'' Thus, the EPA cannot consider the costs of use of the MCLs under other EPA statutes (such as CERCLA) as part of its EA because SDWA specifically excludes such consideration (42 U.S.C. 300g–1(b)(3)(C)(i)(III)). See also *City of Waukesha* v. *EPA,* 320 F.3d 228, 243–244 (D.C. Cir. 2003) (finding that SDWA excludes consideration of the costs of, for example, CERCLA compliance, as part of the required cost/benefit analysis). In addition, whether and how MCLs might be used in any particular clean-up is very site-specific and as a practical matter cannot be evaluated in this rule.

Many commenters compared the proposed MCLs to existing state and international standards, regulations, and guidelines. In particular, these commenters acknowledge the fact that several states have conducted their own rulemakings to promulgate MCLs and suggest that the EPA's analysis in support of the proposed MCLs are inconsistent with these state approaches. Further, these commenters ask the EPA to explain why certain states' cost-benefit analyses supported their respective levels and why the EPA's analysis is different. Regarding state PFAS regulations, the EPA disagrees with commenters who suggested that the agency should develop regulations consistent with current state-led actions in setting a national standard in accordance with SDWA. While some states have promulgated drinking water standards for various PFAS prior to promulgation of this NPDWR, this rule provides a nationwide, health protective level for PFOA and PFOS (as well as four other PFAS) in drinking water and reflects regulatory development requirements under SDWA, including the EPA's analysis of the best available and most recent peer-reviewed science; available drinking water occurrence, treatment, and analytical feasibility information relevant to the PQL; and consideration of costs and benefits. After the NPDWR takes effect, SDWA requires primacy states to have a standard that is no less stringent than the NPDWR. Additionally, analyses conducted by the agency in support of an NPDWR undergo a significant public engagement and peer review process. The EPA notes that the EA for this rule accounts for existing state standards at the time of analysis. Specifically, to estimate the costs and benefits of the final rule, the EPA assumed that occurrence estimates exceeding state limits are equivalent to the state-enacted limit. For these states, the EPA assumed that the state MCL is the maximum baseline PFAS occurrence value for all EP in the state. Additionally, while states may establish drinking water regulations or guidance values absent Federal regulation as they deem appropriate, the presence of state regulations does not preclude the EPA from setting Federal regulations under the authority of SDWA that meets that statute's requirements. For additional information on the EPA's EA, please see section XII.

3. Final Rule

After considering public comments, the EPA is finalizing enforceable MCLs for PFOA and PFOS at 4.0 ng/L as the closest feasible level to the MCLG. First, the agency is establishing non-enforceable MCLGs at zero for contaminants where no known or anticipated adverse effects to the health of persons will occur, allowing for an adequate margin of safety. The EPA then examined the treatment capability of BATs and the accuracy of analytical techniques as reflected in the PQL in establishing the closest feasible level. In evaluating feasibility, the agency has determined that multiple treatment technologies (*e.g.,* GAC, AIX) ''examined for efficacy under field conditions and not solely under laboratory conditions'' are found to be both effective and available to treat PFOA and PFOS to the standards and below. The EPA also determined that there are available analytical methods to measure PFOA and PFOS in drinking water and that the PQLs for both compounds reflect a level that can be achieved with sufficient precision and accuracy across laboratories nationwide using such methods. Since limits of analytical measurement for PFOA and PFOS require the MCL to be set at some

level greater than the MCLG, the agency has determined that 4.0 ng/L (the PQL for each contaminant) represents the closest feasible level to the MCLG and the level at which laboratories using these methods can ensure, with sufficient accuracy and precision, that water systems nationwide can monitor and determine compliance so that they are ultimately delivering water that does not exceed the maximum permissible level of PFOA and PFOS to any user of their public water system. The EPA evaluates the availability and performance of BATs for treating water to minimize the presence of the contaminant consistent with the MCLG as well as the costs of applying those BATs to large metropolitan water systems when treating to that level. In consideration of these factors, the EPA is therefore establishing the MCL of 4.0 ng/L for both PFOA and PFOS. The EPA further notes that the agency has determined that the costs of SSCTs to reach 4.0 ng/L are affordable for households served by small drinking water systems. For additional discussion on the EPA's EA, please see section XII of this preamble. For additional discussion on the PQLs for the PFAS regulated as part of this NPDWR, please see section VII of this preamble. The EPA notes that upon consideration of information submitted by commenters regarding the implementation timeline for the rule, the agency is also exercising its authority under SDWA section 1412(b)(10) to allow two additional years for systems to comply with the MCL. For additional discussion on this extension, please see section XI.

The EPA clarifies that the MCLs for PFOA and PFOS are set using two significant digits in this final rule. In the proposed rule, the EPA proposed MCLGs for PFOA and PFOS at zero (0) and an enforceable MCL for PFOA and PFOS in drinking water with two significant digits at 4.0 ng/L. As previously discussed in section IV of this preamble, the MCLG for PFOA and PFOS is zero because these two PFAS are likely human carcinogens. Because the MCLGs are zero, the number of significant digits in the MCLGs are not the appropriate driver for considering the number of significant digits in the MCLs. This approach is consistent with other MCLs the EPA has set with carcinogenic contaminants, including for arsenic and bromate.

By setting the MCLs at 4.0, the EPA is setting the MCLs as close as feasible to the MCLGs. The EPA guidance states that all MCLs should be expressed in the number of significant digits permitted by the precision and accuracy of the specified analytical procedure(s) and that data reported should contain the same number of significant digits as the MCL (USEPA, 2000h). The EPA determined that two significant digits were appropriate for PFOA and PFOS considering existing analytical feasibility and methods. The EPA drinking water methods typically use two or three significant digits to determine concentrations. The EPA methods 533 and 537.1, those authorized for use in determining compliance with the MCLs, state that ''[c]alculations must use all available digits of precision, but final reported concentrations should be rounded to an appropriate number of significant digits (one digit of uncertainty), typically two, and not more than three significant digits.'' The EPA has determined that both methods 533 and 537.1 provide sufficient analytical precision to allow for at least two significant digits.

B. PFAS Hazard Index: PFHxS, PFNA, HFPO–DA, and PFBS

1. Proposal

The EPA proposed an MCL for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS expressed as a Hazard Index to protect against additive health concerns when present in mixtures in drinking water. As discussed in the March 2023 proposal (USEPA, 2023f), a Hazard Index is the sum of hazard quotients (HQs) from multiple substances. An HQ is the ratio of exposure to a substance and the level at which adverse effects are not anticipated to occur. The EPA proposed the MCL for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS as the same as the MCLG: as proposed, the Hazard Index must be equal to or less than 1.0. This approach would set a permissible level for the contaminant mixture (*i.e.,* a resulting PFAS mixture Hazard Index greater than 1.0 is an exceedance of the health protective level and has potential human health risk for noncancer effects from the PFAS mixture in water). The proposal defined a mixture as containing one or more of the four PFAS and therefore covered each contaminant individually if only one of the four PFAS occurred. Thus, the Hazard Index as proposed ensures that the level of exposure to an individual PFAS remains below that which could impact human health because the exposure for that measured PFAS is divided by its corresponding HBWC. The EPA proposed HBWCs of 9.0 ng/L[5] for PFHxS; 10.0 ng/L for HFPO–DA; 10.0 ng/L for PFNA; and 2000.0 ng/L for PFBS (USEPA, 2023e).

The EPA requested comment on the feasibility of the proposed Hazard Index MCL, including analytical measurement and treatment capability, as well as reasonable costs, as defined by SDWA.

2. Summary of Major Public Comments and EPA Responses

The EPA received many comments supporting the use of the Hazard Index approach and regulation of additional PFAS. Consistent with these comments, through this action, the agency is establishing drinking water standards for PFHxS, PFNA, HFPO–DA, and PFBS (as well as PFOA and PFOS) to provide health protection against these contaminants found in drinking water. The EPA considered PFAS health effects information, evidence supporting dose additive health concerns from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water.

A few commenters disagreed with the EPA's feasibility evaluation in setting the MCL at the MCLG (*i.e.,* Hazard Index value of 1.0). Some of these commenters assert that technologies to remove the Hazard Index PFAS are not the same as those that effectively remove PFOA and PFOS. A couple of commenters were concerned that meeting the Hazard Index MCL may require more frequent media change-outs (*e.g.,* GAC), thereby increasing operating costs such that the Hazard Index MCL of 1.0 is not feasible. The agency disagrees with these commenters. As described above in part A of this section for PFOA and PFOS, the agency similarly considered feasibility as defined by SDWA for PFHxS, PFNA, HFPO–DA, and PFBS. First, the EPA established a Hazard Index MCLG as a Hazard Index of 1 for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS. As part of setting the Hazard Index MCLG, the agency defined an HBWC for PFHxS, PFNA, HFPO–DA, and PFBS used in the calculation (see discussion in section IV of this preamble for further information).[6]

In considering the feasibility of setting the MCLs as close as feasible to the MCLG, the EPA first evaluated the (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2)

[5] Some commenters noted an error in the HBWC calculation for PFHxS which was reported as 9.0 ng/L in the proposal. The agency has corrected the value in this NPDWR and within the requirements under 40 CFR part 141 subpart Z. The correct HRL/HBWC for PFHxS is 10 ng/L.

[6] The EPA notes that the HBWC are akin to an MCLG in that they reflect a level below which there are no known or anticipated adverse effects over a lifetime of exposure, including for sensitive populations and life stages, and allows for an adequate margin of safety.

the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (*i.e.,* the PQLs). The EPA determined that there are available analytical methods approved (*i.e.,* Methods 533 and 537.1, version 2.0) to quantify levels below these HBWC levels. In addition, the PQLs for PFHxS, PFNA, HFPO–DA, and PFBS (between 3.0 to 5.0 ng/L) are all lower than the respective HBWCs used in setting the Hazard Index MCLG for each of these PFAS (10 ng/L for PFHxS, PFNA, and PFHxS, and 2000 ng/L for PFBS). Thus, the PQLs are not a limiting factor in determining the MCL. Second, the EPA evaluated the availability and performance of Best Available Technologies (BATs) for treating water to minimize the presence of these contaminants consistent with the MCLGs (see section X for additional discussion on BATs) as well as the costs of applying those BATs to large metropolitan water systems when treating to that level. The EPA has found the same technologies identified for PFOA and PFOS are also both available and have reliably demonstrated PFAS removal efficiencies that may exceed >99 percent and can achieve concentrations less than the proposed Hazard Index MCL for PFHxS, PFNA, HFPO–DA, and PFBS, and that the cost of applying those technologies is reasonable for large metropolitan water systems. As discussed above, for contaminants where the MCLG is higher than the PQL, the EPA sets the MCL at the MCLG if treatment is otherwise feasible because the PQL is not a limiting factor. In consideration of the availability of feasible treatment technologies, approved analytical methods to reliably quantify levels of the contaminants in drinking water, the EPA's cost analysis, and the fact that the PQLs are below the HBWCs used in setting the Hazard Index MCLG, the agency determines that setting the MCL at the same level as the MCLG for mixtures of PFHxS, PFNA, HFPO–DA and PFBS is feasible. Thus, the EPA is setting the Hazard Index MCL of 1 for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS. For additional discussion and considerations surrounding BATs, please see section X.A of this preamble. For more information about the EPA's cost estimates, please see section XII of this preamble.

Many commenters support excluding PFOA and PFOS from the Hazard Index MCL. The EPA agrees with these commenters as there are analytical limitations that would complicate including PFOA and PFOS in the Hazard Index. As discussed in section IV of this preamble of the Hazard Index approach, individual PFAS hazard quotients (HQs) are calculated by dividing the measured concentration of each component PFAS in water (*e.g.,* expressed as ng/L) by the corresponding health-based water concentration (HBWC) for each component PFAS (*e.g.,* expressed as ng/L). The HBWC is akin to an MCLG in that they reflect a level below which there are no known or anticipated adverse effects over a lifetime of exposure, including for sensitive populations and life stages, and allows for an adequate margin of safety. Since PFOA and PFOS are likely human carcinogens, the MCLG (and if included in the Hazard Index, the HBWC) for each contaminant is zero. The only feasible way to represent PFOA and PFOS in the Hazard Index approach would be to only consider values for PFOA and PFOS at or above the PQL of 4.0 ng/L, however the level at which no known or anticipated adverse effects on the health of persons would occur is well below the PQL. As a result, any measured concentration above 4.0 ng/L for PFOA and PFOS would result in an exceedance of the Hazard Index MCL. The Hazard Index is intended to capture the aggregate risks of the Hazard Index PFAS when the monitored concentration is above the PQL but below the HBWC. These risks are not relevant to PFOA and PFOS given their PQLs. Because of the PQL considerations discussed in the preceding section V.A of this preamble, the EPA is not including PFOA and PFOS in the final rule Hazard Index. Therefore, the EPA is finalizing individual MCLs for PFOA and PFOS but not including these contaminants in the Hazard Index.

A few commenters provided feedback on the EPA's request for comment regarding the usage of significant figures to express the MCLs. See discussion on this issue in section IV of this preamble above. In summary, after considering public comment, the EPA agrees that one (1) significant digit is appropriate for the individual PFAS for PFHxS, PFNA and HFPO–DA (*i.e.,* 10 ng/L rather than 10.0 ng/L), and Hazard Index MCL (*i.e.,* 1 rather than 1.0).

Some commenters asked about inclusion of other PFAS in the Hazard Index in future revisions. The agency believes the Hazard Index approach can be an adaptive and flexible framework for considering additional PFAS. The EPA is required to review NPDWRs every six years and determine which, if any, need to be revised (*i.e.,* the Six-Year Review Process). The purpose of the review is to evaluate current information for regulated contaminants and to determine if there is any new information on health effects, treatment technologies, analytical methods, occurrence and exposure, implementation and/or other factors that provides a health or technical basis to support a regulatory revision that will improve or strengthen public health protection. This process allows the agency to consider these and other information as appropriate in deciding whether existing NPDWRs should be identified as candidates for revision as required by SDWA.

Many commenters compared the proposed MCLs to existing state and international standards, regulations, and guidelines. In particular, these commenters acknowledge that several states have conducted their own rulemakings to promulgate MCLs and suggest that the EPA's analysis in support of the proposed MCLs is inconsistent with these state approaches. Further, these commenters ask the EPA to explain why certain states' cost-benefit analyses supported their respective levels and why the EPA's analysis is different. Regarding state PFAS regulations, the EPA disagrees with commenters who suggested that the agency should not develop regulations different from state-led actions. SDWA mandates Federal regulation where the EPA determines that a contaminant meets the criteria for regulation under the statute. Moreover, the EPA's rule sets a national standard in accordance with SDWA for certain PFAS in drinking water that provides important protections for all Americans served by PWSs. Please see discussion above in part A under this section for consideration for existing state and international standards.

A few commenters suggest a need for effective data management systems to implement the Hazard Index. These commenters indicated that it will be challenging to implement the Hazard Index as proposed due to the tracking of multiple contaminants and automating these data into existing data management systems. For discussion on rule implementation issues, including primacy agency record keeping and reporting requirements, please see section XI of this preamble.

Some commenters raised concerns that the EPA did not consider a sufficient range of regulatory alternatives. For example, a few commenters contend that the EPA violated 1412(b)(3)(C)(i) of SDWA and the Unfunded Mandates Reform Act (UMRA) because the agency did not identify and consider what they deem a

reasonable number of regulatory alternatives for PFHxS, PFNA, HFPO–DA and its ammonium salts, and PFBS. Specifically, these commenters cite that the EPA only considered a single HBWC and did not consider any alternatives to the Hazard Index MCL of 1 itself. The EPA disagrees with these commenters.

SDWA does not require the agency to consider any certain number of alternative MCLs or a range of alternatives. SDWA 1412(b)(3)(C)(i)(IV) only requires that in developing the HRRCA, the agency must consider the ''incremental costs and benefits associated with each alternative maximum contaminant level considered.'' Thus, the agency must conduct a cost-benefit analysis with each alternative MCL that is considered, if any. The EPA maintains that the proposed rule and regulatory alternatives considered at proposal met all requirements to consider alternatives. In the proposed rule, the EPA did not separately present changes in quantified costs and benefits for these approaches because the agency described that including individual MCLs in addition to the Hazard Index approach will be not change costs and benefits relative to the proposal (*i.e.,* the same number of systems will incur identical costs to the proposed option and the same benefits will be realized). For the final rule, the EPA has also estimated the marginal costs for the individual PFHxS, PFNA, and HFPO–DA MCLs in the absence of the Hazard Index (See chapter 5.1.3 and appendix N.4 of the EA for details). The EPA notes that the costs for the individual PFHxS, PFNA, and HFPO–DA MCLs have been considered in this final rule. For further discussion of how the EPA considered the costs of the five individual MCLs and the HI MCL, see section XII.A.4 of this preamble.

The EPA identified and analyzed a reasonable number of regulatory alternatives to determine the MCL requirement in the proposed rule as required by UMRA. UMRA's requirement to identify and consider a reasonable number of regulatory alternatives builds on the assessment of feasible alternatives required in E.O. 12866.[7] Specifically, as described in the proposed rule, the EPA considered an alternative approach to the one proposed that only used the Hazard Index MCL. The proposal took comment on establishing individual MCLs instead of and in addition to using a mixture-based approach for PFHxS, PFNA, HFPO–DA, and/or PFBS in mixtures. In that proposal, the EPA described how a traditional approach may be warranted should the EPA not finalize a regulatory determination for mixtures of these PFAS. Under this alternative, ''the proposed MCLG and MCL for PFHxS would be 9.0 ng/L; for HFPO–DA the MCLG and MCL would be 10.0 ng/L; for PFNA the MCLG and MCL would be 10.0 ng/L; and for PFBS the MCLG and MCL would be 2000.0 ng/L.'' The agency requested comment on these alternatives for PFHxS, PFNA, HFPO–DA, and PFBS and whether these individual MCLs instead of or in addition to the Hazard Index approach would change public health protection, improve clarity of the rule, or change costs. Additionally, the EPA considered alternative mixture-based approaches such as a target organ-specific Hazard Index (TOSHI) or relative potency factor (RPF) approach. The agency requested comment on these approaches. Based on the EPA's technical expertise, the agency determined that the Hazard Index is the most cost-effective and least burdensome alternative for purposes of UMRA because this approach for mixtures that achieves the objectives of the rule because of the level of protection afforded for the evaluation of chemicals with diverse (but in many cases shared) health endpoints. The EPA followed agency chemical mixture guidance (USEPA, 1986; USEPA, 1991b; USEPA, 2000a, which explain that when the Hazard Index value is greater than one (1) then risk is indicated (because exposure exceeds toxicity). The agency did not propose alternative Hazard Index values (*i.e.,* higher Hazard Index values) because the EPA determined that a Hazard Index MCL of 1 is feasible: multiple treatment technologies are available and are found effective to treat to or below the MCL; the costs of applying these technologies to large metropolitan water systems are reasonable; and there are analytical methods available to reliably quantify the four PFAS captured in the Hazard Index MCL. In addition, these alternative Hazard Index or mixture-based approaches would not provide sufficient protection against dose-additive health concerns from co-occurring PFAS. For example, a higher Hazard Index value (*e.g.,* Hazard Index equal to 2) allows for exposure to be greater than the toxicity and will not result in a sufficient health-protective standard that is close as feasible to the MCLG, which is a level at which there are no known or anticipated adverse effects on human health and allows for an adequate margin of safety. The EPA notes that commenters have not provided support justifying an alternative MCL standard for the Hazard Index. For additional discussion on UMRA, please see chapter 9 of USEPA (2024g).

3. Final Rule

Through this action, the EPA is promulgating the Hazard Index MCL for mixtures of two or more of PFHxS, PFNA, HFPO–DA and PFBS. The following equation provides the calculation of the PFHxS, PFNA, HFPO–DA, and PFBS Hazard Index MCL as finalized:

$$HI\ MCL = \left(\frac{[HFPO-DA_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[PFBS_{ng/L}]}{[2000\ ng/L]}\right) + \left(\frac{[PFNA_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[PFHxS_{ng/L}]}{[10\ ng/L]}\right)$$

Where:

$HFPO\text{–}DA_{water}$ = monitored concentration of HFPO–DA in ng/L;

$PFBS_{water}$ = monitored concentration of PFBS;

$PFNA_{water}$ = monitored concentration of PFNA and

$PFHxS_{water}$ = monitored concentration of PFHxS

The presence of PFBS can only trigger an MCL violation if it is present as part of a mixture with at least one of the other three PFAS (PFHxS, PFNA and

[7] See OMB Memorandum M–95–09, Guidance for Implementing Title II of S.1.

HFPO–DA). As such, elevated PFBS concentrations that would normally cause a Hazard Index exceedance in isolation will not cause a violation if none of the other three PFAS are present in the mixture. The EPA is promulgating individual MCLs for PFHxS, PFNA, and HFPO–DA as well the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO–DA and PFBS concurrent with final regulatory determinations for these contaminants (please see section III of this preamble for additional discussion on the EPA's regulatory determinations).

The EPA has determined that it is feasible to set the MCL at the same level as the MCLG for mixtures of PFHxS, PFNA, HFPO–DA and PFBS as current BATs can remove each contaminant to a level equal to or below their respective HBWC. In addition, there are analytical methods available for these contaminants and the PQL for each contaminant is below the level established by the MCLG. The EPA also considered costs and determined that establishing a Hazard Index MCL of 1 is reasonable based on consideration of the costs to large metropolitan water systems. These considerations support a determination that a Hazard Index MCL of 1 for mixtures of two or more of PFHxS, PFNA, HFPO–DA and PFBS is feasible and therefore the EPA is setting the MCL at the same level as the MCLG. The EPA's MCL of 1 establish a ''maximum permissible level of contaminant in water'' because it is a limit for a mixture with PFAS components that must be met before the water enters the distribution system. Public water systems use their monitoring results as inputs into the Hazard Index equation to determine whether they are delivering water to any user that meets the MCL. For additional discussion regarding the derivation of the individual HBWCs and MCLGs, please see discussion in section III and IV of this preamble above.

C. Individual MCLs: PFHxS, PFNA and HFPO–DA

1. Proposal

As described in section V.B of this preamble above, the EPA proposed an MCL for mixtures of PFHxS, PFNA, HFPO–DA and PFBS based on a Hazard Index. The EPA proposed to address its preliminary regulatory determinations for PFHxS, PFNA, HFPO–DA, and/or PFBS and mixtures of these PFAS together through the Hazard Index approach. The proposal defined a mixture as containing one or more of the four PFAS and therefore covered each contaminant individually if only one of the four PFAS occurred. The EPA considered and took comment on establishing individual MCLGs and MCLs in lieu of or in addition to the Hazard Index approach for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS.

2. Summary of Major Public Comments and EPA Responses

Commenters were mixed on the EPA's request for public comment on the establishment of stand-alone MCLs in lieu of or in addition to the Hazard Index MCL. Many of the comments were related to risk communications and messaging to consumers. While several commenters favored stand-alone MCLs in lieu of the Hazard Index to improve communications to their customers, several other commenters recommended stand-alone MCLs in addition to the Hazard Index MCL to achieve this purpose. Several commenters opposed individual MCLs for some or all of the PFAS because they believe it may complicate risk communication. After consideration of public comments, the EPA is addressing the final individual regulatory determination for PFHxS, HFPO–DA, and PFNA by promulgating individual MCLGs and NPDWRs for PFHxS, HFPO–DA, and PFNA. The EPA is addressing the final mixture regulatory determination by promulgating a Hazard Index MCLG and NPDWR for mixtures containing two or more of PFHxS, PFNA, HFPO–DA, and PFBS. This approach avoids confusion caused by the EPA's proposal that covered all the preliminary regulatory determinations in one Hazard Index standard. The EPA agrees that proper risk communication is an important focus for water systems and believes that finalizing individual MCLs for PFHxS, PFNA and HFPO–DA may help support risk communication as utilities and the public may be more familiar with this regulatory framework. At the same time, since those individual MCLs do not address additional risks from co-occurring PFAS, the EPA is finalizing a Hazard Index MCL to address dose additive health concerns associated with mixtures of two or more of PFHxS, PFNA, HFPO–DA, and PFBS that co-occur in drinking water. For additional discussion on the Hazard Index approach and other mixture-based approaches (*e.g.,* TOSHI), please see section IV of this preamble above.

3. Final Rule

The EPA is promulgating individual MCLs for PFHxS, PFNA and HFPO–DA at the same level as their respective MCLGs (which are equivalent to the HBWCs). The EPA is finalizing individual MCLs as follows: HFPO–DA MCL = 10 ng/L; PFHxS MCL = 10 ng/L; and PFNA MCL = 10 ng/L. The EPA is promulgating individual MCLs for PFHxS, PFNA, and HFPO–DA as well the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO–DA and PFBS concurrent with final determinations for these contaminants (please see section III of this preamble for additional discussion on the EPA's regulatory determinations).

The agency considered feasibility as defined by SDWA and the EPA's feasibility justification for these individual PFHxS, PFNA and HFPO–DA MCLs are the same and based on the same information as the Hazard Index MCL discussed in V.B above. The EPA further notes that the Hazard Index MCLG applies to the entire mixture but the EPA's technical justification for the underlying values (*i.e.,* HBWCs) are the same as the individual MCLGs in this rule. In summary, the EPA has determined that it is feasible to set the individual MCLs at the MCLGs for PFHxS, PFNA and HFPO–DA because current BATs can remove each contaminant to a level equal to or below their respective MCLGs. In addition, there are analytical methods available for these contaminants and the practical quantitation level (PQL) for each contaminant is below the level established by the MCLG. The EPA also considered costs and determined that establishing individual MCLs of 10 ng/L for PFHxS, PFNA, and HFPO–DA is reasonable based on consideration of the costs to large metropolitan water systems. These considerations support a determination that individual MCLs of 10 ng/L for PFHxS, PFNA, and HFPO–DA are feasible and therefore the EPA is setting the MCL at the same level as the MCLG. For additional discussion regarding the derivation of the individual HBWCs and MCLGs, please see section III and IV of this preamble above.

VI. Occurrence

The EPA relied on multiple data sources, including Unregulated Contaminant Monitoring Rule (UCMR) 3 and state finished water data, to evaluate the occurrence of PFOA, PFOS, PFHxS, PFNA, and HFPO–DA and probability of co-occurrence of these PFAS and PFBS. The EPA also incorporated both the UCMR 3 and some state data into a Bayesian hierarchical model which supported exposure estimates for select PFAS at lower levels than were measured under UCMR 3. The EPA has utilized similar statistical approaches in past regulatory actions to inform its decision making, particularly where a contaminant's occurrence is at low concentrations

(USEPA, 2006c). The specific modeling framework used to inform this regulatory action is based on the peer-reviewed model published in Cadwallader et al. (2022). Collectively, these data and the occurrence model informed estimates of the number of water systems (and associated population) expected to be exposed to levels of the final and proposed alternative MCLs for PFOA and PFOS, the final MCLs for PFHxS, PFNA, and HFPO–DA, and the final Hazard Index MCL for PFHxS, PFNA, HFPO–DA, and PFBS.

The EPA notes that, as described in sections III and V of this preamble, the EPA is finalizing individual Maximum Contaminant Levels (MCLs) for three of the four Hazard Index PFAS (PFHxS, PFNA, and HFPO–DA) at 10 ng/L each. An analysis of occurrence relative to HRLs for PFHxS, PFNA, and HFPO–DA (which are the same as the final individual MCLs for these compounds at 10 ng/L) using UCMR 3 data and updated state datasets is presented in section III.C of this preamble and further described in the *Occurrence Technical Support Document* (USEPA, 2024b). The information in the following sections supports the agency's finding that PFHxS, PFNA, and HFPO–DA occur at a frequency and level of public health concern as discussed in section III.C of this preamble.

A. UCMR 3

1. Proposal

UCMR 3 monitoring occurred between 2013 and 2015 and is currently the best nationally representative finished water dataset for any PFAS, including PFOA, PFOS, PFHxS, PFNA, and PFBS. Under UCMR 3, 36,972 samples from 4,920 public water systems (PWSs) were analyzed for these five PFAS. PFOA was found above the UCMR 3 minimum reporting level (20 ng/L) in 379 samples at 117 systems serving a population of approximately 7.6 million people located in 28 states, Tribes, or U.S. territories. PFOS was found in 292 samples at 95 systems above the UCMR 3 minimum reporting level (40 ng/L). These systems serve a population of approximately 10.4 million people located in 28 states, Tribes, or U.S. territories. PFHxS was found above the UCMR 3 minimum reporting level (30 ng/L) in 207 samples at 55 systems that serve a population of approximately 5.7 million located in 25 states, Tribes, and U.S. territories. PFBS was found in 19 samples at 8 systems above the UCMR 3 minimum reporting level (90 ng/L). These systems serve a population of approximately 350,000 people located in 5 states, Tribes, and U.S. territories. Lastly, PFNA was found above the UCMR 3 minimum reporting level (20 ng/L) in 19 samples at 14 systems serving a population of approximately 526,000 people located in 7 states, Tribes, and U.S. territories.

2. Summary of Major Public Comments and EPA Responses

Some commenters supported the EPA's use of the best available public health information including data from UCMR 3 and state occurrence data. A few commenters criticized the use of UCMR 3 data, stating that the data suffer from limitations. These commenters expressed concern over the high minimum reporting levels, the exclusion of many small systems, and the lack of national monitoring of HFPO–DA. Some of these commenters assert that UCMR 3 does not represent best available occurrence data for this rule. The EPA disagrees with these commenters. While UCMR 3 does have higher reporting limits than those available through current analytical methods, the data still provides the best available nationwide occurrence data to inform the occurrence and co-occurrence profile for the regulated PFAS for which monitoring was conducted. These data are also a critical component of the EPA's model to estimate national level occurrence for certain PFAS and ensure it is nationally representative (see subsection E of this section). The EPA also disagrees that the UCMR 3 excludes small water systems as it included a statistically selected, nationally representative sample of 800 small drinking water systems. Regarding commenter concerns for lack of UCMR monitoring data on HFPO–DA, the agency notes that the EPA examined recent data collected by states who have made their data publicly available. A discussion of these data and public comments on this information is presented in sections III.C and VI.B of this preamble.

3. Final Rule

After considering public comment, the EPA maintains that UCMR 3 data are the best available, complete nationally representative dataset and they play an important role in supporting the EPA's national occurrence analyses, demonstrating occurrence and co-occurrence of the monitored PFAS in drinking water systems across the country that serve millions of people.

B. State Drinking Water Data

1. Proposal

The agency has supplemented the UCMR 3 data with more recent data collected by states who have made their data publicly available. In general, the large majority of these more recent state data were collected using newer EPA-approved analytical methods and state results reflect lower reporting limits than those in the UCMR 3. State results show continued occurrence of PFOA, PFOS, PFHxS, PFNA, and PFBS in multiple geographic locations. These data also show these PFAS occur at lower concentrations and significantly greater frequencies than were measured under the UCMR 3 (likely because the more recent monitoring was able to rely on more sensitive analytical methods). Furthermore, these state data include results for more PFAS than were included in the UCMR 3, including HFPO–DA.

At the time of proposal, the EPA evaluated publicly available state monitoring data from 23 states, representing sampling conducted on or before May 2021. The EPA acknowledged that the available data were collected under varying circumstances; for example, targeted vs. non-targeted monitoring (*i.e.,* monitoring not conducted specifically in areas of known or potential contamination). Due to the variability in data quality, the EPA further refined this dataset based on representativeness and reporting limitations, resulting in detailed technical analyses using a subset of the available state data. A comprehensive discussion of all the available state PFAS drinking water occurrence data was included in the *Occurrence Technical Support Document* (USEPA, 2023l).

2. Summary of Major Public Comments and EPA Responses

Commenters generally supported the use of state datasets. A few commenters discussed their own PFAS occurrence data, some of which were provided to the EPA, relative to the EPA's proposed regulatory levels and/or provided summaries of other monitoring efforts. Where possible, the EPA presents this information within its occurrence analysis—see the *Other Data* sections of USEPA (2024b). A few commenters recommended that the EPA expand the datasets used for the final rule to include additional and updated state sampling information. The EPA agrees with these suggestions to rely on additional and updated sampling information in order to evaluate PFAS occurrence in drinking water. Therefore,

the agency has included updated information in its occurrence analyses as described in section VI.B.3 of this preamble. The EPA notes that this information is consistent with the analyses contained in the proposal for this action.

A few commenters criticized the use of state datasets in occurrence analyses. These commenters claimed that the state datasets were insufficient for national extrapolation and not dependable due to being collected under variable circumstances. These commenters expressed the need for enhanced quality control (QC) by the EPA to exclude data below reasonable reporting thresholds. The agency disagrees with commenters who contend that state datasets are insufficient for national extrapolation. For both the rule proposal and this final action, the EPA took QC measures to ensure the EPA used the best available data for national extrapolation. For example, the EPA acknowledged in the proposal that states used various reporting thresholds when presenting their data, and for some states there were no clearly defined reporting limits. The EPA identified state reporting thresholds where possible and, when appropriate, incorporated individual state-specific thresholds when conducting data analyses. For other states, the EPA presented the data as provided by the state. Due to the reporting limitations of some of the available state data (*e.g.,* reporting combined analyte results rather than individual analyte results), the EPA did not utilize all of these data in the subsequent occurrence analyses/co-occurrence analyses. Specific data analysis criteria (*e.g.,* separation of non-targeted and targeted monitoring results) were also applied. Additionally, the agency also verified that the vast majority of the data were collected using EPA-approved methods. Further, the EPA reviewed all available data thoroughly to ensure that only finished drinking water data were presented. A description of the scope and representativeness of the state data was provided in the proposal of this action in the *PFAS Occurrence and Contaminant Background Support Document* (USEPA, 2023l). These include describing the states the EPA found to have publicly available data, identifying the reporting thresholds where possible, and distinguishing whether monitoring was non-targeted or targeted (*i.e.,* monitoring in areas of known or potential PFAS contamination). These QC measures ensured that the EPA utilized the best available data for national extrapolation.

3. Final Rule

In the proposed rule preamble, the EPA discussed how states may have updated data available and that additional states have or intend to conduct monitoring of finished drinking water and that the agency would consider these additional data to inform this final regulatory action. After consideration of all the public comments on this issue, the EPA has updated its analysis of state monitoring data by including results that were available as of May 2023. This updated state dataset includes publicly available data from 32 states: Alabama, Arizona, California, Colorado, Delaware, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Vermont, Virginia, West Virginia, and Wisconsin. The dataset includes data from 9 states that were not available at the time of proposal.

Tables 4 and 5 in this section demonstrate the number and percent of samples with PFOA and PFOS based on state-reported detections, and the number and percent of systems with PFOA and PFOS based on state-reported detections, respectively, for the non-targeted state finished water monitoring data. Section III.B. of this preamble describes the state reported finished water occurrence data for PFHxS, PFNA, HFPO–DA, and PFBS data.

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Table 4. Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Samples with State Reported Detections[1]

State	PFOS state reported sample detections	PFOS state reported sample detection (percent)	PFOA state reported sample detections	PFOA state reported sample detections (percent)
Alabama[2]	249	N/A	176	N/A
Colorado	60	10.3%	54	9.3%
Illinois	306	14.3%	298	14.0%
Indiana	8	1.7%	8	1.7%
Kentucky	33	40.7%	24	29.6%
Maine	101	14.3%	142	20.1%
Maryland	17	19.3%	20	22.7%
Massachusetts	4432	47.4%	5363	57.4%
Michigan	489	4.6%	557	5.2%
Missouri	22	9.2%	17	7.1%
New Hampshire	495	27.3%	1010	55.7%
New Jersey	6502	40.9%	8063	50.7%
New York	1576	22.3%	1751	24.8%
North Dakota	3	2.6%	2	1.7%
Ohio	113	5.8%	116	6.0%
South Carolina	135	17.6%	141	18.3%
Tennessee	0	0.0%	0	0.0%
Vermont	192	12.3%	225	14.4%
Wisconsin	187	23.9%	167	21.2%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

Table 5: Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Monitored Systems with State Reported Detections[1]

State	PFOS Monitored Systems with State Reported Detections	PFOS Monitored Systems with State Reported Detections (Percent)	PFOA Monitored Systems with State Reported Detections	PFOA Monitored Systems with State Reported Detections (Percent)
Alabama[2]	88	N/A	65	N/A
Colorado	50	12.6%	45	11.3%
Illinois	73	7.3%	67	6.7%
Indiana	7	1.9%	8	2.2%
Kentucky	30	40.5%	22	29.7%
Maine	94	14.6%	132	20.4%
Maryland	9	14.3%	10	15.9%
Massachusetts	417	31.4%	520	39.1%
Michigan	105	4.2%	135	5.4%
Minnesota	55	9.5%	69	12.0%
Missouri	11	8.8%	7	5.6%
New Hampshire	189	33.8%	310	55.4%
New Jersey	541	48.2%	625	55.7%
New York	496	26.3%	558	29.6%
North Dakota	6	5.4%	7	6.3%
Ohio	29	2.0%	33	2.2%
South Carolina	80	26.7%	85	28.3%
Tennessee	0	0.0%	0	0.0%
Vermont	38	6.7%	49	8.7%
Wisconsin	70	29.3%	66	27.6%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

As illustrated in Tables 4 and 5, there is a wide range in PFOA and PFOS results between states. Nonetheless, more than one-third of states that conducted non-targeted monitoring observed PFOA and/or PFOS at more than 25 percent of systems. Among the detections, PFOA concentrations ranged from 0.21 to 650 ng/L with a range of median concentrations from 1.27 to 5.61 ng/L, and PFOS concentrations ranged from 0.24 to 650 ng/L with a range of median concentrations from 1.21 to 12.1 ng/L.

Monitoring data for PFOA and PFOS from states that conducted targeted monitoring efforts, including 15 states, demonstrate results consistent with the non-targeted state monitoring. For example, in Pennsylvania, 26.3 and 24.9 percent of monitored systems found PFOA and PFOS, respectively, with reported concentrations of PFOA ranging from 1.7 to 59.6 ng/L and PFOS ranging from 1.8 to 94 ng/L. California reported 35.8 and 39.0 percent of monitored systems found PFOA and PFOS, respectively, including reported concentrations of PFOA ranging from 0.9 to 190 ng/L and reported concentrations of PFOS from 0.4 to 250 ng/L. In Maryland, PFOA and PFOS were found in 57.6 and 39.4 percent of systems monitored, respectively, with reported concentrations of PFOA ranging from 1.02 to 23.98 ng/L and reported concentrations of PFOS ranging from 2.05 to 235 ng/L. In Iowa,

PFOA and PFOS were found in 11.2 and 12.1 percent of systems monitored, respectively, with reported concentrations of PFOA ranging from 2 to 32 ng/L and reported concentrations of PFOS ranging from 2 to 59 ng/L.

As discussed above in section V of this preamble, the EPA is finalizing individual MCLs of 4.0 ng/L for PFOA and PFOS, individual MCLs for PFHxS, PFNA, and HFPO–DA, and a Hazard Index level of 1 for PFHxS, PFNA, HFPO–DA, and PFBS. The EPA also evaluated occurrence for the regulatory alternatives discussed in section V of this preamble, including alternative MCLs for PFOA and PFOS of 5.0 ng/L and 10.0 ng/L. Table 6, Table 7, and Table 8 demonstrate, based on available state data, the total reported number and percentages of monitored systems that exceed these proposed and alternative MCL values across the non-targeted state finished water monitoring data.

Table 6: Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Monitored Systems with State Reported Detections[1] ≥ 4.0 ng/L

State	PFOS Monitored Systems with State Reported Detections	PFOS Monitored Systems with State Reported Detections (Percent)	PFOA Monitored Systems with State Reported Detections	PFOA Monitored Systems with State Reported Detections (Percent)
Alabama[2]	64	N/A	36	N/A
Colorado	22	5.5%	18	4.5%
Illinois	30	3.0%	22	2.2%
Indiana	1	0.3%	1	0.3%
Kentucky	4	5.4%	9	12.2%
Maine	48	7.4%	76	11.8%
Maryland	9	14.3%	8	12.7%
Massachusetts	261	19.6%	335	25.2%
Michigan	40	1.6%	47	1.9%
Minnesota	8	1.4%	15	2.6%
Missouri	3	2.4%	3	2.4%
New Hampshire	107	19.1%	210	37.5%
New Jersey	356	31.7%	457	40.7%
New York	201	10.7%	217	11.5%
North Dakota	0	0.0%	0	0.0%
Ohio	29	2.0%	33	2.2%
South Carolina	45	15.0%	52	17.3%
Tennessee	0	0.0%	0	0.0%
Vermont	20	3.5%	27	4.8%
Wisconsin	12	5.0%	11	4.6%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

Table 7: Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Monitored Systems with State Reported Detections[1] ≥ 5.0 ng/L

State	PFOS Monitored Systems with State Reported Detections	PFOS Monitored Systems with State Reported Detections (Percent)	PFOA Monitored Systems with State Reported Detections	PFOA Monitored Systems with State Reported Detections (Percent)
Alabama[2]	53	N/A	30	N/A
Colorado	16	4.0%	14	3.5%
Illinois	23	2.3%	13	1.3%
Indiana	1	0.3%	1	0.3%
Kentucky	3	4.1%	4	5.4%
Maine	38	5.9%	67	10.4%
Maryland	5	7.9%	8	12.7%
Massachusetts	220	16.5%	280	21.0%
Michigan	36	1.4%	35	1.4%
Minnesota	7	1.2%	12	2.1%
Missouri	2	1.6%	3	2.4%
New Hampshire	86	15.4%	186	33.2%
New Jersey	306	27.2%	409	36.4%
New York	154	8.2%	183	9.7%
North Dakota	0	0.0%	0	0.0%
Ohio	29	2.0%	33	2.2%
South Carolina	36	12.0%	38	12.7%
Tennessee	0	0.0%	0	0.0%
Vermont	16	2.8%	23	4.1%
Wisconsin	10	4.2%	5	2.1%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

Table 8: Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Monitored Systems with State Reported Detections[1] ≥ 10.0 ng/L

State	PFOS Monitored Systems with State Reported Detections	PFOS Monitored Systems with State Reported Detections (Percent)	PFOA Monitored Systems with State Reported Detections	PFOA Monitored Systems with State Reported Detections (Percent)
Alabama[2]	34	N/A	18	N/A
Colorado	3	0.8%	2	0.5%
Illinois	5	0.5%	7	0.7%
Indiana	0	0.0%	0	0.0%
Kentucky	1	1.4%	1	1.4%
Maine	10	1.5%	32	5.0%
Maryland	5	7.9%	7	11.1%
Massachusetts	112	8.4%	123	9.2%
Michigan	16	0.6%	17	0.7%
Minnesota	2	0.3%	4	0.7%
Missouri	0	0.0%	1	0.8%
New Hampshire	39	7.0%	83	14.8%
New Jersey	159	14.2%	223	19.9%
New York	57	3.0%	64	3.4%
North Dakota	0	0.0%	0	0.0%
Ohio	21	1.4%	15	1.0%
South Carolina	12	4.0%	8	2.7%
Tennessee	0	0.0%	0	0.0%
Vermont	7	1.2%	7	1.2%
Wisconsin	8	3.3%	0	0.0%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

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Based on the available state data presented in Table 6, Table 7, and Table 8, within 20 states that conducted non-targeted monitoring there are 1,260 systems with results above the PFOS MCL of 4.0 ng/L and 1,577 systems with results above the PFOA MCL of 4.0 ng/L. These systems serve populations of 12.5 and 14.4 million people, respectively. As expected, the number of systems exceeding either of the proposed alternative MCLs decreases as the values are higher; however, even at the highest alternative PFOS and PFOA MCL values of 10.0 ng/L, there are still 491 and 612 systems with exceedances, serving populations of approximately 5.3 and 6.0 million people, respectively.

Monitoring data for PFOA and PFOS from states that conducted targeted sampling efforts shows additional systems that would exceed the final and alternative MCLs. For example, in California, Maine, Maryland, and Pennsylvania, 30.9 percent (38 PWSs), 27.8 percent (5 PWSs), 25 percent (18 PWSs), and 19.3 percent (66 PWSs) of monitored systems reported results above the proposed PFOS MCL of 4.0 ng/L, respectively, and 29.3 percent (36 PWSs), 27.8 percent (5 PWSs), 25 percent (18 PWSs), and 21.1 percent (72 PWSs) of monitored systems reported results above the proposed PFOA MCL of 4.0 ng/L, respectively. While these frequencies may be anticipated given the sampling locations, within only these four states that conducted limited, targeted monitoring, the monitored

systems with results above the proposed PFOS MCL and proposed PFOA MCL serve significant populations of approximately 5.7 million people and approximately 5.6 million people, respectively.

C. PFAS Co-Occurrence

While the discussions in sections III.B, VI.A. and VI.B of this preamble describe how PFOA, PFOS, PFHxS, PFNA, and HFPO–DA occur individually, numerous studies and analyses have documented that PFAS co-occur in finished drinking water (Adamson et al., 2017; Cadwallader et al., 2022; Guelfo and Adamson, 2018). As discussed in section V of this preamble, the EPA is finalizing regulation of mixtures that include at least two of PFHxS, PFNA, HFPO–DA, and PFBS (collectively referred to as ''Hazard Index PFAS'') as part of a Hazard Index approach.

1. Proposal

In the March 2023 proposal preamble, the EPA presented occurrence data that illustrated the extent to which PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS co-occur in drinking water. Co-occurrence analyses primarily utilized available non-targeted state PFAS finished drinking water data, though UCMR 3 data analysis is presented in the *PFAS Occurrence and Contaminant Background Support Document* (USEPA, 2024b). The EPA also conducted two separate analyses using state datasets to determine the extent to which these six PFAS co-occur: a groupwise analysis and a pairwise analysis.

When analyzing PFAS co-occurrence, groupwise analysis is important for determining whether the presence of PFOA and PFOS provides insight regarding the likelihood of Hazard Index PFAS being present as well, which has broad implications for public health. This is because occurrence information for the Hazard Index PFAS is less extensive than the occurrence information for PFOA and PFOS due to fewer states monitoring the Hazard Index PFAS; therefore, establishing co-occurrence with PFOA and PFOS helps with understanding the extent of general Hazard Index PFAS occurrence. For the groupwise analysis, the six PFAS were separated into two groups—one consisted of PFOS and PFOA and the other group included the four Hazard Index PFAS. The analysis broke down the systems and samples according to whether chemicals from the respective groups were detected. Results were also shown separated by state. Results generally indicated that when PFOA or PFOS were found, Hazard Index PFAS were considerably more likely to also be found. This implies that, for systems that only measured PFOA and/or PFOS, detected those PFAS, and did not measure the Hazard Index PFAS, the Hazard Index PFAS are more likely to also be present than if PFOA and/or PFOS were not detected. At a national level, since many systems monitored for PFOA and PFOS only and detected these PFAS, this means that estimates of Hazard Index PFAS occurrence based on state Hazard Index PFAS data alone are likely to be underestimated. Given that the state datasets varied in the specific PFAS that were monitored, the analysis also compared the number of Hazard Index PFAS analyzed with the number of Hazard Index PFAS reported present. As more Hazard Index PFAS were analyzed, more Hazard Index PFAS were found. Further, systems and samples where Hazard Index PFAS were found were more likely to find multiple Hazard Index PFAS than a single Hazard Index PFAS (when monitoring for 3 or 4 Hazard Index PFAS).

Given that the groupwise co-occurrence analysis established that the Hazard Index PFAS, as a group, occur with a substantial level of frequency, particularly alongside PFOA or PFOS, the pairwise co-occurrence is relevant for understanding how the individual PFAS included in the rule co-occur with each other. The pairwise co-occurrence analysis explored the odds ratios for each unique pair of PFAS included in the regulation. Pairwise co-occurrence through odds ratios showed statistically significant relationships between nearly all unique pairs of PFAS included in the proposed rule. Odds ratios reflect the change in the odds of finding one chemical (*e.g.,* Chemical A) given that the second chemical (*e.g.,* Chemical B) is known to be present compared to the odds of finding it if the second chemical is not present. For example, an odds ratio of 2 would indicate that the presence of the second chemical would be expected to double the odds of the first chemical being reported present. An odds ratio of 1 indicates that there is no association between the two chemicals. At the system level, point odds ratios estimates ranged from 1.7–142.7, indicating that in some instances the odds of finding one PFAS increased by more than two orders of magnitude if the other PFAS was reported present (in other words, for some PFAS combinations, if one PFAS is present, there is more than 100 times the odds of certain other PFAS being present). HFPO–DA and PFHxS was the only pair of PFAS chemicals included in the proposed regulation that did not have a statistically significant relationship; 1 fell within the 95 percent confidence interval, indicating that the odds ratio was not determined to be statistically significantly different from 1.

In the proposed rule, the agency determined that, both as a group and as individual chemicals, the Hazard Index PFAS had a higher likelihood of being reported if PFOS or PFOA were present, First, the groupwise analysis established that the Hazard Index PFAS, in addition to PFOA and PFOS, occur at a significant frequency in drinking water. Then, the pairwise analysis demonstrated that PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS (the individual PFAS) generally co-occur with each other, as opposed to occurring independently. These data further support the EPA's finding that these PFAS are likely to occur, and that there is a substantial likelihood that combinations of PFHxS, PFNA, HFPO–DA, and PFBS co-occur in mixtures with a frequency of public health concern in drinking water systems.

2. Summary of Major Public Comments and EPA Responses

Some commenters agreed with the agency's conclusion in the March 2023 proposal that the PFAS included in the regulation appeared to meaningfully co-occur. However, some other commenters stated that they believed the data used to assess PFAS co-occurrence were too limited to make substantive conclusions. The EPA disagrees that the data were too limited or that the co-occurrence analysis was inconclusive. Based on the non-targeted state monitoring data used in the co-occurrence analysis (from 11 states), findings of the pairwise and groupwise analyses established a strong likelihood that these chemicals meaningfully co-occur in drinking water. This was observed through odds ratios statistically significantly greater than 1 in the pairwise analysis as well as frequency at which multiple chemicals were detected in the groupwise analysis. Based on public comment, the agency has updated its analysis to include more recent non-targeted state data that became publicly available after the proposal analyses were finalized. This ensures that findings are up to date; as discussed further in the following subsection, the more recent data confirms the proposal analysis.

3. Final Rule

After considering public comment and updating analyses, the EPA concluded that the co-occurrence analyses continue to support the

premise in the proposed rule that PFAS are likely to co-occur and support the EPA's final rule approach. Following is a discussion and presentation of information related to the EPA's co-occurrence analysis for this final rule effort. These data include all data from the rule proposal, in addition to the updated data the EPA incorporated based on public comment. As discussed elsewhere in this preamble, the newer data confirm the EPA's conclusions from proposal.

a. Groupwise Chemical Co-Occurrence

Table 9 shows the distribution of systems and samples according to whether states reported detections for any Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) and whether they also reported detections of PFOS or PFOA. USEPA (2024b) provides additional information for this analysis.

Table 9: Non-Targeted State PFAS Finished Water Data – Samples and Systems Binned According to Whether PFOS or PFOA were Reported by States and Whether Additional Hazard Index PFAS were Reported

Type	No PFOS or PFOA Reported		PFOS or PFOA Reported		Total Count
	No HI PFAS Reported	At Least One HI PFAS Reported	No HI PFAS Reported	At Least One HI PFAS Reported	
Samples	28,249 (57.8%)	1,321 (2.7%)	7,365 (15.1%)	11,954 (24.5%)	48,889
Systems	8,576 (70.6%)	401 (3.3%)	1,079 (8.9%)	2,089 (17.2%)	12,145

Considering eligible samples and systems within the aggregated state dataset, states reported either PFOA, PFOS, or one or more Hazard Index PFAS in 42.2 percent (20,640 of 48,889) of samples and 29.4 percent (3,569 of 12,145) of systems. When any PFAS (among PFOA, PFOS, and the Hazard Index PFAS) were reported, at least one Hazard Index PFAS was also reported in 64.3 percent (13,275 of 20,640) of samples and at 69.8 percent (2,490 of 3,569) of systems. Further, among samples and systems that reported PFOS or PFOA, at least one Hazard Index PFAS was reported in 61.9 percent (11,954 of 19,319) of samples and at 65.9 percent (2,089 of 3,168) of systems. This demonstrated strong co-occurrence of Hazard Index PFAS with PFOA and PFOS and a substantial likelihood (over 60 percent) of at least one Hazard Index PFAS being present at systems reporting the presence of PFOS or PFOA. Overall, one or more Hazard Index PFAS were reported at about 20.5 percent (2,490 of 12,145) of systems included in the aggregated state dataset of non-targeted monitoring. If this percentage were extrapolated to the nation, one or more Hazard Index PFAS would be found in over 13,000 systems. Table 10 shows the distribution of systems in a similar manner but provides a breakdown by state and includes only systems that monitored for either three or four of the Hazard Index PFAS.

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Table 10: Non-Targeted State PFAS Finished Water Data – Systems that Sampled for 3 or 4 Hazard Index PFAS Binned According to Whether PFOS or PFOA were Reported and Whether Any Additional Hazard Index PFAS were Reported by State

State	No PFOA/S Reported		PFOA/S Reported		Total System Count
	No HI Reported	HI Reported	No HI Reported	HI Reported	
CO	270 (68.0%)	26 (6.5%)	11 (2.8%)	90 (22.7%)	397
IL	880 (88.4%)	28 (2.8%)	25 (2.5%)	63 (6.3%)	996
IN	339 (91.4%)	19 (5.1%)	6 (1.6%)	7 (1.9%)	371
KY	38 (51.4%)	3 (4.1%)	17 (23.0%)	16 (21.6%)	74
MA	479 (36.5%)	33 (2.5%)	146 (11.1%)	655 (49.9%)	1,313
MD	51 (81.0%)	0 (0.0%)	3 (4.8%)	9 (14.3%)	63
ME	469 (73.2%)	12 (1.9%)	84 (13.1%)	76 (11.9%)	641
MI	2,205 (87.9%)	130 (5.2%)	66 (2.6%)	107 (4.3%)	2,508
MO	102 (90.3%)	2 (1.8%)	4 (3.5%)	5 (4.4%)	113
ND	99 (89.2%)	9 (8.1%)	0 (0.0%)	3 (2.7%)	111
NH	64 (27.0%)	13 (5.5%)	68 (28.7%)	92 (38.8%)	237
NJ	227 (34.1%)	7 (1.1%)	142 (21.4%)	289 (43.5%)	665
NY	275 (40.1%)	15 (2.2%)	132 (19.2%)	264 (38.5%)	686
OH	1,397 (94.5%)	31 (2.1%)	25 (1.7%)	26 (1.8%)	1,479
SC	187 (62.8%)	11 (3.7%)	28 (9.4%)	72 (24.2%)	298
TN	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1
VT	492 (87.2%)	14 (2.5%)	26 (4.6%	32 (5.7%)	564
WI	140 (60.1%)	24 (10.3%)	10 (4.3%)	59 (25.3%)	233

Tennessee only had data from one system which did not report the presence of any of the six PFAS. Otherwise, the percentage of systems included in Table 10 that reported any Hazard Index PFAS ranged from 3.9 to 52.4 percent of systems when broken down by state, with eight states exceeding 20 percent of systems. The percentage of systems that reported any PFAS ranged from 5.5 to 73.0 percent. Many systems and/or samples that were included in the aggregated state dataset did not monitor for all four Hazard Index PFAS. It is possible that more systems would have reported the presence of Hazard Index PFAS if they had monitored for all four Hazard Index PFAS. Additionally, as demonstrated in Table 10, when PFOA and/or PFOS were reported, at least one of the Hazard Index PFAS chemicals were also frequently reported. For systems that did not measure Hazard Index PFAS but measured and detected PFOA and/or PFOS, the groupwise analysis demonstrates that the Hazard Index PFAS were more likely to have been present in those systems as well. Table 11 presents system counts for systems where PFOS or PFOA were reported according to a) how many Hazard Index PFAS were monitored and b) how many Hazard Index PFAS were reported present.

Table 11: Non-Targeted State PFAS Finished Water Data – System Counts According to Hazard Index PFAS Analyzed and Reported Present for Systems Where PFOS and PFOA were Reported

HI Analyzed	HI Reported Present					Total
	0	1	2	3	4	
1	148 (65.5%)	78 (34.5%)	-	-	-	226
2	138 (48.6%)	85 (29.9%)	61 (21.5%)	-	-	284
3	282 (36.5%)	183 (25.0%)	183 (25.0%	84 (11.5%)	-	732
4	511 (26.5%)	449 (23.3%)	668 (34.7%)	278 (14.4%)	20 (1.0%)	1,926
Total	1,079	795	912	362	20	

Among systems that reported the presence of PFOS and/or PFOA, the fraction of systems that also reported any Hazard Index PFAS tended to increase as systems monitored for more of the Hazard Index PFAS. At systems monitoring for a single Hazard Index PFAS, 34.5 percent reported a positive result at some point during sampling. This increased to 73.5 percent of systems reporting the presence of at least one Hazard Index PFAS when monitoring for all four Hazard Index PFAS. Not only did the fraction of systems reporting the presence of any Hazard Index PFAS increase as the number of Hazard Index PFAS monitored increased, so did the number of Hazard Index PFAS that were reported as present. When four Hazard Index PFAS were monitored, nearly 50 percent of systems reported the presence of two to three of the Hazard Index PFAS. Thus, if PFOS or PFOA are reported, there is a reasonable likelihood that multiple Hazard Index PFAS would be present as well.

b. Pairwise Chemical Co-Occurrence

In addition to considering the co-occurrence of six PFAS as two groups, the EPA conducted a pairwise analysis to further explore co-occurrence relationships. Table 12 shows the calculated system-level odds ratios for every unique pair of PFAS chemicals evaluated. The equation for calculating odds ratios is symmetrical. Because of this, in a given row it does not matter which chemical is ''Chemical A'' and which is ''Chemical B.'' Additional information on odds ratios may be found in USEPA (2024b) and a brief explanation is described following Table 12 as well as in section III.C of this preamble.

Table 12: Non-Targeted State PFAS Finished Water Data – System-level Counts of Pairwise Chemical Occurrence and Odds Ratios Calculated from Aggregated State Dataset PFAS Samples for PFOA, PFOS, and HI PFAS

Chem A	Chem B	Chems A and B Reported	Only Chem B Reported	Only Chem A Reported	Neither Chem Reported	Odds Ratio [95% CI]
HFPO-DA	PFBS	33	1,532	21	7,614	7.8 [4.5-13.5]
HFPO-DA	PFHxS	23	1,137	31	8,007	5.2 [3.1-8.9]
HFPO-DA	PFNA	20	327	34	8,818	15.9 [9.1-27.7]
HFPO-DA	PFOA	39	1,665	16	7,480	11.0 [6.2-19.5]
HFPO-DA	PFOS	37	1,530	18	7,613	10.2 [5.9-17.9]
PFBS	PFHxS	1,282	245	721	9,093	66.0 [56.4-77.2]
PFBS	PFNA	423	85	1,510	8,735	28.8 [22.7-36.6]
PFBS	PFOA	1,605	852	401	8,485	39.9 [35.0-45.4]
PFBS	PFOS	1,497	692	509	8,645	36.7 [32.4-41.7]
PFHxS	PFNA	415	108	1,115	9,455	32.6 [26.1-40.7]
PFHxS	PFOA	1,374	1,259	230	8,820	41.9 [35.9-48.7]
PFHxS	PFOS	1,369	939	235	9,140	56.7 [48.6-66.2]
PFNA	PFOA	575	2,190	23	8,764	100.1 [65.9-151.8]
PFNA	PFOS	555	1,864	43	9,089	62.9 [46.0-86.1]
PFOA	PFOS	2,304	341	729	9,972	92.4 [80.6-106.0]

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Odds ratios reflect the change in the odds of finding one chemical (*e.g.,* Chemical A) given that the second chemical (*e.g.,* Chemical B) is known to be present compared to the odds of finding it if the second chemical is not present. For example, as shown in Table 12, the point estimate of 92.4 for the odds ratio between PFOA and PFOS indicates that the odds of finding PFOA after knowing that PFOS has been observed are 92.4 times what the odds would have been if PFOS was not observed, and vice versa. For every pair of chemicals, both the point estimate and 95 percent confidence interval (CI) were above 1, indicating significant increases in the likelihood of detecting one chemical if the other is present.

Both as a group and as individual chemicals, the Hazard Index PFAS had a higher likelihood of being reported if PFOS or PFOA were present. PFHxS, PFNA, HFPO–DA, and PFBS (the individual Hazard Index PFAS) are demonstrated to generally co-occur with each other, as well. These data support that there is a substantial likelihood that PFHxS, PFNA, HFPO–DA, and PFBS co-occur in mixtures with a frequency of public health concern in drinking water systems as discussed in section III.C of this preamble.

D. Occurrence Relative to the Hazard Index

1. Proposal

In the proposed rule, the EPA analyzed the available state data in comparison to the proposed Hazard Index MCL of 1.0 to evaluate the co-occurrence of PFHxS, PFNA, HFPO–DA, and PFBS. The EPA requested comment on the number of systems estimated to solely exceed the Hazard Index (but not the PFOA or PFOS MCLs) according to the approach outlined in USEPA (2024b).

2. Summary of Major Public Comments and EPA Responses

The EPA received comments on the analyses presented in the proposal of occurrence relative to the Hazard Index. Many commenters agreed that the Hazard Index PFAS co-occurred in mixtures at levels of health concern. Two of these comments came from states that conducted monitoring of Hazard Index PFAS post-UCMR 3 and stated that those occurrence data supported the EPA's findings. Several state agencies provided a summarized analysis of the number of systems expected to exceed the proposed Hazard Index of 1.0 in their state. The EPA notes that these estimates were based on the proposed Hazard Index, which included two significant figures. Since the EPA has determined to finalize the Hazard Index with one significant figure, these estimations are likely high. Nonetheless, these state data and the analyses provided by commenters provide illustrative confirmatory insight of the EPA's Hazard Index analyses (please see section IV of this preamble for additional discussion on the usage of significant figures).

One commenter suggested that a national dataset and model complete with all four Hazard Index PFAS are necessary to accurately estimate the number of systems that may exceed the Hazard Index. The EPA disagrees with the commenter; as described in section F, state data and model outputs were appropriately combined to estimate exceedance of the Hazard Index on a national level. Several commenters stated that there was a limited amount of available data to determine the prevalence of co-exposure of the Hazard Index compounds, and that further review would be needed prior to establishing the Hazard Index. The EPA disagrees with these commenters and believes that sufficient data were available to reasonably assess the occurrence of Hazard Index PFAS. An analysis of co-occurrence of Hazard Index compounds using a substantial amount of data encompassing tens of thousands of samples across over 10,000 systems is provided in section VI.C. of this preamble above and demonstrates that the four Hazard Index PFAS co-occur with each other as well as with PFOA and PFOS. One commenter suggested that more systems may exceed the Hazard Index than the PFOA and PFOS MCLs, since current treatment technologies have been optimized for PFOA and PFOS and not for other PFAS. The EPA's analysis of state datasets clearly contradicts this claim; using the best available data and scientifically robust analytical approaches, the EPA estimates more systems will exceed the PFOA and PFOS MCLs than the Hazard Index MCL. The use of a single significant figure for the Hazard Index MCL in this final rule will further increase the likelihood of this being the case.

3. Final Rule

The EPA used its updated state dataset to update analyses related to Hazard Index occurrence and found the analyses generally consistent with the proposal analyses. In the final rule, the EPA is reducing the number of significant figures used to determine Hazard Index exceedance following all calculations and rounding from two to one; this change had the effect of reducing system counts expected to exceed the Hazard Index. For purposes of the final analyses, only systems with an unrounded Hazard Index of 1.5 or greater were counted as an exceedance. Table 13 presents the total number and percentage of monitored systems with results above the proposed Hazard Index MCL based on state reported Hazard Index PFAS data for the states that conducted non-targeted monitoring and that sampled all four Hazard Index PFAS as a part of their overall monitoring efforts. The EPA notes that for equivalent comparison purposes Table 13 only accounts for samples that included reported values (including non-detects) of all four Hazard Index PFAS. As shown within the table, the majority of states evaluated had monitored systems with results above the proposed Hazard Index MCL, ranging from 0.35 to 3.17 percent of total monitored systems. For additional discussion on the usage of significant figures in this rule, please see section IV of this preamble.

Table 13: Non-Targeted State PFAS Finished Water Data – Summary of Total Number and Percent of Monitored Systems Exceeding the Hazard Index with Samples Containing Reported Values of All Four Hazard Index PFAS

State	Total Monitored Systems > Final HI of 1	Percent Systems > Final HI of 1
Colorado	2	0.50%
Illinois	7	0.70%
Indiana	0	0.00%
Kentucky	2	2.70%
Maryland	2	3.17%
Massachusetts	23	1.76%
Michigan	17	0.68%
Missouri	1	0.91%
New York	7	1.28%
New Hampshire	3	2.17%
North Dakota	0	0.00%
Ohio	16	1.08%
South Carolina	2	0.68%
Vermont	2	0.35%
Wisconsin	7	3.03%

Further evaluating the available state data related to the proposed Hazard Index MCL of 1, Table 14 presents the total number of systems that exceed the final Hazard Index of 1 based on state reported Hazard Index PFAS results for the same states shown in Table 13. However, in this case, the EPA also analyzed the same non-targeted state data, including additional samples even if those samples did not contain reported values (including non-detects) for all four Hazard Index PFAS (*i.e.,* exceeding the Hazard Index based on two or three Hazard Index PFAS with reported values included within a sample). Moreover, while these states did monitor for all four Hazard Index PFAS as a part of their overall monitoring, in a subset of those states some samples did not include reported data on all four Hazard Index PFAS (*i.e.,* values of one or more of the Hazard Index PFAS were not reported as non-detect, rather no value was reported). This analysis, presented in Table 14, shows an increase in the number of monitored systems exceeding the proposed Hazard Index of 1 and demonstrates prevalence of these PFAS at levels of concern, even when all four PFAS may not be included within a sample.

Table 14: Non-Targeted State PFAS Finished Water Data – Summary of Total Monitored Systems Exceeding the Hazard Index with Samples Containing Reported Values of 2 or More Hazard Index PFAS

State	Total Monitored Systems > Final HI of 1	Percent Systems > Final HI of 1
Colorado	2	0.50%
Illinois	7	0.70%
Indiana	0	0.00%
Kentucky	2	2.70%
Maine	4	0.62%
Maryland	7	5.19%
Massachusetts	31	2.34%
Michigan	17	0.68%
Missouri	1	0.87%
New Jersey	27	4.06%
New York	18	2.67%
New Hampshire	17	3.04%
North Dakota	0	0.00%
Ohio	16	1.08%
South Carolina	2	0.67%
Vermont	2	0.35%
Wisconsin	7	2.95%

Combining the non-targeted monitoring results shown previously with targeted state monitoring conducted for all four Hazard Index PFAS showed at least 864 samples from 211 PWSs in 21 states had results above the final Hazard Index of 1. These systems serve approximately 4.7 million people. More information on occurrence in state monitoring is available in section III.C of this preamble and in USEPA (2024b).

In summary, the finished water data collected under both non-targeted and targeted state monitoring efforts from 32 states showed there are at least 1,772 PWSs serving a total population of approximately 24.3 million people that have at least one result exceeding the final PFOA MCL of 4.0 ng/L. In those same 32 states, there are also at least 1,432 PWSs serving a total population of approximately 21.0 million people that have at least one result exceeding the final PFOS MCL of 4.0 ng/L. Finished water data showed that there are at least 187 systems in 23 states serving a total population of approximately 4.4 million people with at least one result exceeding the final PFHxS MCL of 10 ng/L. Finished water data from 12 states showed there are at least 52 systems serving a total population of approximately 176,000 people that have at least one result exceeding the final PFNA MCL of 10 ng/L. Finished water data showed 13 systems from 5 states serving over 226,000 people have at least one result exceeding the final HFPO–DA MCL of 10 ng/L. Related to the Hazard Index, finished water data collected under both non-targeted and targeted state monitoring efforts in 21 states showed there are at least 211 systems serving a total population of approximately 4.7 million people with results above the final Hazard Index value of 1 for PFHxS, PFNA, HFPO–DA, and PFBS. Samples that only had monitoring results for one Hazard Index PFAS were not included. USEPA (2024b) presents a detailed discussion on state PFAS monitoring information.

E. Occurrence Model

A Bayesian hierarchical occurrence model was developed to characterize national occurrence of the four PFAS that were most frequently detected in the UCMR 3: PFOA, PFOS, PFHxS, and PFHpA.[8] This model was used to generate the baseline national occurrence estimates for PFOA, PFOS, and PFHxS, which were used in the subsequent economic analysis in USEPA (2024g). Bayesian hierarchical models are a widely used statistical approach in which subsets of data may be recognized as more related than others (such as samples from the same PWS are more related than samples between different PWSs) to capture complex relationships between levels of data and can aid in understanding the factors that influence outcomes. The objective of this model was to use both UCMR 3 data and supplemental state data to develop national estimates of

[8] PFHpA was included in the model because of its UCMR 3 occurrence data availability.

PFAS occurrence that inform occurrence distributions both within and across PWSs. Supplemental state data were incorporated to improve the model's ability to estimate PFAS occurrence at levels below the UCMR 3 minimum reporting levels (20 ng/L for PFOA, 40 ng/L for PFOS, and 30 ng/L for PFHxS). The state data incorporated to supplement the model came from publicly available datasets. In order to maintain the statistically robust UCMR 3 sampling framework, thereby enabling the agency to make conclusions about national representativeness of the model results, incorporation of state data into the model was limited only to data from systems that took part in the UCMR 3. The model does not include PFNA and PFBS due to data limitations; PFNA and PFBS lacked sufficient reported values above the UCMR 3 minimum reporting levels to be incorporated into the model. The model has been peer reviewed and is described extensively in Cadwallader et al. (2022).

The model uses Markov chain Monte Carlo (MCMC) simulation and the assumption of lognormality in PFAS chemical occurrence. Markov chain Monte Carlo is a powerful statistical tool used to understand uncertainty and making informed decisions when analyzing data. The EPA has used similar hierarchical models to inform regulatory decision making in the past, such as for development of the NPDWR for Arsenic and *Cryptosporidium parvum* (USEPA, 2006c; USEPA, 2000e).

After log-transformation of data informing the model, system-level means (where each system has a mean concentration for each chemical) were assumed to be distributed multivariate normally. Further, within-system occurrence was assumed to be distributed normally for each chemical. Since system-level means were modeled multivariate normally, correlation between estimated system-level means across chemicals could also be assessed. The assumption of lognormality as well as the incorporation of state data with lower reporting limits allowed the model to generate reasonable estimates for PFAS occurrence at levels below the UCMR 3 minimum reporting levels.

After the model was fit with available data from PWSs that were included in the UCMR 3, it was used to simulate occurrence at an inventory of active community water systems (CWS) and non-transient non-community water systems (NTNCWS) extracted from the Safe Drinking Water Information System (SDWIS). System-level means for non-UCMR 3 systems were simulated by sampling from the multivariate normal distribution of system-level means that was produced during the model fitting process. For systems that were included in the UCMR 3, the fitted system-level mean was used directly. This approach allowed national occurrence distributions to be estimated alongside the associated populations when combined with population data from SDWIS.

1. Proposal

In the March 2023 proposal preamble, model estimates of contaminant occurrence were presented. For the analysis presented in the proposal, UCMR 3 data were supplemented with 23,130 analytical results from 771 systems across 17 states that were available from public state websites through August 2021. Key model results that were presented directly included correlation coefficients across pairs of chemicals included in the model, extrapolated estimates of the number of system level means anticipated to exceed various threshold, and the estimated population associated with systems that had mean concentrations exceeding the various thresholds. The results indicated that system-level mean concentrations were moderately to strongly correlated across the modeled PFAS and that thousands of systems were estimated to have mean PFAS concentrations in the range of single digit ng/L.

2. Summary of Major Public Comments and EPA Responses

A few commenters stated that they believed the model was an overly complicated approach to characterizing chemical occurrence and found it difficult to understand. Further, a few commenters stated that they believed the model was not transparent. The EPA disagrees; the occurrence approach used by the agency in this rule is based on a widely utilized and accepted statistical approach which is used in a variety of fields from education to health care and from business to the environment. These models allow exploration of the relationships among groups of data and the EPA used this model to better inform the agency's understanding of probable PFAS occurrence. For more information about Bayesian statistics and the wide variety of potential applications, see, for example, Hoff (2009); van de Schoot et al. (2021); Aguilera et al. (2011); and Messner et al. (2001). While the model uses an advanced statistical method and requires some statistical background to fully understand, Bayesian hierarchical models have previously been employed to assess occurrence for drinking water contaminants, as was discussed in the March 2023 proposal preamble as well as Cadwallader et al. (2022). Cadwallader et al. (2022) describes the model structure while the annotated model code and inputs were provided directly as supporting information alongside the manuscript. This information was incorporated into the docket for this rule's proposal. Sufficient information to replicate the model run was provided. Thus, the agency disagrees with the assertion that the model was not transparent.

Regarding the model complexity, the core structure of this specific model is comparatively simple among Bayesian hierarchical models. The model uses a multivariate normal distribution of system-level means (of log transformed data) for the four modeled PFAS. It also includes a parameter for small systems to assess whether they appear to have systematically different (higher or lower) concentrations than large systems. As stated in Cadwallader et al. (2022), the model extrapolates to the nation by sampling from the multivariate normal distribution and accounting for whether the system being simulated was small. The multivariate normal distribution and the parameter to distinguish small systems from large systems are two simple but important pieces of the model structure.

Many commenters stated that the model relied on insufficient data and produced substantial underestimates of the number of systems that would fail to meet MCL requirements. The agency disagrees both that the approach taken would systematically underestimate PFAS occurrence and that the data were insufficient inform the model. The Bayesian approach used here makes a precedented assumption about drinking water contaminant occurrence distributions (lognormality) and uses the available data to generate iterative estimates of distribution parameters that capture uncertainty through MCMC simulation. Across these iterations, the density of the posterior distribution for model parameters is proportionate to the likelihood that a given value would have produced the observed data. The subsequent national extrapolations also reflect this uncertainty.

For the results presented in the March 2023 proposal preamble, the model was fit using 171,017 analytical results across the 4,920 UCMR 3 systems. This was a nationally representative set of systems. 147,887 of the analytical results were collected as part of UCMR 3 while 23,130 were aggregated from 17 subsequently collected state datasets. The model was designed to utilize both results reported as observed concentrations (8,209 results) and

results reported as less than a reporting limit (162,808 results). While the UCMR 3 used higher reporting limits than are currently available, both reported concentrations and values reported as below the minimum reporting level cumulatively make substantial contributions to informing the model's estimates of the PFAS occurrence distribution because of this statistically robust framework. Due to this efficient use of data, and the steps taken to maintain a nationally representative set of systems, the agency believes that the over 170,000 analytical results were sufficient to generate reasonable estimates of occurrence for the modeled contaminants.

Several commenters expressed concern with model bias resulting from the supplemental state data that was incorporated when fitting the model. The hierarchical structure of the model minimizes the bias impact of introducing additional state data for only some UCMR 3 systems (those with additional data available) because the data are explicitly linked to their parent systems rather than being pooled with all other data informing the model. The primary impact that these data have is on the model's estimate of specific system means for those systems that had additional data and informing the within-system variability parameters in the model. Refinement of a single system's mean estimate has a much smaller impact on the high-level distribution of system-level means and such shifts are proportionate to the added evidence derived from the supplemental data.

The addition of data from systems not included in the UCMR 3 would pose a much greater concern for bias, since not all states have publicly available data. States with additional data would become disproportionately represented in the fit of the high-level distribution, since each system acts as a data point in fitting the distribution. The resulting high-level distribution would shift to resemble the states more closely with higher system representation in the source dataset. This would also be reflected in the subsequent national extrapolation. This same bias concern applies to national extrapolation approaches where some fraction of systems in a subset are identified as exceeding a given threshold and the national inventory of systems is multiplied by that fraction to generate a national estimate of systems that would exceed the threshold. If certain states have a disproportionate number of systems included in the subset compared to in the nation as a whole, the national estimate will be biased towards the tendencies of those states. In addition to this bias, the simple example approach discussed above would not naturally reflect uncertainty. Thus, for the purpose of national extrapolation, a nationally representative set of systems is more appropriate, even if data from other systems are available.

While the EPA believes the model design and data selected for the analysis presented in the March 2023 proposal remain appropriate given the data availability at the time, the EPA has also continued to collect newly available data from publicly available state datasets, as the agency committed to in the proposed rulemaking (USEPA, 2023f). The Bayesian hierarchical model has been refit using the updated dataset with the same methods and criteria for data selection that were used for the analysis presented in the March 2023 proposal.

3. Final Rule

After considering public comment, the agency has used the Bayesian statistical model described in Cadwallader et al. (2022) to support the economic analysis for this final regulation by combining the available occurrence information from UCMR 3 and state data subsequently collected at UCMR 3 systems to maintain the nationally representative nature of the set of drinking water systems informing the model, utilizing those data to compute estimates of national occurrence for PFAS contaminants, and providing estimates on the number of systems impacted by this final rule. These estimates directly informed the economic analysis in USEPA (2024g). For the final rule, the model was updated with additional state data collected through May 2023. In total, based on public comment, the EPA supplemented the state dataset with 65,537 analytical results from 1,156 systems across 28 states. Of these supplemental data, 24,950 analytical results were observed concentrations while 40,587 results were reported as below some reporting limit. The previously presented results have been updated and are presented in Table 15. The EPA notes that results from the updated dataset and model were confirmatory of its proposal analyses and did not result in changes to the EPA's final decisions. Median estimates and 90 percent credible intervals are shown for counts of systems with system-level means at or above various PFAS concentrations in Table 15 and the population served by those systems in Table 16.

Table 15: National Occurrence Model Estimate – Estimated Number of Systems With System-level Means at or Above Various Concentrations

Concentration (ng/L)	PFHxS [90% CI]	PFOA [90% CI]	PFOS [90% CI]
4.0	1,828 [1,226-2,689]	3,260 [2,416-4,349]	3,368 [2,461-4,566]
5.0	1,252 [823-1,888]	2,194 [1,588-2,994]	2,447 [1,757-3,386]
10.0	340 [209-555]	523 [354-771]	793 [537-1,166]

Table 16: National Occurrence Model Estimate – Estimated Population Served by Systems with System-level Means at or Above Various Concentrations

Concentration (ng/L)	PFHxS [90% CI]	PFOA [90% CI]	PFOS [90% CI]
4.0	20,386,000 [17,436,000-24,351,000]	34,343,000 [30,897,000-40,600,000]	34,313,000 [30,703,000-41,110,000]
5.0	15,436,000 [12,524,000-18,458,000]	24,287,000 [21,551,000-28,222,000]	26,594,000 [23,793,000-31,240,000]
10.0	4,645,000 [3,557,000-7,205,000]	7,132,000 [4,871,000-8,987,000]	10,205,000 [7,552,000-12,232,000]

For PFOA, PFOS, and PFHxS, thousands of systems were estimated to have mean concentrations over the lowest thresholds (*i.e.,* 4.0 and 5.0 ng/L) presented in Tables 15 and 16 with the total population served estimated to be in the tens of millions. The populations shown here represent the entire populations served by systems estimated to have system-level means over the various thresholds. It is likely that different subpopulations would be exposed to different mean PFAS concentrations if multiple source waters are used.

In addition to the estimates of individual chemical occurrence, the multivariate normal distribution of system-level means allowed the model to provide insight on estimated co-occurrence. The model results support the co-occurrence of PFOA, PFOS and Hazard Index PFAS. The model evaluated whether untransformed (*i.e.,* expressed in the original units of measurement) estimates of system-level means were correlated across each unique pair of the four modeled chemicals included in the model. Estimates of the Pearson correlation coefficient are shown in Table 17. The Pearson correlation coefficient serves as an indicator of the strength of the linear relationship between two variables and may range from −1 to 1. Positive values indicate a positive relationship (*i.e.,* as one variable increases, so does the other). shown in Table 17. The Pearson correlation coefficient serves as an indicator of the strength of the linear relationship between two variables and may range from −1 to 1. Positive values indicate a positive relationship (*i.e.,* as one variable increases, so does the other).

Table 17: National Occurrence Model Estimate – Median Estimated Pearson Correlation Coefficient and 90% Credible Interval Among System-level Means

Chemical Pair	Pearson Correlation Coefficient [90% CI]
PFOS-PFOA	0.73 [0.63-0.80]
PFOS-PFHpA	0.67 [0.56-0.75]
PFOS-PFHxS	0.82 [0.72-0.89]
PFOA-PFHpA	0.83 [0.79-0.87]
PFOA-PFHxS	0.51 [0.39-0.60]
PFHpA-PFHxS	0.58 [0.44-0.67]

The EPA considered a moderate strength correlation as greater than 0.5 and a strong correlation as greater than 0.7. Each point estimate of correlation coefficients between two chemicals was above the threshold for a moderate strength correlation. The carboxylic acids (PFOA–PFHpA) and sulfonic acids (PFOS–PFHxS) had the highest estimated correlation strengths, with both the point estimate and the 90 percent credible interval above the threshold for a strong correlation. PFOS–PFOA and PFOS–PFHpA had similar point estimates and 90 percent credible interval ranges, spanning the moderate-to-strong correlation range. Both PFOA–PFHxS and PFHpA–PFHxS had the bulk of their posterior distributions fall in the range of a moderate strength correlation. Thus, the

model predicted significant positive relationships among system-level means of all four chemicals that were included. These results support the co-occurrence discussion presented in section VI.C of this preamble that indicated extensive co-occurrence of PFOA, PFOS, and the Hazard Index PFAS observed in state datasets from both groupwise and pairwise chemical perspectives.

F. Combining State Data With Model Output To Estimate National Exceedance of Either MCLs or Hazard Index

In order to broadly estimate the number of systems that would be impacted by the regulation, including MCLs of 4.0 ng/L for PFOA and PFOS alongside a Hazard Index of 1 for PFHxS, PFNA, HFPO–DA, and PFBS, findings from non-targeted monitoring in state datasets were combined with model estimates. Specific details on the methodology can be found in USEPA (2024b). Briefly, information collected from non-targeted state datasets included the fractions of systems that reported a measurement at or above the UCMR 5 minimum reporting level for a given analyte and an empirical cumulative distribution function (eCDF) consisting of system-level maximum observed concentrations of that chemical at these systems. The UCMR 5 minimum reporting levels for PFNA, HFPO–DA, and PFBS are equivalent to 4 ng/L, 5 ng/L, and 3 ng/L, respectively (USEPA, 2022j). This applies the assumption that the fraction of systems that observed PFNA, HFPO–DA, and PFBS at or above UCMR 5 minimum reporting levels and the maximum concentrations observed at those systems are reasonably representative of the nation.

1. Proposal

The model was used to simulate EP-level concentrations of the four modeled PFAS (PFOA, PFOS, PFHpA, and PFHxS) under the assumption that within-system concentrations are lognormally distributed (a common assumption for drinking water contaminants, see (Cadwallader et al. (2022)) and that variability in concentrations is entirely across EP (thus a given EP is assumed to have a constant concentration). For each system, the maximum estimated EP PFOA or PFOS concentration was selected to determine whether the system exceeded either of the proposed MCLs of 4.0 ng/L. The EP with the maximum concentration is the point that determines whether a system has an EP that is above an MCL. Estimates of the system-level maximum for PFHxS were also selected for the Hazard Index calculation. The maximum value of the sum of the four modeled PFAS at each system was selected and used as a basis for determining which systems would receive superimposed concentrations of the three remaining Hazard Index chemicals (PFNA, HFPO–DA, and PFBS). This approach was selected due to the extensive observed co-occurrence of PFAS in the UCMR 3, state data, and modeled estimates.

Multiple methods of system selection were used that reflected different degrees of co-occurrence. The chemical concentration that was applied to selected systems were randomly sampled from the eCDF for each chemical. Based on the model output, this assumes that system-level maximums for PFNA, HFPO–DA, and PFBS would occur at the same location within a system. Given the substantial co-occurrence among PFAS observed and estimated across various analyses, combination of system-level maximums independently pulled from chemical eCDFs is a reasonable simplifying assumption. This is particularly true since systems selected for each chemical are not necessarily the same and in most cases were probability weighted. Estimates of the range of systems impacted were developed by taking Q5 and Q95 estimates for each method. The low end of the range was taken as the lowest Q5 estimate across methods, rounded down, while the high end of the range was taken as the highest Q95 estimate across methods, rounded up. This was also done for the total population served by these systems.

The analysis to support the March 2023 proposal estimated that 100–500 systems that were not already exceeding an MCL for PFOA or PFOS would exceed the Hazard Index. This resulted in a total of 3,400–6,300 systems estimated to be exceeding either the Hazard Index, the MCL for PFOA, or the MCL for PFOS.

2. Summary of Major Public Comments and EPA Responses

One commenter stated that they believed it is difficult to determine whether the estimated number of systems exceeding the Hazard Index is a reasonable estimate until a complete national dataset is available. The EPA disagrees with this commenter. The agency believes that it has taken steps to produce reasonable estimates using a robust set of available data, and that the data and analyses are sufficient to inform the EPA's regulatory decisions. Namely, this includes the use of non-targeted state datasets and multiple scenarios reflecting varying degrees of co-occurrence as described in USEPA (2024b). Among other important uses for these data, the EPA considered them to inform the regulatory determination for the mixture of the Hazard Index PFAS and the EA. The EPA has used these data to clearly demonstrate that there is a substantial likelihood that combinations of the Hazard Index PFAS co-occur as mixtures in public water systems with a frequency and at levels of public health concern. See section III of this preamble for additional discussion. Additionally, these data support the EPA's EA, and considerations of costs and benefits consistent with SDWA's requirements. See section XII of this preamble for further discussion.

3. Final Rule

The method to combine state data for non-modeled Hazard Index PFAS with model estimates has largely remained the same for this final rule as it was for the March 2023 proposal. One key change, based on public comments, was to use an updated set of non-targeted state data to inform Hazard Index contaminant prevalence above UCMR 5 minimum reporting levels and eCDFs. Another key alteration, also based on public comments, was accounting for significant figures when counting systems exceeding the MCL for PFOA, the MCL for PFOS or the Hazard Index. For a system to be exceeding the Hazard Index, it must be greater than or equal to 2 (*i.e.,* greater than 1) after rounding (for additional discussion on significant figure usage in the final rule, please see section IV of this preamble). To exceed the MCLs for PFOA or PFOS, the concentration must be greater than or equal to 4.1 ng/L after rounding. Finally, model estimates of PFHxS were converted to zero for the purposes of calculating the Hazard Index if they fell below the PQL of 3 ng/L.

The total number of systems estimated to be exceeding one or more MCLs in the rule was 4,100–6,700 (compared to 3,400–6,300 in the proposal) serving a total population of 83–105 million people. Among these systems, 100–300 are estimated to be exceeding the Hazard Index without exceeding the PFOA or PFOS MCLs. The EPA used these modeled estimates to inform the costs and benefits determination as described in section XII of this preamble. Additional details regarding the approach used here can be found in USEPA (2024b).

G. UCMR 5 Partial Dataset Analysis

1. Summary of Major Public Comments and EPA Responses

UCMR 5 occurrence data were not available to inform the proposal, but the agency discussed that additional nationwide monitoring data would be available for systems participating in the monitoring program. Some commenters called for the EPA to delay issuance of the final PFAS rule until the complete UCMR 5 occurrence dataset can be analyzed, and some commenters stated that rule promulgation should be delayed until at least a portion of the UCMR 5 data is obtained. The EPA disagrees with these commenters. The EPA is not required under the statute to wait for another round of UCMR data to be collected before proposing or finalizing a regulation; in this case, the completion of UCMR 5 data reporting is expected at the end of 2025, with the final dataset not being available until 2026. Rather, SDWA section 1412(b)(1)(B)(ii)(II) expressly provides that the EPA must use the ''best *available* public health information'' in making a regulatory determination (emphasis added). The EPA has sufficiently robust occurrence information to make regulatory determinations and promulgate a regulation for the six PFAS in this regulation. In addition to serving as a significant way for helping many utilities reduce initial monitoring costs, the final full UCMR 5 dataset will also be valuable for informing future regulatory decisions for the 23 PFAS included in UCMR 5 that are not directly addressed by this rulemaking. The agency believes that the best currently available occurrence data demonstrate sufficient occurrence or substantial likelihood of occurrence for the contaminants included in the final rule.

2. Final Rule

While the EPA is under no legal obligation to consider the preliminary, partial UCMR 5 dataset prior to rule promulgation, based on public comment and interest, the agency examined UCMR 5 data released as of February 2024 (USEPA, 2024n). While these data were not available for this rule's proposal, are not complete, and are not a basis for informing the agency's decisions for the final rule, the EPA notes that they generally confirm the extensive occurrence analyses the agency has conducted: namely, that all six regulated PFAS occur in finished drinking water and that the six regulated PFAS co-occur with one another. The EPA notes some important caveats when considering these data. First, as of February 2024, the partial UCMR 5 dataset is a subset of data that will be collected, representing approximately 24 percent of the total data that might be collected under that effort. Additionally, under UCMR 5, systems must collect either 2 or 4 samples, depending on their source water characteristics. In this preliminary dataset, systems have varying degrees of completeness in their sample collection and results may shift at the system level as additional samples are collected. Analyses included examination of sample-level results as well as EP mean-level results.

The UCMR 5 data publicly available as of February 2024 included a combined total of 100,629 analytical results for PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS ranging from 16,766 to 16,778 analytical results for each chemical. 16,743 complete sample sets where an analytical result was reported for each chemical were available. 9,528 EPs and 3,719 PWS had at least one analytical result for each of the six PFAS and one sample for which the Hazard Index could be calculated. As mentioned previously, this partial dataset is estimated to contain approximately 24 percent of the data that will be available once the dataset is completed and finalized.

The preliminary dataset was assessed for sample-level threshold exceedances of PFOA (4.0 ng/L), PFOS (4.0 ng/L), PFHxS (10 ng/L), PFNA (10 ng/L), HFPO–DA (10 ng/L), and the Hazard Index (1). Note that for PFOA and PFOS, two significant figures were considered (*i.e.,* analytical results had to meet or exceed 4.05 to be considered exceedances) while for PFHxS, PFNA, HFPO–DA, and the Hazard Index one significant figure was considered (*i.e.,* an analytical result had to meet or exceed 15 to be considered an exceedance for PFHxS, PFNA, and HFPO–DA and 1.5 to be considered an exceedance for the Hazard Index). Sample-level analysis only included complete sample sets while EP and system-level analysis included only systems that provided sufficient data to determine maximum PFOA, PFOS, PFHxS, PFNA, and HFPO–DA, and Hazard Index (which required at least one sample set where the Hazard Index could be calculated). The EPA notes that this analysis does not represent an estimate for the number of systems that will be in compliance with the MCL; as discussed in section V of this preamble, MCL compliance is determined based on an RAA. Additionally, samples below the PQL would be treated as zero in the compliance calculation. In the preliminary UCMR 5 dataset, PFOA exceeded 4.0 ng/L in 6.1 percent of samples (1,024 samples), at 7.5 percent of EPs (719 EPs), and at 11.2 percent of systems (415 systems). PFOS exceeded 4.0 ng/L in 6.6 percent of samples (1,100 samples), at 8.0 percent of EPs (766 EPs), and at 12.4 percent of systems (462 systems). PFHxS exceeded 10 ng/L in 0.4 percent of samples (66 samples), at 0.6 percent of EPs (53 EPs), and at 1.1 percent of systems (42 systems). PFNA exceeded 10 ng/L in <0.1 percent of samples (5 samples), at <0.1 percent of EPs (5 EPs), and at 0.1 percent of systems (5 systems). HFPO–DA exceeded 10 ng/L in <0.1 percent of samples (2 samples), at <0.1 percent of EPs (1 EP), and at <0.1 percent of systems (1 system). The Hazard Index exceeded 1 in 0.5 percent of samples (76 samples), at 0.6 percent of EPs (60 EPs), and at 1.3 percent of systems (48 systems). When the thresholds were considered simultaneously, 9.0 percent of samples (1,504 samples), 10.9 percent of EPs (1,043 EPs), and 15.8 percent of systems (589 systems) exceeded a threshold. Note that single sample exceedances of thresholds do not necessarily reflect the averages that might be observed in the completed dataset. Specifically, the EPA notes that it is likely that many of the 15.8 percent of systems with an exceedance would not exceed the MCLs because additional samples used to determine an RAA may produce lower results.

To further illustrate this point, though there is insufficient data to fully evaluate RAAs,[9] EP-level means and systems with EP-level means exceeding an MCL threshold were also assessed with the preliminary dataset. For this analysis, only complete sample sets and EPs with multiple complete sample sets were included. 5,269 EPs and 2,498 systems had data that met these criteria. When calculating EP means, results reported as less than the minimum reporting limit were treated as zero. Note that for PFOA and PFOS, two significant figures were considered (*i.e.,* calculated means had to meet or exceed 4.05 to be considered exceedances) while for PFHxS, PFNA, HFPO–DA, and the Hazard Index one significant figure was considered (*i.e.,* calculated mean had to meet or exceed 15 to be considered an exceedance for PFHxS, PFNA, and HFPO–DA and 1.5 to be considered an exceedance for the Hazard Index). Mean PFOA concentration exceeded 4.0 ng/L at 4.8

[9] An RAA is calculated using results for samples taken at a particular monitoring location during the previous four consecutive quarters (see section XIII.B for more information).

percent of EPs (253 EPs) and at 6.0 percent of systems (149 systems). Mean PFOS concentration exceeded 4.0 ng/L at 5.3 percent of EPs (278 EPs) and at 7.2 percent of systems (179 systems). Mean PFHxS concentration exceeded 10 ng/L at 0.3 percent of EPs (15 EPs) and at 0.4 percent of systems (11 systems). Mean PFNA concentration exceeded 10 ng/L at <0.1 percent of EPs (1 EP) and at <0.1 percent of systems (1 system). Mean HFPO–DA concentration exceeded 10 ng/L at <0.1 percent of EPs (1 EP) and at <0.1 percent of systems (1 system). Mean Hazard Index exceeded 1 at 0.3% of EPs (18 EPs) and at 0.6% of systems (14 systems). Considered simultaneously, an MCL was exceeded at 7.2 percent of EPs (381 EPs) and 9.4 percent of systems (235 systems). While the EP means described above include multiple sample sets, observed mean concentrations are likely to change as systems complete UCMR 5 sampling.

Among 16,743 completed sample sets and 9,529 EPs and 3,719 systems which had at least one result for each analyte, 13.9 percent of samples (2,335 samples), 16.5 percent of EPs, and 22.6 percent of systems (842 systems) had an observed concentration at or above the minimum reporting level for at least one of the 6 PFAS. Table 18 shows counts of samples, EPs, and systems according to how many of the 6 PFAS included in this final rule were present at or above the minimum reporting level. As shown in Table 18, about 7.5 percent of samples, 9.4 percent of EPs, and 14.2 percent of systems observed multiple PFAS at or above the minimum reporting level.

Table 18: Preliminary UCMR 5 Dataset[1] – Samples, EPs, and Systems Binned According to Number of PFAS Among PFOA, PFOS, PFHxS, PFNA, HFPO-DA and PFBS That Were Reported at or Above the Minimum Reporting Level

PFAS Observed	Samples	EPs	Systems
0	14,408 (86.1%)	7,954 (83.5%)	2,877 (77.4%)
1	1,077 (6.4%)	676 (7.1%)	313 (8.4%)
2	541 (3.2%)	379 (4.0%)	191 (5.1%)
3	393 (2.3%)	289 (3.0%)	172 (4.6%)
4	303 (1.8%)	215 (2.3%)	148 (4.0%)
5	21 (0.1%)	16 (0.2%)	18 (0.5%)
6	0 (0.0%)	0 (0.0%)	0 (0.0%)

Notes:

1 The preliminary UCMR 5 dataset contains approximately 24 percent of the samples anticipated to be available once the dataset is complete.

Groupwise co-occurrence was also examined in the preliminary UCMR 5 dataset. Table 19 provides the counts and percentages of systems, EPs, and samples where PFOA and/or PFOS were reported as well as whether any of the Hazard Index PFAS were reported. Sample-level results only included completed sample sets while system-level results only included systems which provided one analytical result for each of the 6 PFAS.

Table 19: Preliminary UCMR 5 Dataset[1] – Samples, EPs, and Systems Binned According to Whether PFOS or PFOA were Reported by States and Whether Additional Hazard Index PFAS were Reported

Type	No PFOS or PFOA Reported		PFOS or PFOA Reported		Total Count
	No HI PFAS Reported	At Least One HI PFAS Reported	No HI PFAS Reported	At Least One HI PFAS Reported	
Samples	14,408 (86.1%)	786 (4.7%)	498 (3.0%)	1,051 (6.3%)	16,743
EPs	7,954 (83.5%)	508 (5.3%)	317 (3.3%)	750 (7.9%)	9,529
Systems	2,877 (77.4%)	242 (6.5%)	145 (3.9%)	455 (12.2%)	3,719

Notes:

[1] The preliminary UCMR 5 dataset contains approximately 24 percent of the samples anticipated to be available once the dataset is complete.

In samples, at EPs, and at systems where PFOA and/or PFOS were reported present, one or more Hazard Index contaminant was reported at or above the minimum reporting level about 68, 70, and 76 percent of the time, respectively. As UCMR 5 monitoring continues, it is possible that additional systems from this subset will report the presence of PFOA, PFOS or a Hazard Index PFAS. The percentage of systems detecting neither PFOA, PFOS, nor a Hazard Index PFAS would then decrease. Table 20 shows the number of Hazard Index PFAS that were observed in samples, at EPs, and at systems where PFOA and/or PFOS were reported.

Table 20: Preliminary UCMR 5 Dataset[1] – Sample, EP, and System Counts According Number of Hazard Index PFAS Reported Present for Systems Where PFOS and/or PFOA were Reported

HI Observed	Samples	EPs	Systems
0	498 (32.1%)	317 (29.7%)	145 (24.2%)
1	573 (37.0%)	403 (37.8%)	223 (37.2%)
2	453 (29.2%)	329 (30.8%)	214 (35.7%)
3	25 (1.6%)	18 (1.7%)	18 (3.0%)
4	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	1,549	1,067	600

Notes:

[1] The preliminary UCMR 5 dataset contains approximately 24 percent of the samples anticipated to be available once the dataset is complete.

At systems where Hazard Index PFAS were reported in addition to PFOA/PFOS, about 51.0 percent of systems reported multiple Hazard Index PFAS. As described above, it is possible that systems may detect additional PFAS as sample collection continues under UCMR 5. System-level pairwise odds ratios based on the first release of UCMR 5 data are shown in Table 21.

Table 21: Preliminary UCMR 5 Dataset[1] – System-level Counts of Pairwise Chemical Occurrence and Odds Ratios Calculated from Aggregated State Dataset PFAS Samples for PFOA, PFOS, and Hazard Index PFAS

Chem A	Chem B	Chems A and B Reported	Only Chem B Reported	Only Chem A Reported	Neither Chem Reported	Odds Ratio [95% CI]
HFPO-DA	PFBS	10	560	7	3,143	8.0 [3.1-20.5]
HFPO-DA	PFHxS	3	371	14	3,333	1.9 [0.6-6.3]
HFPO-DA	PFNA	0	26	17	3,679	0.0 [0.0-32.6]
HFPO-DA	PFOA	12	417	5	3,286	18.9 [6.9-51.8]
HFPO-DA	PFOS	13	464	4	3,239	22.7 [7.7-66.4]
PFBS	PFHxS	259	115	311	3,034	22.0 [17.1-28.2]
PFBS	PFNA	19	7	551	3,143	15.5 [6.6-36.1]
PFBS	PFOA	290	139	280	3,011	22.4 [17.7-28.4]
PFBS	PFOS	327	150	243	2,999	26.9 [21.3-34.0]
PFHxS	PFNA	17	9	357	3,338	17.7 [8.0-39.2]
PFHxS	PFOA	204	225	170	3,120	16.6 [13.0-21.2]
PFHxS	PFOS	273	204	101	3,142	41.6 [31.8-54.5]
PFNA	PFOA	22	407	4	3,287	44.4 [15.9-123.9]
PFNA	PFOS	20	457	6	3,237	23.6 [9.7-57.4]
PFOA	PFOS	306	171	123	3,119	45.4 [35.0-58.9]

Notes:

[1] The preliminary UCMR 5 dataset contains approximately 24 percent of the samples anticipated to be available once the dataset is complete.

Except for two chemical pairings with HFPO–DA, each pairwise odds ratio estimate between PFAS is statistically significantly greater than one. As previously described, this indicates an increased likelihood of reporting one chemical given that the other chemical is known to be present. HFPO–DA odds ratios with PFBS, PFOS, and PFOA were also statistically significantly above 1. Given that the UCMR 5 dataset is not complete, it is important to note that, for chemical pairs where very few systems have fallen into one or more of the categories of chemical pairings, subsequent sampling may result in substantial shifts in the odds ratio estimate and the associated CI. For example, if one more system reported both HFPO–DA and PFHxS, the odds ratio estimate would increase by 33 percent. On the other hand, if one more system detected both PFOA and PFOS, the odds ratio estimate would shift by less than 1 percent. As the count of systems in each category increases, the odds ratio estimate becomes more stable with subsequent sampling. This may be particularly relevant for relationships with HFPO–DA and other Hazard Index PFAS, given the relatively low number of systems (17 systems) that reported HFPO–DA at or above the minimum reporting level in the preliminary UCMR 5 dataset as of February 2024.

After the release of approximately 24 percent of the data that will be available in the full UCMR 5 dataset, there appears to be considerable PFAS occurrence and co-occurrence demonstrated (USEPA, 2024n). Over 15 percent of systems with appropriate data described above have observed a sample-level exceedance of any of the MCLs while over 9 percent of systems have had an EP with a mean concentration exceeding an MCL. Approximately 75 percent of systems that reported the presence of PFOA or PFOS also observed at least one Hazard Index contaminant. Over half of these systems reported the presence of multiple Hazard Index contaminants. The national PFAS occurrence model estimated between about 6.2 percent and 10.1 percent of all CWS and NTNCWS would have an exceedance of an MCL. The 9.4 percent of UCMR 5 systems that had an EP mean concentration over an MCL is not a direct comparison to this because not all EPs have sampled a year worth of quarterly data and because large systems make up a larger fraction of UCMR systems than systems in the national inventory (the model estimated generally higher concentrations at larger systems). However, separating these UCMR 5 results by system size and weighting according to system counts in the national inventory of systems would result in an estimation of 7.8 percent of all systems having an EP with a mean concentration exceeding an MCL threshold. These estimates are likely to shift as UCMR 5 sampling continues and system sampling regimes are completed.

VII. Analytical Methods

A. Analytical Methods and Practical Quantitation Levels (PQLs) for Regulated PFAS

1. Proposal

The agency proposed two EPA methods to support the monitoring requirements of this regulation. The EPA developed the two liquid chromatography/tandem mass spectrometry (LC/MS/MS) analytical methods to quantitatively monitor drinking water for targeted PFAS: EPA Method 533 (USEPA, 2019b) and EPA Method 537.1, Version 2.0 (USEPA, 2020c). The agency found that all six PFAS proposed for regulation can be measured by both EPA Methods 533 and 537.1, ver. 2.0 and both methods are acceptable for meeting the monitoring requirements of this regulation.

Additionally, the EPA proposed PQLs for the six PFAS proposed for regulation, as outlined in Table 22.

Table 22: PQLs for Regulated PFAS

Contaminant	PQL (ng/L)
PFOA	4.0
PFOS	4.0
HFPO-DA	5.0
PFHxS	3.0
PFNA	4.0
PFBS	3.0

In the proposed rule preamble (USEPA, 2023f), the EPA discussed laboratory performance in the EPA's Unregulated Contaminant Monitoring Rule (UCMR) 5 Laboratory Approval Program (LAP) and found that the UCMR 5 minimum reporting levels are appropriate as the basis for the practical quantitation level (PQL) in this rule. These quantitation levels account for the measurement precision and accuracy that the EPA estimates can be achieved across laboratories nationwide.

2. Summary of Major Public Comments and EPA Responses

Several commenters note analytical differences between EPA Methods 533 and 537.1 such as differences in the quality control (QC) acceptance levels between the methods, sample preservation and holding times, as well as variability in sample and spike duplicates. In some instances, these commenters request specific modification to the methods, revisions to the EPA laboratory certification manual, or for the agency to develop guidance that laboratories and state accreditation/certification bodies could use. These commenters note that while both methods are valid under the proposed rule, variability between the two may lead to differences in sampling results and may impact a water system's compliance status. The EPA agrees that Methods 533 and 537.1 have some differences that allow for analysis of varying chain lengths and molecular structures of PFAS. Method 533 generally captures ''short chain'' PFAS (*i.e.,* those with carbon chain lengths of 4 to 12) and fluorotelomer sulfonic acids. Method 537.1 includes some overlap with Method 533's analyte list while including some longer-chain PFAS. However, the agency notes that

all six PFAS proposed for regulation can be analyzed by either Method 533 or 537.1 and neither method has inherent QC issues that lead to significant variation in sampling results when followed. While there are differences between the methods and how they measure their respective target analytes, both EPA Methods 533 and 537.1 perform comparably. The methods are clear and outline specific instructions regarding requirements that are needed for compliance monitoring measurements.

Some public commenters suggested that the EPA allow alternate analytical procedures or modifications to the two published EPA methods for meeting the monitoring requirements in the final rule. The EPA continues to specify the use of Methods 533 and 537.1 because consistent, reliable compliance data are necessary for implementation of the regulation at the maximum contaminant level (MCL) However, the EPA recognizes that improvements in analytical technology and methodology occur. The EPA's Drinking Water Alternate Test Procedure (ATP) Program provides a mechanism for submission and review of alternative methods to measure a contaminant for nationwide use under 40 CFR 141.27. A method developer may apply for the EPA review of a method modification or a new method through the ATP Program. In the meantime, the agency has concluded that Methods 533 and 537.1 are reliable for use in compliance monitoring with respect to accuracy and recovery (lack of bias) and precision (good reproducibility) at the MCL levels.

Several commenters requested that all laboratories be required to identify their quantitation limits (*i.e.,* the smallest detectable concentration of an analyte greater than the detection limit where the accuracy (precision and bias) achieves the objectives of the intended purpose) and/or method detection limits (*i.e.,* the minimum result which can be reliably discriminated from a blank). Specifically, some commenters note if labs have to demonstrate they can get below the PQL, the EPA should establish reporting or detection limits demonstrating they can get to these levels. The EPA is finalizing rule trigger levels below the PQL to support the monitoring provisions discussed in section VIII of this preamble. The EPA disagrees with these commenters that such reporting is needed to support compliance monitoring for the rule and that such reporting would be a cost burden on laboratories. All labs are required per the approved methods to demonstrate whether laboratory reagent blank (LRB) QC samples have background concentrations of less than one-third the minimum reporting level (*i.e.,* the minimum concentration that can be reported as a quantitated value for a method analyte in a sample following analysis). Therefore, for a laboratory to be compliant with the methods, they must be able to detect, not necessarily quantify, analytes at or above ⅓ the minimum reporting level.

Some commenters sought clarity on which methods are approved for use in compliance monitoring for the final PFAS National Primary Drinking Water Regulation (NPDWR). Some of these commenters requested that only Method 533 be approved for monitoring under the final NPDWR, noting that it may be more suitable should additional PFAS analytes within its scope be targeted for regulation at the future date. Others requested that they be permitted to use Method 537, version 1.1. The EPA disagrees and reaffirms that Methods 537.1, version 2.0 and Method 533 are both applicable and suitable for use in compliance monitoring in the final rule. The EPA notes that HFPO–DA is one of the PFAS regulated under this action and only Method 537.1, version 1.0 and version 2.0, and Method 533 support the collection of data for HFPO–DA. The agency notes that the primary difference between Method 537.1, version 1.0 and Method 537.1, version 2.0 is the field reagent blank (FRB) preparation: version 2.0 exposes the FRB to the preservative (Trizma) at the time of field sample collection. Version 1.0 combines the lab reagent water and the preservative together in the FRB prior to field sampling. Version 2.0 was created to more-closely mimic the FRB process used in Method 533. Additionally, Version 2.0 explicitly states that the solid phase extraction (SPE) cartridge sorbents may not be modified with monomers other than styrene divinylbenzene (SDVB).

A few commenters critiqued how the proposed PQLs were established for the rule. Some of these commenters provided feedback on the feasibility of the proposed PQL and suggested that it may be too low, resulting in recurring QC failures that will necessitate repeat sample analysis, increased cost, and reduced laboratory capacity. Other commenters suggest that lower PQLs can be attainable by larger labs with advanced analytical instruments. The agency disagrees that PQLs should be established at either a higher or lower level than that proposed. As discussed in the proposed rule preamble, the PQLs are based on a multi-laboratory assessment of analytical capacity. The EPA derives PQLs which reflect the level that can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions. Based on the multi-laboratory data acquired for the UCMR 5 rule, the EPA has defined the PQL for the PFAS regulated in this rule (Table 22). This quantitation level considers the precision and accuracy that the EPA estimates can be achieved across laboratories nationwide. The EPA anticipates that over time, as technology advances and as laboratories gain experience with the PFAS Methods, laboratories will generally improve their capability to measure at lower levels.

3. Final Rule

The EPA is establishing the following approved methods for use in compliance monitoring in the final PFAS NPDWR: EPA Method 533 (USEPA, 2019b) and EPA Method 537.1, Version 2.0 (USEPA, 2009b; USEPA, 2020c). The PFAS addressed by this regulation can be measured by both EPA Methods 533 and 537.1 and either method is acceptable for meeting the monitoring requirements of this regulation. Table 1 to paragraph (f)(1)(iv) of § 141.903 of subpart Z lists the PQLs for the PFAS regulated under this action.

VIII. Monitoring and Compliance Requirements

A. What are the Monitoring Requirements?

1. Proposal

The EPA proposed requirements for community water systems (CWS) and non-transient non-community water systems (NTNCWSs) to monitor for six PFAS. The agency proposed to amend 40 CFR part 141 by adding a new subpart to incorporate the regulated PFAS discussed in this preamble. Under this new subpart, public water systems (PWSs) would be required to sample EP using a monitoring regime based on the EPA's Standard Monitoring Framework (SMF) for Synthetic Organic Contaminants (SOCs).

The EPA proposed the following requirements for initial monitoring, which systems would be required to complete by the date three years after the date of rule promulgation (see section VIII.F of this preamble for more information). The EPA proposed that, consistent with the SMF for SOCs, groundwater systems serving greater than 10,000 persons and all surface water systems would be initially required to monitor quarterly within a 12-month period for regulated PFAS. To provide additional flexibilities for small groundwater systems, the EPA proposed to modify the SMF for SOCs such that

groundwater systems serving 10,000 or fewer persons would be initially required to monitor only twice for regulated PFAS within a 12-month period, each sample at least 90 days apart. In the proposal, all systems would be allowed to use previously acquired monitoring data to satisfy the initial monitoring requirements (see section VIII.C of this preamble for additional details about using previously acquired monitoring data to satisfy initial monitoring requirements). Based on the SMF, the EPA also proposed that primacy agencies be able to use initial monitoring results to reduce compliance monitoring frequency for a system to once or twice every three years (depending on system size) if the monitoring results are below the proposed rule trigger level (defined in the following paragraphs).

The EPA proposed that, after initial monitoring, water systems would conduct compliance monitoring to demonstrate that finished drinking water does not exceed the maximum contaminant levels (MCLs) for regulated PFAS. The EPA proposed that systems with multiple EP may establish different compliance monitoring schedules for those EP depending on their monitoring results.

The EPA proposed to base compliance monitoring requirements on initial monitoring results and on system size. Then subsequent monitoring requirements would be based on results from compliance monitoring and, for systems on triennial monitoring, also on system size. To determine compliance monitoring frequency only, the EPA proposed a rule trigger level of one-third the MCLs (1.3 ng/L for PFOA and PFOS and 0.33 for Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS)). If results for an EP are below the trigger level, systems would be eligible for reduced monitoring. To implement this provision, the EPA proposed to include the ''trigger level'' concept in the new subpart.

As proposed, each water system would be eligible for reduced compliance monitoring at each EP for which all PFAS results are below the rule trigger level, according to the following schedule:

- A water system that serves 3,300 or fewer customers would be required to analyze one sample for all regulated PFAS per three-year compliance period at each EP where the water system does not have results for any regulated PFAS at or above the rule trigger level (1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS)),
- A water system that serves more than 3,300 persons would be required to analyze two samples for all regulated PFAS at least 90 days apart in one calendar year per three-year compliance period at each EP where the water system does not have results for any regulated PFAS at or above the rule trigger level (1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS).

In the proposal, if any result for an EP is at or above the rule trigger level for regulated PFAS, the water system would be required to monitor at that EP for all regulated PFAS quarterly. For compliance monitoring collection schedules, the EPA did not specify the required number of days between sampling events and only required collection during a quarter. Systems monitoring an EP less frequently than quarterly whose sample result is at or above the rule trigger level would also be required to begin quarterly sampling at the EP where regulated PFAS were observed at or above the trigger level. In either case, the primacy agency would be able to allow a system to move an individual EP to a reduced monitoring frequency when the primacy agency determines that the EP is below the rule trigger level and reliably and consistently below the MCL. However, primacy agencies would not be permitted to determine that the EP is below the rule trigger level and reliably and consistently below the MCL until at least four consecutive quarters of quarterly compliance monitoring have occurred with all sample results below the rule trigger level.

Additionally, related to laboratory capacity considerations, the EPA described in the proposal that it anticipates that laboratories will be able to adjust to demand and that the demand will be distributed across the three-year implementation period.

2. Summary of Major Public Comments and EPA Responses

The following discussion details numerous comments the EPA received on the proposed monitoring requirements, both for initial monitoring and long-term compliance monitoring.

The majority of comments the EPA received on the initial monitoring requirements related to the number of initial samples systems would be required to collect and the intervals between required samples. Most commenters were generally supportive of the EPA's proposed initial monitoring requirements, including the flexibilities to use previously acquired monitoring data to satisfy some or all the initial monitoring requirements and, for those groundwater systems serving 10,000 or fewer that do not have this data, that they be required to only collect two samples at each EP to satisfy initial monitoring requirements. For a discussion of comments and final rule requirements specific to the use of previously acquired monitoring data to satisfy the initial monitoring requirements see section VIII.C of this preamble.

While most commenters were supportive of the number of initial monitoring samples the EPA proposed, a few commenters indicated they thought the EPA should not allow the flexibility for groundwater systems serving 10,000 or fewer to collect only two samples and instead require quarterly samples be collected by all systems to meet initial monitoring requirements, which would be fully consistent with the SMF framework for other SOCs. A couple of these commenters suggested that there are no data demonstrating that smaller systems are less likely to have elevated levels of PFAS than large systems or that groundwater systems are less likely to have elevated levels of PFAS than surface water systems. Additionally, other commenters generally suggested that two samples may not generate enough data to accurately capture the level of PFAS in drinking water and any potential seasonal variability. Related to potential seasonal changes in measured PFAS concentrations, some commenters from state agencies indicated that they have not observed seasonal variations in concentrations of PFAS measured by groundwater systems, whereas other commenters suggested the opposite and that they have seen changes seasonally based on their state's monitoring data.

The EPA disagrees with commenters that suggest two samples for small groundwater systems would not accurately capture the baseline level of regulated PFAS in drinking water. The EPA determined the initial monitoring requirements based on both source water type and system size considerations. First, from a national-level perspective, the EPA's model for estimating national PFAS drinking water occurrence (see section VI.E of this preamble) indicates that, regardless of source water type, small systems generally have lower mean PFAS concentrations and lower within-system variability than large systems. Further accounting for source water type, as compared to all groundwater systems, all surface water systems potentially have a larger number of sources of contamination and greater hydrology variability so more monitoring data is

necessary to ensure an appropriately protective monitoring schedule. Both the differences in the occurrence estimations for large and small sized systems as well as the general source water characteristics of groundwater systems were collectively considered as part of establishing the proposed initial monitoring requirements for small groundwater systems. Consequently, the agency expects that small groundwater systems would be less likely to experience variations throughout a year and, where there may be seasonal variations, requiring the samples to be collected in different parts of a year would provide sufficient information to determine the appropriate compliance monitoring schedule. Furthermore, given the different experiences cited by commenters, possible seasonal variation is likely based on the specific geographic location and other localized factors. If there are regional factors that suggest more frequent sampling is warranted, the rule provides that primacy agencies may increase the required monitoring frequency, where necessary, to detect variations within the system (*e.g.,* fluctuations in concentrations due to seasonal use or changes in water source).

In response to comments about the alignment of Unregulated Contaminant Monitoring Rule (UCMR) 5 sampling with initial monitoring requirements, a couple of commenters indicated that requiring larger groundwater systems to collect four samples would translate into these systems needing to collect two additional samples beyond those collected for the UCMR 5 monitoring effort. The EPA acknowledges that while the initial monitoring requirements generally align with the UCMR 5 sampling requirements, groundwater systems serving greater than 10,000 would need to collect two additional samples and notes that they have the three years following rule promulgation to complete this monitoring. As described previously, the model for estimating national PFAS drinking water occurrence indicates that larger systems have greater within-system variability than smaller systems, therefore it is appropriate that these larger groundwater systems collect four initial monitoring samples; this is consistent with initial monitoring requirements for groundwater systems under existing SOC National Primary Drinking Water Regulations (NPDWRs).

In addition, a couple of commenters recommended that the number of required samples for initial monitoring be based on the results of the first two samples, with subsequent monitoring only required if regulated PFAS are detected in those earlier samples. The EPA recognizes there is some logic to this approach; however, there would be challenges implementing it. Specifically, it could be challenging for primacy agencies to track and implement the proposed approach, particularly for groundwater systems serving 10,000 or fewer which would require the additional samples to occur in quarters not represented by the first two samples. Furthermore, tracking this varying monitoring would result in additional administrative burden and oversight challenges for primacy agencies, rather than having a consistently defined schedule for monitoring requirements as is used for other SOCs.

The EPA also received several comments from state agencies about the required intervals associated with initial quarterly and semiannual sample collection. In its proposal, the EPA specified that samples be collected at least 90 days apart, whether the samples were required of a system monitoring on a quarterly basis or a system monitoring semi-annually. A couple of commenters noted that they believed that semiannual samples should be separated by more than 90 days to better capture seasonal variations (*e.g.,* seasonal changes in the percent contributions of water blended from different sources, other fluctuations in concentrations). One commenter suggested semiannual samples should be collected at least 180 days apart, which would also be in better alignment with the required schedule for UCMR 5 semiannual sampling. The EPA agrees with these comments. In the final rule, the EPA is requiring that the samples be collected 5 to 7 months apart for semiannual initial monitoring (see table 2 to paragraph (a)(4)(i)(B) of the regulations governing the UCMR program in 40 CFR 141.40).

With respect to the sample collection timing requirements for quarterly initial monitoring (for all surface water systems and groundwater systems serving greater than 10,000), a few commenters indicated that they were opposed to the proposed requirement for samples to be spaced at least 90 days apart. These commenters indicated that such a requirement was unnecessarily prescriptive and would make sample collection logistically challenging for public water systems. These commenters suggested the EPA change the required spacing in a way that still satisfies the EPA's intent to not have samples collected only a few days apart, but in different quarters, so that quarterly samples are more representative of fluctuations in concentrations over time. The EPA agrees with these comments and sees the value of systems being able to use four existing samples collected in separate quarters but also allow flexibility that they are not all spaced at least 90 days apart. In the final rule, the EPA is modifying the required spacing of quarterly initial monitoring samples to be 2 to 4 months apart if samples are collected in a 12-month period. For systems that would need to supplement previously acquired data to satisfy all the initial monitoring requirements, the final rule requires that they must also be 2 to 4 months apart from the months of available pre-existing data. This will also better parallel the language outlining the required spacing of quarterly samples collected for the UCMR 5 monitoring effort.

Some commenters asked the EPA to clarify which systems would be subject to the initial monitoring requirements for surface water systems and which systems would be subject to the requirements for groundwater systems, in some cases presenting examples of specific scenarios. One example is when a system relies on surface water at some EP and groundwater at other EP. The EPA has modified the language of the final rule in § 141.902(b)(1)(ii) to clarify that initial monitoring requirements are to be determined based on the type(s) of water serving as the source for a given EP; thus, one system may have different initial monitoring requirements that apply to different EP. In response to questions, the EPA is clarifying in § 141.902(b)(1)(iv) that, if an EP uses water blended from multiple sources (some groundwater and some surface water), or if it uses different types of sources throughout the year, the system must follow the monitoring frequency for a surface water system (since water from surface water sources is used at least in part, for at least a portion of the year). This approach is more protective of public health because, as described earlier, generally surface water systems have more variable hydrology and potentially more sources of contamination so more monitoring data is necessary to ensure an appropriately protective monitoring schedule.

A couple of commenters asked for clarification about whether EP supplying groundwater under the direct influence of surface water (GWUDI) would qualify for semiannual initial monitoring. As noted in § 141.902(b)(1)(iii), GWUDI systems follow the requirements for surface water systems. GWUDI systems may be as susceptible to contamination as surface water systems; thus, these systems must use the sampling

requirements for surface water during the initial sampling phase to establish baseline levels of regulated PFAS.

Regarding the requirements for longer-term compliance monitoring, the comments the EPA received related primarily to the frequency with which sampling would occur under different circumstances, whether each EP would be allowed to be on a different compliance monitoring schedule, and the trigger levels that would support decisions about reduced triennial monitoring. Regarding the latter point, commenters also addressed laboratory capabilities to measure levels below practical quantitation levels (PQLs).

The EPA's proposal would allow systems eligible for reduced monitoring, and serving 3,300 or fewer, to collect one sample triennially and would allow eligible larger systems to collect two samples during a three-year compliance period. The EPA specifically requested comment on whether all water systems, regardless of system size, should be allowed to collect and analyze one sample per three-year compliance period if the system does not measure any regulated PFAS in their system at or above the rule trigger level. A few commenters stated that they did not agree with a different number of triennial samples eligible systems must collect based on the size of the population a system serves. These commenters indicated that they believe that one sample collected every three years is sufficient for systems of any size on reduced monitoring. The EPA agrees with these commenters that systems eligible for triennial monitoring should be allowed to collect one sample every three years, regardless of system size, especially considering other changes to the compliance monitoring framework, as described subsequently.

Several commenters recommended that an annual sampling frequency tier be added to the required monitoring framework for various reasons including the mobility and persistence of PFAS in the environment, to ensure that systems that have demonstrated elevated levels of regulated PFAS are not allowed to move directly from quarterly to triennial monitoring, and based on their concerns that some laboratories may not be able to produce results at or below the rule trigger levels (resulting in some systems remaining on quarterly monitoring indefinitely even if they can consistently demonstrate they are below the MCLs). A few commenters supported offering three possible monitoring frequencies: quarterly, annually, and triennially, whereas many other commenters recommended against allowing triennial sampling at all and recommended that sampling be required no less than annually, to best protect public health. Those commenters supportive of allowing both annual and triennial monitoring, depending on prior sample results, suggested that annual monitoring should be an option for systems with regulated PFAS concentrations that are reliably and consistently below the MCLs. This modification would parallel the three tiers of monitoring allowed for other organic chemicals under the SMF.

The EPA does not agree with the comments suggesting that no systems should be allowed to sample triennially and that the longest sampling interval at any location should be one year. Based on the EPA's national occurrence estimates, most water systems subject to the rule's requirements will not have results for regulated PFAS that exceed the MCLs, and many will not identify PFAS at or above the triggers for reduced monitoring. These systems, after demonstrating results below the trigger level and therefore no or very little presence of regulated PFAS during the initial monitoring period or through ongoing compliance monitoring, should be able to reduce their monitoring burden and conduct triennial sampling. These monitoring requirements will sufficiently maintain public health protection. If a system monitoring triennially did have a sample result with elevated levels of a regulated PFAS (at or above the trigger level), it would be required to immediately initiate quarterly monitoring. Additionally, the rule specifically provides that primacy agencies may increase the required monitoring frequency for compliance sampling for a variety of reasons, including to detect variations within specific systems (*e.g.,* fluctuations in concentrations due to seasonal use patterns or changes in water sources).

For any system that has regulated PFAS concentrations at or above the trigger level, but reliably and consistently below the applicable MCL, the EPA is introducing in the final rule an annual monitoring frequency within the compliance monitoring framework, consistent with the SMF for SOCs. A demonstration of reliably and consistently below the MCL would include consideration of at least four quarterly samples below the MCL. Annual samples would be collected during the quarter with the highest concentration measured during the prior round of quarterly sampling. The EPA expects this modification in the final rule to reduce the number of systems that are required to be on quarterly monitoring for extended periods of time, compared to the EPA's proposal.

In adopting a three-tiered monitoring framework, the EPA is modifying the required sampling frequency from triennial to annual for systems determined by states to be reliably and consistently below the MCL and changing the threshold for this determination from the trigger level to the MCL. To further reduce monitoring, any system that transitions into annual sampling will be required to collect three years of annual samples each of which show concentrations of regulated PFAS below trigger levels (*i.e.,* not an average of the three annual sample results) before then being eligible for triennial monitoring. Moreover, no system required to collect quarterly samples during compliance monitoring would be allowed to transition to triennial monitoring without first conducting three years of annual monitoring, with all results below the trigger level. If eligible for triennial monitoring, the sample collected triennially would need to be collected in the same quarter during which prior results were highest.

This additional tier is intended to create a gradual step-down schedule for affected EP to confirm levels of regulated PFAS are remaining consistently low or decreasing. The modifications to the requirements for a reliable and consistent determination and the creation of the new annual sampling tier in the final rule make the requirements for regulated PFAS more consistent with the NPDWR requirements for SOCs. They also represent flexibilities that address concerns about laboratory capability concerns. The EPA believes this three-tier approach, including the eligibility criteria for each outlined above, provides the best approach to protect public health and moderate the total cost of sampling borne by a system.

The EPA also received a few comments about the practice by systems that have installed treatment for PFAS to regularly sample finished water to ensure the efficacy of their treatment media (*e.g.,* filters), above and beyond what they would do for compliance monitoring. A few commenters suggested systems that have installed treatment would conduct this additional sampling voluntarily, typically for process control purposes. A few state agency commenters suggested that any system that is treating its water for PFAS should be required to sample more frequently than triennially (*e.g.,* annually) no matter the levels of previous PFAS detections, since the effectiveness of treatment media may decline over time, if not replaced. The EPA disagrees with the commenters

recommending a greater sampling frequency for systems that treat their water for PFAS and does not see a compelling reason to depart from the three-tier compliance monitoring program for a system that has installed treatment. In the final rule, the EPA is adding an annual tier of sampling for any system with concentrations reliably and consistently below the MCL but not consistently below the trigger level. The EPA believes this tier will likely apply to most systems treating their water for regulated PFAS, at least for the first three years of treatment, as the EPA estimates as part of its rule costs that systems needing to install treatment will assume a treatment target of 80 percent of the MCLs. The majority of systems with elevated levels of regulated PFAS contamination are likely to sample quarterly, at least initially (unless they have treatment for PFAS in place prior to the collection of initial monitoring samples). In practice, the result is that most systems with PFAS contamination will likely not be eligible for triennial sampling unless their PFAS treatment is consistently optimized and maintained. However, the rule provides that primacy agencies may increase the required monitoring frequency, where necessary to detect variations within the system, and this approach could be applied to those systems that have installed treatment. In addition, the EPA notes that, when systems are treating for other regulated chemicals pursuant to NPDWRs, no distinctions are made between the monitoring frequency required of a system that is treating for a chemical and a system that has not installed treatment. Thus, not establishing a different monitoring frequency specifically for systems that are treating their water for PFAS is consistent with existing NPDWRs.

The EPA requested comment on the proposed allowance of a water system to potentially have each EP on a different compliance monitoring schedule based on specific EP sampling results (*i.e.,* some EP being sampled quarterly and other EP sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of a system's sampling points. A few commenters recommended that all EP used by a system monitor at the same frequency, or that doing so be optional, to reduce the complexity of monitoring requirements or the potential for mistakes to be made with respect to sampling windows. However, the overwhelming majority of those who commented on this topic indicated they supported allowing different sampling frequencies for different EP. The EPA agrees that it would be beneficial to allow different sampling frequencies for different EP because it would allow utilities to realize cost savings if only the EP with elevated levels of PFAS are required to sample most frequently. In addition, the EPA notes it allows systems to use different sampling frequencies for different EP for compliance with other NPDWRs.

The EPA requested comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection, including setting a rule trigger level at different values than the proposed values of 1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS). Alternative values of 2.0 ng/L for PFOA and PFOS and 0.50 for the Hazard Index PFAS were identified as possibilities. The EPA received numerous comments on the proposed rule trigger levels. Comments addressed the proposed values, specifically for PFOA and PFOS, and their intended purpose for determination of compliance monitoring frequency. Several commenters suggested that the proposed values (*i.e.,* 1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index) are too high and the EPA should instead set lower trigger level to ensure greater public health protection. Many other commenters suggested the opposite, stating that the proposed levels are too low, that laboratories will not be able to achieve these levels, and that it may exacerbate any laboratory capacity issues. Consequently, some of these commenters were concerned that water systems would be ineligible for reduced monitoring based on their laboratory's analytical limitations. Several commenters suggested that the proposed values are inconsistent with the SMF for SOCs.

Many who commented on the subject were fully supportive of the EPA's proposed alternative trigger level values of 2.0 ng/L for PFOA and PFOS and 0.50 for the Hazard Index, while others expressed support for the inclusion of trigger levels only if these higher levels were incorporated. Some noted that these higher trigger levels would better align with current laboratory capabilities and allow greater use of previously collected drinking water data (to demonstrate systems are eligible for reduced triennial monitoring under the rule's initial monitoring requirements). A few commenters recommended alternative values of 70–80 percent of the MCLs be used as the trigger levels.

The EPA agrees with commenters that the trigger levels should be finalized as one-half of the MCLs (*i.e.,* PFOA and PFOS at 2.0 ng/L each, PFHxS, PFNA, and HFPO–DA at 5 ng/L each, and Hazard Index at 0.5). Using data submitted as part of the UCMR 5 LAP as a reference point, the EPA notes that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a minimum reporting level confirmation at 2 ng/L (one-half the proposed MCL) or less for Method 533. This suggests that most laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide screening measurement results at the revised trigger level of one-half of the MCL. This corresponds with other comments described in section VIII.C of this preamble that provided their experience that laboratories are capable of reliably quantifying values below the PQLs, particularly to 2.0 ng/L for PFOA and PFOS.

Additionally, based on the EPA's evaluation of state drinking water data, updating the final rule trigger levels (to one-half of the MCL) will result in a considerable number of additional water systems significantly reducing their ongoing monitoring frequency from quarterly or annual monitoring to triennial monitoring. Although this modification from one-third of the MCL to one-half of the MCLs may provide slightly less information on a water system's measured PFAS levels as a result of their less frequent monitoring, the trigger levels for the final rule (*i.e.,* one-half of the MCLs) will ensure sufficient public health protection while reducing burden for water systems.

Many other commenters stated that either trigger levels should be removed from the rule entirely or that trigger levels should not be set to any levels below PQLs since these represent the level that can be reliably measured with a high degree of precision and accuracy across all laboratories. Several of these commenters suggested that data below the PQL are unreliable, would result in higher costs, and should not be used as the basis for any regulatory decisions. Thus, they suggested that if trigger levels are incorporated, they should be the same as the PQLs. These commenters also cited laboratory challenges in achieving measurement below the PQLs and suggested that water systems would not be eligible for reduced triennial monitoring as a result of these limitations. Additionally, some of these commenters suggested that decision making based on any values below the PQLs may exacerbate laboratory capacity issues, claiming that such trigger levels would result in

errors, such as false positives, which would lead to increased monitoring where samples need to be re-tested.

The EPA emphasizes that the use of trigger levels set at values below the MCLs is consistent with other SOCs under the SMF and not novel for drinking water regulations (as described in the subsequent paragraph). Their use allows water systems the opportunity to reduce their monitoring schedule and burden where it can be demonstrated through sampling results that they are at low risk of PFAS contamination. In the absence of trigger levels, or some other threshold, all water systems would be deprived of the opportunity for reduced monitoring. At a national level, were the EPA to eliminate reduced monitoring options, this would result in a significant increase in costs to utilities. Consequently, the EPA is choosing to incorporate these levels to allow flexibility and reduce burden for water systems while maintaining health protection.

For commenters that suggest the trigger levels should be identical to the PQLs, particularly for PFOA and PFOS, the EPA disagrees as the agency must have greater assurance that the levels are below the regulatory standard, the systems are actually lower risk, and a reduced monitoring schedule is appropriate. Specifically, in the case of PFOA and PFOS, the EPA believes it would represent an unacceptable public health risk to set trigger levels at the PQLs because the EPA is setting the MCL at the PQL which means that it represents the ''maximum permissible level.'' Moreover, the approach of considering measured levels lower than PQLs for determining monitoring frequency is not novel but has been part of the drinking water standards for many years. Many drinking water standards even use a method detection limit, which by definition is lower than the PQL. Under the SMF for SOCs, for example, results both at or below detection limits and between detection limits and the MCL are utilized for monitoring frequency determination. Additionally, 40 CFR 141.24(h)(7) prescribes the monitoring frequency for organic contaminants based on sample results relative to detection limits (as defined in in paragraph (h)(18) of the same section). In each of these cases, detection limits are below their PQLs (often by a factor of 10). The approach in this rule—using levels lower than the PQL to determine monitoring frequency—is consistent with the EPA's approach for other NPDWRs (see section V of this preamble).

As described earlier, some commenters raised concerns about potential laboratory analytical and capacity issues. Some suggested that laboratories cannot achieve levels below the PQLs, which would result in water systems not being eligible for reduced monitoring based on not demonstrating results below trigger levels. The EPA recognizes that some laboratories may not be able to produce results at these lower levels with the same degree of accuracy and precision as results at or above the PQLs, and notes that there is not a requirement that they do so for these purposes. The EPA uses the PQL to inform the MCL feasibility determination and the same level of precision and accuracy is not required to determine monitoring frequency. Along these lines, several commenters questioned if the sample results must be quantified to be used for the determination of monitoring frequency, given the proposed trigger level values were set below the PQLs, requesting further clarity from the EPA on how to interpret and utilize quantified and non-quantified data. Furthermore, some commenters suggested that if values below the PQLs are used, only quantified results should be used for determining monitoring frequency. Other commenters stated there should not be a numerical value associated with results below the PQL (*e.g.,* results between the trigger levels and the PQLs) and instead such results should only be reported on an absence/presence basis.

The EPA agrees that results below the PQL may not have the same precision and accuracy as higher-level measurements; however, results below the PQL can be sufficiently determined for these purposes. Data below the PQL will be critical to ensuring that systems are monitoring at the correct frequency and whether a contaminant is present within a certain range. Moreover, while results near the trigger level may be less definitive than results at or above the PQL, such results are appropriate for establishing monitoring frequency, as well as for reporting as part of the annual Consumer Confidence Report (CCR). CCR reporting is based on *detected* contaminants and for the purposes of the PFAS NPDWR, § 141.151(d) defines ''detections'' as results at or above the rule trigger levels (see section IX of this preamble for more information on CCR requirements).

Under this final rule, for monitoring frequency determination purposes, systems are required to use all compliance sample results, including those below the PQLs and not quantified with the same precision and accuracy as is associated with the MCL compliance calculation determination. Additionally, the determination of monitoring frequency is not based on a running annual average result, but each individual sampling result. As an illustration of the approach, if a water system has quarterly sampling results at an EP from initial monitoring for PFOA that are 2.0, 1.5, 5.0, and 1.5 ng/L, there are two results (*i.e.,* 2.0 and 5.0 ng/L) at or above the EPA's final trigger level for PFOA (*i.e.,* 2.0 ng/L). Thus, the water system would not be eligible for triennial monitoring at this EP for all regulated PFAS when compliance monitoring begins. Providing a different example, if a water system that is currently required to conduct quarterly compliance monitoring has quarterly sampling results at an EP for PFOA that are 2.0, 3.5, 2.5, and 1.5 ng/L, all results are below the MCL for PFOA (*i.e.,* 4.0 ng/L), however three results are above the PFOA trigger level. In this case, because four quarters of data have been collected and assuming all other regulated PFAS sampling results are below their MCLs as well, the water system could be deemed reliability and consistently below the MCL by the primacy agency and be eligible to monitor annually at this EP. For all frequencies of ongoing compliance monitoring, including quarterly, annual and triennial, this determination would be done the same where all sample results are used, even those below the PQLs.

Many commenters requested that the EPA provide clarification on how laboratories and PWSs should report levels below the PQLs for monitoring frequency purposes. All results at or above the trigger level are to be reported as numeric values and used for determining monitoring frequency. Under the EPA approved analytical methods discussed in section XII, numeric values as low as the rule trigger levels will be available because of the need to meet ongoing QC requirements of the methods for blanks, demonstrating no background contamination. Within each analytical batch of samples, the laboratory must document passing blank QC criteria by attaining qualitative measurements of the regulated PFAS that are no higher than one-third of the laboratories reporting limit, which must be at or below the PQL. The EPA intends to provide guidance materials with details and examples on this to support successful implementation of the final rule.

Some commenters suggested the potential for confusion related to the differences in how results less than PQLs are used in monitoring frequency determination and the MCL compliance determination. Several commenters

suggested that there should be a consistent approach. Most commenters suggested that the approach should follow that of the MCL compliance determination, where zero is used in the calculation of annual averages when measured values are below PQLs. The EPA reiterates that the trigger levels are used for establishing appropriate monitoring frequency. For certain regulated PFAS, they are set at a defined threshold that shows if these PFAS are present or absent. The PQLs, which are used for the MCL compliance determination, are set at specific concentrations that laboratories nationwide can measure with high certainty. To alleviate possible confusion, the EPA intends to provide communication materials on these monitoring requirements to support successful implementation of the final rule. Nevertheless, the difference in approach (between data used for compliance monitoring determinations and data used to determine monitoring frequency) reflects the most appropriate application of the data for each of the intended purposes and assures that adequate monitoring is occurring in systems where the regulated PFAS have been shown to be present at the trigger level or higher. The EPA's rationale is described in detail in section VIII.B of this preamble.

Several other issues related to monitoring flexibilities were raised in public comments. One commenter asked, if one EP has a result for a single regulated PFAS at a concentration above the trigger level, but other regulated PFAS are below trigger levels, must the system initiate quarterly sampling for all regulated PFAS at the EP or are they only required to initiate quarterly sampling for PFAS observed at or above the trigger level. As described in the rule proposal, if a regulated PFAS is detected at or above a trigger level, the system must monitor quarterly at that sampling point for all regulated PFAS. This is appropriate as the same analytical methods are used for the analysis of all regulated PFAS (no extra analyses need to be performed to measure the other PFAS) and the regulated PFAS have been shown to significantly co-occur.

In addition, commenters questioned whether quarterly sampling would be triggered when a result is equal to but does not exceed the trigger level for systems monitoring triennially. One commenter pointed out that the language proposed for inclusion in § 141.905(b)(2) stated that systems monitoring triennially whose sample result is at or exceeds the trigger level must begin quarterly sampling, whereas § 141.902(b)(2)(ii) stated the trigger level must be exceeded before quarterly monitoring is required. The EPA is clarifying this point in the final rule to reflect the EPA's intent that quarterly sampling would be triggered when a result is at or above the trigger level as prescribed in § 141.905(b)(2). This same approach has been used in other NPDWRs (*e.g.,* for SOC trigger levels).

3. Final Rule

This final rule establishes initial monitoring requirements and reflects minor modifications to the proposed approach. Groundwater CWS and NTNCWS serving 10,000 or fewer must collect two (semiannual) samples in a consecutive 12-month period and must collect the samples 5 to 7 months apart, to better capture seasonal variation. Groundwater CWS and NTNCWS serving greater than 10,000 and all surface water CWS and NTNCWS must collect four (quarterly) samples 2 to 4 months apart in a consecutive 12-month period. The EPA is maintaining the provision described in the proposed rule that allows PWSs to use previously collected data to satisfy initial monitoring requirements; see § 141.902(b)(1)(vi). Systems that need to collect additional quarterly samples to meet the initial monitoring requirements may sample outside of a 12-month period, if all quarters are represented with sample months 2 to 4 months apart. This 2-to-4-month interval also aligns with UCMR 5 sampling requirements for surface water systems subject to this rule and better captures possible seasonal variability establishing a well-informed baseline. In addition, the EPA is modifying the proposed initial monitoring requirements to now specify that if the water source for the EP is surface water, a blend of surface water and groundwater, or GWUDI, the initial monitoring requirements for surface water source (4 quarterly samples) apply. If the EP source is only groundwater, initial semiannual monitoring is required.

The EPA is modifying the number of samples required for some systems with sampling locations eligible for triennial monitoring. Regardless of the population served, all systems with sampling locations eligible for triennial sampling will collect one sample every three years. The sample is to be collected during the quarter with the highest prior concentration identified in the most recent year when samples were collected.

In the final rule the EPA is establishing a third tier for monitoring frequencies and updating the proposed requirements for each tier. The new monitoring frequency tier provides for annual monitoring at sampling locations that have collected at least four consecutive quarterly samples following initial monitoring if the primacy agency determines the results at that EP are reliably and consistently below the MCL. In establishing this tier, the EPA is removing the proposed rule requirement for a state to determine that the running annual average (RAA) concentration is below the trigger levels to reach this reliably and consistently below the MCL determination. Instead, in the final rule, reliably and consistently below the MCL means that each of the sample results for the regulated PFAS are below the applicable MCLs. In this new annual monitoring tier, if EP receive the reliably and consistently below the MCL determination and remain below the MCLs in subsequent sampling, even if above a trigger level, they may continue on an annual monitoring schedule.

The criteria eligibility for triennial monitoring have been changed accordingly. EP with all results below the trigger levels during initial monitoring are eligible for triennial monitoring, as described in the proposed rule. But, under the final rule, if an EP is required to conduct quarterly sampling during the compliance monitoring period, then triennial monitoring is only available after the EP has three consecutive annual samples that each contain concentrations below the trigger level. For EP that consistently have results between the trigger levels and the MCLs, as described previously most would remain on annual monitoring, rather than quarterly monitoring, which provides a sufficient indication of contaminant level while reducing the total sampling costs.

With respect to whether different EP for a particular water system may be sampled at different compliance monitoring frequencies, based on specific EP sampling results, the final NPDWR affirms this flexibility, as proposed. In addition, there is no change to the language in the final rule discussing the timing for taking quarterly samples during the long-term compliance monitoring period. The EPA does not specify a required interval between samples; the requirement is quarterly.

The EPA is finalizing rule trigger levels for compliance monitoring frequency purposes only at one-half of the MCLs for regulated PFAS (*i.e.,* 2.0 ng/L for PFOA and PFOS, 5 ng/L for PFHxS, PFNA, and HFPO–DA, and 0.5 for Hazard Index). If all PFAS results for an EP are below these levels, the EP

would be eligible for triennial monitoring, with the following exception. If sampling location is under an annual monitoring schedule, it would be eligible for triennial monitoring following three consecutive annual samples with all sample results below the trigger levels.

The EPA's proposed rule included monitoring requirements specific to PFAS. To avoid possible confusion, the EPA is amending 40 CFR 141.24(h) to clarify that the applicable monitoring requirements for PFAS are in 40 CFR 141.902 and that the monitoring requirements for non-PFAS SOCs in 40 CFR 141.24(h) do not apply to PFAS.

B. How are PWS compliance and violations determined?

1. Proposal

Consistent with existing rules for determining compliance with NPDWRs, the EPA proposed that compliance would be determined based on the analytical results obtained at each sampling point. For systems monitoring quarterly, compliance with the proposed MCLs would be determined by calculating RAAs for each sampling point. As proposed, eligibility for reduced monitoring would be determined by the sample result(s) at the sampling point. If the sample result(s) are at or exceed the rule trigger level, the system would be required to revert to quarterly sampling, for all regulated PFAS, at each EP where a result is at or above the trigger level. In such case, the sample event that included a result(s) at or above the trigger level would be considered the first quarter of monitoring in calculating the RAA.

An RAA is calculated using results for samples taken at a particular monitoring location during the previous four consecutive quarters. As proposed, if a system takes more than one compliance sample during each quarter at a particular monitoring location, the system must average all samples taken in the quarter at that location to determine the quarterly average, which would then be used in calculating the RAAs. Conversely, if a system does not collect required samples for a quarter, the RAA would be based on the total number of samples collected for the quarters in which sampling was conducted. As proposed, MCL compliance determinations would not be made until a system has completed one year of quarterly sampling, except in the case where a quarterly sampling result is high enough that it will clearly cause the RAA to exceed an MCL (*i.e.,* the analytical result is greater than four times the MCL). In that case, the system would be in violation with the MCL immediately.

In the proposal, when calculating the RAAs, if a sample result is less than the PQL for the monitored PFAS, the EPA proposed to use zero to calculate the average for compliance purposes.

2. Summary of Major Public Comments and EPA Responses

The agency received a few different types of comments on how the compliance determination and violations were proposed to be assessed. Many commenters supported the EPA's approach to assess violations, including that violations are only assessed through an RAA for systems conducting quarterly monitoring. A couple of commenters suggested that in a scenario where a particular high quarterly sample (*i.e.,* result greater than four times the MCL) would cause the RAA to exceed an MCL, the system should not be deemed out of compliance until the end of the quarter (to allow utilities to conduct additional monitoring during that quarter and average the results from the multiple samples). The EPA disagrees with commenters that suggest additional voluntary sampling be used in calculating the quarterly average. The final rule requires that a compliance sample be taken during each quarter for those systems conducting quarterly monitoring. Further, as prescribed under 141.902(b)(2)(v), the state may require a confirmation sample for any sampling results and, if this sample is required, the result must be averaged with the first sampling results and used for the compliance determination. Therefore, any samples other than a state-required confirmation sample should not be averaged within the quarterly compliance result which will be assessed at the end of the quarter.

A couple of other commenters suggested changing the time periods for determining compliance (for both systems conducting quarterly monitoring and those conducting triennial monitoring). These recommendations included assessing compliance based on the results from eight consecutive quarterly samples (rather than four). For those systems conducting triennial monitoring, some commenters proposed that the compliance determination be based on one triennial sample result. For systems determining compliance through an RAA calculation, the EPA believes four consecutive quarterly samples is an adequate representation of the regulated PFAS levels while also assessing compliance in a timely manner. For systems conducting triennial monitoring, if a water system has a sample result at or above the EPA's trigger levels, the system will immediately be required to begin quarterly monitoring. This is consistent with other monitoring requirements for other SOCs and, given the change in measured concentration, will provide additional information over a consistent and longer period of time to better assess the average level of regulated PFAS within the water supply and ensure the water system is reliably and consistently below the MCL.

In the proposed rule, the EPA requested comment on whether the agency should consider an alternative to the approach of using zero when calculating the RAAs if a sample result is less than the PQL. Specifically, in the case where a regulated PFAS is detected but the result is below its proposed PQL, the proposed rule invited comment on whether the trigger level (proposed as one third of the PQL) should be used as the value in calculating the RAA for compliance purposes.

The EPA received numerous comments related to the proposed approach for calculating the RAA for compliance with the NPDWRs, particularly on the incorporation of sample results below the PQLs for the regulated PFAS (see sections V and VII for more information on PQLs.) Many commenters, including some states, supported the EPA's proposed approach to utilize zero for results below PQL to calculate the average for compliance purposes. These commenters cited the definition of the PQL as the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory conditions and noted that this is a level that all laboratories should be able to achieve. Consequently, they suggested that values below these PQLs should not be used for the compliance calculation. Several of these commenters expressed concern that using estimated or other values with less precision in the compliance calculation could result in utilities needing to take actions to address levels of regulated PFAS that are not well-quantified and may not be representative of regulated PFAS levels. Many commenters suggested that since all laboratories cannot achieve values less than the PQLs, this would result in equity issues with respect to disparate laboratories capabilities. Some also suggested that the approach could exacerbate any potential laboratory capacity issues.

The EPA agrees with these commenters that values below the PQLs

for the regulated PFAS should not be used in the compliance calculation. As cited previously by commenters and the EPA in sections V and VII, PQLs are the lowest concentration that can be reliably measured within specified limits of precision and accuracy during routine laboratory operations. As noted in the rule proposal, ''the agency must have a high degree of confidence in the quantified result as it may compel utilities to make potentially costly compliance decisions in order to comply with the MCL.'' Moreover, because compliance with the MCL is determined by analysis with approved analytical techniques, the ability to analyze consistently and accurately for a contaminant is important to enforce a regulatory standard. The EPA recognizes the potential for minor analytical variabilities within sampling procedures and laboratory analyses below the PQL and this approach offers operational certainty to utilities, provides assurances of precision and accuracy in the concentrations at or above the PQL that are achievable for all laboratories, ensures equitable access to all laboratories with comparable analytical capabilities for the purposes of compliance sample results, and reduces the potential for laboratory capacity issues.

Many other commenters did not support the EPA's proposed approach and offered that all sample results between method detection limits and PQLs, even if estimated, should be used. Alternatively, some suggested that any results that laboratories are able to quantify should be used in calculating the RAA for compliance. A subset of these commenters suggested that using zero (instead of an estimated or semi-quantitative value) biases the RAA compliance calculation, is even less precise and accurate than using the values below the PQLs, is contrary to the RAA compliance calculation for other SOC NPDWRs and demonstrates a reduction in public health protection. Some commenters also suggested that this could result in public communication challenges if laboratories are able to estimate or quantify values below the PQLs and zero is instead used in the calculation. Further, several commenters submitted that, in their experiences, some laboratories are capable of reliably and accurately reporting below the PQLs.

While the EPA recognizes that using zero for values below the PQL would result in a differing RAA compliance calculation result than if the values below the PQL were instead used, on a national scale, these values below the PQL do not consistently represent values with the precision, accuracy, and reliability the EPA believes are necessary for compliance determination purposes. Therefore, the EPA's national approach to achieve consistency (recognizing that laboratories have varying analytical capabilities) is to judge compliance based on results at or above the PQL. Using inconsistent values below the PQL may result in MCL compliance determination inequities across systems.

The EPA agrees that some laboratories are capable of reliably measuring the regulated PFAS below the EPA's PQLs. This is supported by a subset of state PFAS monitoring data that represents some sampling with quantified values below the EPA's PQLs. Further, in the March 2023 proposal, the EPA recognized that ''quantitation of the contaminants can be achieved between the method detection limit and the PQL'' though the EPA also noted in the proposal that this is ''not necessarily with the same precision and accuracy that is possible at and above the PQL.'' The EPA must set requirements evaluating the circumstances of all PWSs and laboratory capabilities throughout the country. The agency notes that states must establish requirements at least as stringent as the EPA to maintain primacy; however, under the Safe Drinking Water Act (SDWA), states with primacy may establish more stringent requirements. In instances where a laboratory can demonstrate it is capable of precisely and accurately quantifying values below the PQLs, some states may choose to establish their own requirements that are more stringent and use these values for the compliance calculation.

The agency also received a few comments on the possible alternative approach of using the proposed trigger level as the value in calculating the RAA for compliance purposes when the result is estimated as between the trigger level and PQL. Most commenters did not agree with using the trigger levels as an estimate instead of zero when values are below the PQL and noted that these values could result in inequitable implementation of the rule based on laboratory analytical capabilities.

After consideration of all these comments and for the reasons described previously, the EPA does not believe it is appropriate to use trigger level values or any other values above defined detection limits but below the PQL as part of the RAA compliance calculation based on the information available to the agency today. Trigger levels are appropriate to determine if the contaminant is present (*i.e.,* detected) and for the determination of reduced monitoring frequency, however the EPA concludes that values below the PQL would not consistently and reliably demonstrate the accuracy and reliability necessary for compliance determination purposes that can result in make potentially costly expenditures for PWSs.

3. Final Rule

For the final rule, the EPA is maintaining the proposed compliance calculation determination approach. For systems with sampling locations monitoring quarterly, compliance with the MCLs for regulated PFAS is determined by calculating RAAs using compliance results for particular sampling points. Based on final rule changes to the compliance monitoring requirements previously described in section VIII.A of this preamble above, systems with sampling locations monitoring less frequently than quarterly are required to revert to quarterly sampling for *all* regulated PFAS in the next quarter at each EP with the exceedance where either the sample result(s) are at or above the rule trigger level (for those on triennial monitoring) or the sample result(s) are at or exceed the MCL (for those on annual monitoring). In both cases, the triggered sample result is required to be used for the first quarter of monitoring in calculating the RAA. If a system takes more than one compliance sample during each quarter at a particular monitoring location, the system must average all samples taken in the quarter at that location to determine the quarterly average and this will be used in calculating the RAAs. Conversely, if a system does not collect the required compliance samples for a quarter, the RAA will be based on only those quarters where samples were collected during the past four quarters. A system will generally not be considered in violation of an MCL until it has completed one year of quarterly sampling (*i.e.,* a system on an annual or triennial monitoring schedule with an exceedance of the MCL is not in violation until it completes one year of quarterly sampling with the sample exceeding the MCL used as the sample result for the first quarter of the RAA). However, regardless of the result of subsequent monitoring, if a quarterly sample result will cause the RAA to exceed an MCL at any sampling point (*e.g.,* the first quarter sample result is greater than twice the MCL and the second quarter sample result is also greater than twice the MCL) or if an annual or triennial sample result causes the RAA to exceed an MCL at any sampling point (*i.e.,* the analytical result

is greater than four times the MCL), then the system is out of compliance with the MCL immediately.

The EPA is also retaining the proposed approach for the MCL compliance calculation where, if a sample result is less than the PQL for the monitored PFAS, zero will be used to calculate the RAA (if monitoring quarterly). To clarify how to implement approach, the EPA is providing a few different examples related to calculating the RAA for the PFOA/PFOS MCLs, the individual MCLs for PFHxS, PFNA, and HFPO–DA, and the Hazard Index MCL for the mixtures of PFHxS, PFNA, HFPO–DA, and PFBS.

If a system conducting quarterly monitoring has sample results for PFOA that are 2.0, 1.5, 5.0, and 1.5 ng/L for their last four quarters at a sample location, the values used to calculate the RAA for that sample location would be 0, 0, 5.0, and 0 ng/L with a resulting PFOA RAA of 1.3 ng/L (*i.e.,* (0 + 0 + 5.0 + 0)/4 = 1.3 ng/L). For PFOA and PFOS, as described in section V of this preamble, the MCLs of 4.0 ng/L are promulgated with two significant figures and must be expressed as such in the calculation with any rounding not occurring until the end of the calculation. Data reported to the primacy agency must contain the same number of significant digits as the MCL. In calculating data for compliance purposes, the number must be rounded to two significant digits. The last significant digit should be increased by one unit if the digit dropped is 5, 6, 7, 8, or 9, and if the digit is 0, 1, 2, 3, or 4, the preceding number does not change (*e.g.,* 1.37 is reported as 1.4).

As described in section V of this preamble, the EPA is finalizing individual MCLs and Health Based Water Concentrations (HBWCs) for PFHxS (10 ng/L), HFPO–DA (10 ng/L), and PFNA (10 ng/L), the HBWC for PFBS (2000 ng/L), and the Hazard Index MCL (1 unitless) with one significant figure. Similar to PFOA and PFOS, if a sample result is less than the respective PQLs for these PFAS (*i.e.,* 3.0 ng/L for PFHxS, 5.0 ng/L for HFPO–DA, and 4.0 ng/L for PFNA), zero will be used to calculate compliance both for the PFHxS, PFNA, and HFPO–DA MCLs and the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS. As an example, for the HFPO–DA MCL compliance calculation (which would be the same for the PFHxS and PFNA MCLs using their respective PQLs), if a system conducting quarterly monitoring has HFPO–DA sample results that are 3.2, 6.1, 5.5, and 2.7 ng/L for the last four quarters at a sample location, the values used to calculate the RAA for that sample location would be 0, 6.1, 5.5, and 0 ng/L with a resulting HFPO–DA RAA of 3 ng/L after rounding to one significant figure at the end of the calculation (*i.e.,* (0 + 6.1 + 5.5 + 0)/4 = 2.9 ng/L). Therefore, this system has not violated the MCL for HFPO–DA. The EPA notes that for all MCL RAA calculations, water systems are required to retain the unrounded RAA value (2.9 ng/L in this example) for use in the next RAA calculation as no rounding should occur until the end of the overall compliance calculation (*i.e.,* 2.9 ng/L, not 3 ng/L, should be used).

To provide an example calculation for determining compliance with the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS, if the quarterly sample results at a sample location are 2.1 ng/L for PFHxS, 3.4 for HFPO–DA, 4.1 for PFNA, and 20.0 for PFBS, the water system would first determine the Hazard Index value for that quarter, which is 0.42 (*i.e.,* ((0/10) + (0/10) + (4.1/10) + (20.0/2000) = 0.42). To then calculate the RAA Hazard Index MCL, if the preceding three quarters had unrounded Hazard Index values of 0.76, 1.10, and 0.53 at the same sample location, the resulting RAA Hazard Index MCL would be 0.7 after rounding to one significant figure at the end of the calculation (*i.e.,* (0.76 + 1.10 + 0.53 + 0.42)/4 = 0.70). Consequently, this system has not violated the Hazard Index MCL.

C. Can systems use previously collected data to satisfy the initial monitoring requirement?

1. Proposal

The EPA proposed that systems be allowed to use previously collected monitoring data to satisfy the initial monitoring requirements. In general, a system with appropriate historical monitoring data for each EP, collected using EPA Methods 533 or 537.1 as part of UCMR 5 or a state-level or other appropriate monitoring campaign, could use that monitoring data to satisfy initial monitoring requirements. The EPA notes that for systems monitoring under UCMR 5, all surface water systems are required to collect four quarterly samples and all groundwater systems are required to collect two quarterly samples over a period of 12 months.

While the EPA expects most systems serving 3,300 or greater will have some UCMR 5 data, the EPA also proposed that systems with previously acquired monitoring data from outside UCMR 5, including state-led or other appropriate occurrence monitoring using EPA Methods 533 or 537.1 would also be permitted to use these other monitoring data in lieu of separate initial monitoring for regulated PFAS. The proposed approach may have allowed systems serving fewer than 3,300 (many of whom do not participate in UCMR 5) to otherwise satisfy the initial monitoring requirements. The EPA proposed that data collected after January 1, 2023, be accepted for EP samples, and data collected between January 1, 2019, and December 31, 2022, also be accepted if it is below the proposed rule trigger level of 1.3 ng/L for PFOA and PFOS and a Hazard Index of 0.33 for PFHxS, PFNA, HFPO–DA, and PFBS. Additionally, the EPA proposed that if systems have multiple years of data, the most recent data were to be used.

In the proposal, the EPA stated that if a system had conducted prior monitoring involving fewer than the number of samples required for initial monitoring under this PFAS NPDWR, then all surface water systems, GWUDI systems, and groundwater systems serving greater than 10,000 would be required to collect at least one sample in each quarter of a calendar year that was not acquired and groundwater systems serving 10,000 or fewer would be required to collect one sample in a different quarter of the calendar year than the one in which the previous sample was acquired.

2. Summary of Major Public Comments and EPA Responses

The EPA requested comment on the proposal to allow the use of previously acquired monitoring data to satisfy the initial monitoring requirements. This included a request for feedback on the data collection timeframe requirements and on whether particular QA requirements should be established for such data. Of commenters that provided input on the proposed allowance, nearly all supported the use of previously collected data to support the initial monitoring requirements. The EPA agrees with these commenters that appropriate, previously collected data should be allowed and notes that there will be significant data available from UCMR 5 monitoring and from the many states that have been proactively conducting PFAS drinking water monitoring. This will allow for a significant opportunity to reduce burden for numerous water systems, as well as decrease the potential for laboratory capacity issues. One commenter suggested that the use of this data may not be sufficiently representative of current PFAS concentrations in drinking water systems as the laboratory analyses previously used may not have been

sufficiently sensitive to detect the analytes, relative to the proposed PFAS regulatory standards. The EPA disagrees with this commenter as the analytical methods proposed for PFAS analysis were available for the majority of the time period (*i.e.,* 2019 and after) in which data are allowed to be used to satisfy the initial monitoring requirements. Furthermore, the rule provides that a primacy agency may choose to not allow these data to satisfy initial monitoring requirements and may require more frequent monitoring on a system-specific basis. Additionally, the EPA clarifies that previous monitoring does not automatically qualify water systems for reduced compliance monitoring; rather it is the results from that monitoring that determine the eligibility for a reduced compliance monitoring schedule.

Many commenters suggested that the use of these data should be at the state's discretion and requested that the EPA provide additional flexibility to the primacy agencies in the determination of which data are allowed, including the number of samples and the QA requirements. Moreover, several commenters asked that the EPA clarify how much additional data would be needed to satisfy the initial monitoring requirements if a previous monitoring campaign included less sampling than required under the rule initial monitoring requirements. Specifically, a few commenters noted that, under the requirements of UCMR 5 monitoring, groundwater systems serving greater than 10,000 would have results from two sampling events, not the four needed to satisfy the initial monitoring requirements of this rule. Commenters requested that the EPA explain if these UCMR 5 systems would need to collect additional (supplemental) samples. A few commenters suggested UCMR 5 monitoring should sufficiently meet the requirements for all systems, even though the proposed rule requires quarterly sampling for all groundwater systems serving greater than 10,000.

Having considered the public comments, the EPA is establishing in the final rule that water systems that have collected fewer samples (under UCMR or other programs) than required in this rule for initial monitoring must conduct supplemental monitoring that allows them to meet the minimum requirements. Additional details on this requirement are in section VIII.C.3 of this preamble. In the case of UCMR 5, for example, groundwater systems serving greater than 10,000 will be required to collect two additional samples beyond the two collected for UCMR 5. For more information on the initial monitoring requirements, please see section VIII.A of this preamble.

Several commenters requested that the EPA clarify whether only samples collected under UCMR 5 would be allowed to fulfill initial monitoring requirements, or if data under other monitoring efforts, such as state monitoring, would also be acceptable. As provided in the proposal and final rule, a state may accept results from all appropriate monitoring efforts, as determined by the state, including, but not limited to, UCMR 5 and other state-led efforts.

Several commenters provided various comments related to QA requirements for previously collected data, including data analysis methods, minimum reporting levels, and data collection timeframe. A few commenters expressed that the EPA should allow the use of results from modified EPA methods and/or other state-developed analytical methods. The EPA disagrees with these commenters. While there are other methods that have been used for data collection and analysis, the EPA is requiring that any data used for this rule be collected and analyzed using Methods 533 and 537.1 to ensure consistency across analytical results, as well as to align with the final rule analytical method requirements described in § 141.901. A few commenters requested that the EPA provide additional information on reporting level requirements of the data, with one commenter suggesting that the EPA should not allow this data to be used for initial monitoring purposes if the reporting limits of the laboratory are higher than the EPA's proposed PQLs. The rule provides that the available data can be used regardless of reporting or detection limits to satisfy the initial monitoring requirements; however, given these factors, the results may not support determinations for reduced compliance monitoring. Regarding data collection timeframes, a few commenters questioned why data collected prior to 2023 would not be accepted where the results are higher than the proposed rule trigger levels. In response, the EPA has modified the rule to allow data from January 1, 2019, and later to satisfy initial monitoring requirements, even if it is not below the final rule trigger levels if it meets all other requirements (including being analyzed using Methods 533 and 537.1). Data collected prior to 2019 may not be representative of water quality conditions and likely would not have been analyzed using these methods (given when they were published). The EPA notes if the results exceed the final rule trigger levels the system will not be eligible for a reduced monitoring schedule at that EP.

3. Final Rule

The EPA is retaining the proposed allowance of using previously collected monitoring data to satisfy some or all of the initial monitoring requirements. The agency notes that while use of this data is allowed, water systems may choose to conduct additional monitoring to satisfy their initial monitoring requirement in lieu of using pre-existing data. As described previously in section VIII.A of this preamble, the final rule initial monitoring requirements specify that all system sizes with surface water or GWUDI sources and groundwater systems serving greater than 10,000 are required to collect four quarterly samples, and groundwater systems serving 10,000 or fewer are required to collect two samples. The EPA is clarifying that the number of samples required is based at the EP; therefore, if a system serving 10,000 or fewer has EP with different source water types, the required monitoring is based on the source water type of that EP (*i.e.,* a system serving 10,000 or fewer that has surface water, groundwater, and/or GWUDI sources during the initial monitoring period must collect two samples at the EP sourced by groundwater and four samples at the EP sourced by surface water or GWUDI). For systems serving 10,000 or fewer that change the source water type at EP throughout the initial monitoring period (*i.e.,* one part of the year is surface water, and the remaining part of the year is groundwater and/or GWUDI), the EP must follow the sampling requirements of surface water systems.

In the final rule under § 141.902(b)(1)(viii), the EPA is maintaining that if a system has some previously collected results, but fewer than the number required to satisfy the initial monitoring requirements, they must conduct additional monitoring such that it, coupled with the previous monitoring, meets the requirements of this rule. All surface water and GWUDI systems, and groundwater systems serving greater than 10,000, must collect the required additional samples 2–4 months apart from the months with available data, without regard to year, such that all quarters are represented (see section VIII.A of this preamble for more information).

In § 141.902(b)(1)(vi), the final rule maintains the requirement that the data must have been collected and analyzed using EPA Methods 533 or 537.1, and eliminates the requirement that data collected between January 1, 2019, and December 31, 2022, must reflect the

laboratory's ability to measure at or below the rule trigger level to satisfy initial monitoring requirements. Data collected before January 1, 2019, cannot be used to satisfy these requirements. Additionally, any results above the final rule trigger levels of 2.0 ng/L each for PFOA and PFOS, 5 ng/L each for PFHxS, PFNA, and HFPO–DA, and a Hazard Index of 0.5 for PFHxS, PFNA, HFPO–DA, and PFBS would not allow the associated EP to be eligible for reduced monitoring.

D. Can systems composite samples?

1. Proposal

Subpart C of 40 CFR 141.24 describes instances where primacy agencies may reduce the samples a system must analyze by allowing samples to be composited. Composite sampling can potentially reduce analytical costs because the number of required analyses is reduced by combining multiple samples into one and analyzing the composited sample. However, in the proposal, the EPA noted that based on input the agency received from consulting with state regulators and small business entities (operators of small PWSs), PFAS are ubiquitous in the environment at low concentrations, which necessitates robust laboratory analytical precision at these low concentrations. Based on these potential implementation issues, the EPA proposed that compositing of samples would not be allowed.

2. Summary of Major Public Comments and EPA Responses

The EPA received comments related to composite sampling. The majority of these commenters agreed with the EPA's proposal to not allow samples to be composited due to analytical limitations and the increased potential for background contamination, along with the physical and chemical characteristics of PFAS. A few commenters suggested that they believed composite sampling could be implemented and would reduce the cost of analyses. Further, some of these commenters suggested that with proper guidelines and procedures for analyzing samples, possible contamination issues could be mitigated and asserted that issues with false negative and positive samples also impact discrete samples (*i.e.,* that they are not unique to composite sampling).

The EPA received other comments regarding the specifics of composite monitoring. One commenter noted grab samples as more appropriate and suggested that individual systems be permitted to request alternative sampling methodologies if needed. One other commenter suggested that compositing samples from varying EP should not be allowed. In addition, one commenter requested that the EPA provide information as to the increased risk of compositing samples, along with discussion of the proposed departure from the SMF for SOC ahead of rule finalization.

For commenters who offered that composite sampling could be implemented, the EPA agrees it would potentially decrease sampling analysis costs and that sampling errors can occur when handling and analyzing discrete samples. However, the compositing of samples necessarily involves additional handling, opening, and transfer steps than are required for the collection and analysis of individual samples. Therefore, the combining of samples that must be done for composite sample analysis represents an increased risk of sampling error, which could result in decreased public health protection and additional sampling costs. The agency also does not agree that alternative sampling methodologies should be permitted and requires the use of EPA Methods 533 and 537.1 for monitoring per the requirements of the rule. Please see section VII of this preamble for more information on methods.

As discussed previously, PFAS are pervasive in the environment and require robust laboratory analytical precision, particularly at low concentrations. Accordingly, the EPA agrees with commenters that do not support the allowance of composite sampling and maintains that discrete sampling is the most appropriate type of sampling for regulated PFAS.

3. Final Rule

Based on consideration of public comments (many of which supported the EPA's concerns about the ubiquitous nature of PFAS at low concentrations in the environment, the necessary robust laboratory analytical precision required, and potential implications for implementation), the final rule does not allow composite samples.

E. Can primacy agencies grant monitoring waivers?

1. Proposal

Subpart C of 40 CFR 141.24 describes instances where the primacy agency may grant waivers predicated on proximity of the system to contaminant sources (*i.e.,* susceptibility to contamination) and previous uses of the contaminant within the watershed (including transport, storage, or disposal). The EPA did not include a provision to allow primacy agencies to grant monitoring waivers as a regulatory flexibility in the proposed rule. The EPA did, however, request public comment on whether to allow systems to apply to the primacy agency for a monitoring waiver of up to nine years (one full compliance cycle) if, after at least one year of quarterly sampling, the results are below the rule trigger level, or for systems that may be approved for reduced monitoring, if at least two consecutive results are below the rule trigger level. The EPA also requested comment on allowing similar monitoring waivers to be granted based on previously acquired monitoring data as described in section VIII.C of the preamble for the proposed rulemaking. The EPA additionally sought comment on possible alternatives to traditional vulnerability assessments that should be considered in order to identify systems as low risk and potentially eligible for monitoring waivers.

2. Summary of Major Public Comments and EPA Responses

Several commenters suggested that monitoring waivers should not be allowed for this rule. Several additional commenters cited the persistence and mobility of PFAS in the environment and advised that reduced monitoring frequencies should be no less than every three years on the basis that drinking water consumers in unmonitored areas may unknowingly be exposed to these PFAS. Furthermore, many other commenters suggested that PFAS contamination can migrate significantly over a three-year period.

Many other commenters were supportive of monitoring waivers for this rule under certain circumstances. Several commenters indicated that waivers would be appropriate if they were based on monitoring results. A few commenters recommended that if monitoring waivers were to be allowed, that they should not be based solely on a traditional vulnerability assessment. A couple of commenters stated that waivers based on vulnerability alone should not be allowed during the initial monitoring period. One commenter recommended waiting until UCMR 5 monitoring is complete before allowing monitoring waivers to be granted through vulnerability assessments. A couple of commenters suggested that waivers be considered if they are based on a combination of vulnerability *and* monitoring results, while one other commenter suggested that assessing watershed characteristics to demonstrate eligibility for monitoring waivers would be protective of chronic health risks. One commenter noted that

merely allowing waivers to be granted would not necessarily reduce public health protection under the rule, as primacy agencies will retain the ability to deny waiver applications.

After consideration of these comments, and due to the mobility and persistence characteristics of the regulated PFAS, the final rule does not allow monitoring waivers. These specific properties of the regulated PFAS and their observed ubiquity in both drinking water and within many other sources make waivers impractical and complicate the ability to maintain public health protection if such a provision were included as part of this rule. Moreover, the EPA is not confident that allowing monitoring any less frequently than every three years or conducting vulnerability assessments will accurately capture potential concentration variations over the long term or protect against risks from new contamination sources.

3. Final Rule

Consistent with the proposal, the final rule does not include a provision that would allow primacy agencies to issue monitoring waivers. These waivers would increase the potential for public health risks and the EPA does not consider them necessary to reduce burdens on primacy agencies, water systems and communities given the other flexibilities provided in the rule.

F. When must systems complete initial monitoring?

1. Proposal

Pursuant to section 1412(b)(10), the proposed rule required compliance with all aspects of the NPDWR three years after promulgation. This included satisfying initial monitoring requirements as described in sections VIII.A and VIII.C within the three years following rule promulgation.

2. Summary of Major Public Comments and EPA Responses

In the proposal, the EPA requested public comment on the proposed initial monitoring timeframe, particularly for NTNCWS or all systems serving 3,300 or fewer. Many commenters expressed support for the EPA requiring initial monitoring as soon as possible with a few commenters explicitly supporting the EPA's proposed initial monitoring timeframe noting it allows sufficient time for water systems to comply with the initial monitoring requirements. However, other commenters suggested that water systems would not be able to utilize the full three years following rule promulgation to perform initial monitoring and take actions to ensure compliance with the MCL if monitoring results showed elevated levels of PFAS. While the agency agrees that it may be difficult to conduct initial monitoring and take necessary remedial actions (*e.g.,* treatment installation) within three years, the EPA finds that it is practicable for all systems to complete their initial monitoring within three years. This is particularly the case since the large majority of systems serving greater than 3,300 will have sufficient monitoring data from UCMR 5 and many other systems will have at least some data to satisfy the rule's initial monitoring requirements. Moreover, as described in section XI.D. of this preamble, the EPA is exercising its authority under SDWA section 1412(b)(10) to implement a nationwide two-year capital improvement extension to comply with MCL. Consequently, water systems will have up to the full three years following rule promulgation to plan and conduct monitoring and still have two additional years to complete any actions needed to comply with the MCLs.

Several commenters suggested that the EPA consider a staggered initial monitoring timeframe by system size, such as those used in other previous NPDWRs, where, for example, larger sized systems conduct monitoring first followed by smaller systems. In the examples provided by commenters, this staggered monitoring could also allow systems to achieve compliance on a staggered schedule. A few commenters suggested that this is necessary to address potential laboratory capacity issues and to allow smaller systems additional time to plan and obtain resources to conduct the monitoring. The EPA disagrees that staggering the monitoring requirements to allow different compliance dates is necessary. SDWA 1412(b)(10) specifies that all systems must demonstrate compliance three years following rule promulgation except where a state or the EPA may grant an extension of up to two additional years to comply with MCL(s) if the EPA or the state (for an individual system) needs additional time for capital improvements. Therefore, the intent of the statute is to allow extensions to complete the capital improvements necessary to comply with the MCL. The EPA considers the three years sufficient for completing the rule's initial monitoring requirement. The EPA's allowance of previously collected monitoring data will also significantly reduce the potential for laboratory capacity challenges. As previously noted in section VIII.A of this preamble, the EPA has revised the required intervals between samples collected for initial monitoring under this rule to closely parallel the intervals required for UCMR 5, to promote the useability of existing data.

The EPA is not prescribing any staggering of monitoring (*e.g.,* based on system size) but encourages primacy agencies to work with the systems they oversee to ensure their initial monitoring occurs and adjust schedules (within the three years following rule promulgation) as appropriate.

3. Final Rule

The EPA is finalizing the requirement that initial monitoring, or demonstration of previously collected data to satisfy initial monitoring requirements, must be completed within the three years following rule promulgation (*i.e.,* April 26, 2027) to ensure that water systems have the information needed to inform decisions to meet the MCL compliance date. As described previously and in section XI.D, the EPA is providing a two-year capital improvement extension under SDWA 1412(b)(10), allowing additional time for those systems to comply with the MCL. Requiring water systems to conduct initial monitoring within the three years following rule promulgation will ensure public health protection as soon as practicable and allow these water systems to maximize utilization of the capital-improvement extension time. Additionally, the flexibility in the final rule for systems to use previously acquired monitoring data to satisfy some or all of their initial monitoring will reduce the potential for laboratory capacity challenges. The EPA encourages systems that may not have available data and/or choose to conduct additional monitoring to conduct their initial monitoring as soon as practicable following rule promulgation to allow for remedial actions that may needed, based on monitoring results, and to comply with the MCL by the compliance date.

G. What are the laboratory certification requirements?

1. Proposal

The EPA proposed that laboratories demonstrate their capability to meet the objectives of this regulation. The proposal would require laboratories to analyze performance evaluation (PE) samples every year for each method and contaminant in order to achieve and maintain certification from their primacy agency.

2. Summary of Major Public Comments and EPA Responses

A few commenters requested that the EPA develop guidance and training for

drinking water laboratory certification programs to evaluate laboratories seeking certification. The EPA agrees that training for laboratory certification officers is appropriate. The EPA will develop training materials and guidance for drinking water certification programs to evaluate laboratories to ensure adherence to the requirements of EPA Methods 533 and 537.1 (USEPA, 2005b).

One commenter requested that the EPA establish reciprocity between laboratory certification programs to utilize all potential laboratory capacity available. As described in the EPA's *Manual for the Certification of Laboratories Analyzing Drinking Water,* laboratory certification programs may recognize drinking water laboratory certifications (or comparable ''accreditation'') from other laboratory certification programs, by reciprocity (USEPA, 2005b). Most laboratory certification programs do utilize the practice of reciprocal certification. Reciprocal certification can only be granted to laboratories utilizing EPA Methods 533 and 537.1.

3. Final Rule

Under the final rule, certified laboratories must demonstrate their capability to meet the objectives of this regulation. Laboratories are required to analyze PE samples every year for each method and contaminant in order to achieve and maintain certification from their primacy agency.

H. Laboratory Quality Assurance/ Quality Control

In the proposal, the EPA requested comment on other monitoring-related considerations including quality assurance/quality control (QA/QC) associated with drinking water sampling and analysis.

Many commenters suggested the potential for false positives to misrepresent actual levels of the regulated PFAS within the drinking water sample due to the ubiquity of PFAS and the possible background interference. The EPA is aware of the potential for background contamination due to the ubiquitous nature of PFAS in the environment. The EPA agrees that PFAS sampling is highly sensitive and there is potential for sample contamination. However, with proper training tools and communications, that potential can be mitigated, though not sufficiently enough to allow for composite sampling as discussed in section VIII.D of this preamble. For example, the UCMR program has released several sampling guidance documents and a small-systems sampling video to assist small and medium utilities with the PFAS sampling. These products have also been distributed to the UCMR laboratory community, which has been encouraged to share them with their PWS clients.

Also, Method 533 and Method 537.1 require the analysis of an LRB with each extraction batch. If method analytes are detected at or above ⅓ the minimum reporting level, suggestive of background contamination, all positive field sample results associated with that extraction batch are invalid for the impacted analytes. Both methods also require the analysis of an FRB (a blank that is prepared at the sampling location) when any PFAS are detected above the minimum reporting level in field samples. The use of laboratory and field blanks were incorporated into the methods as QC to reduce the potential for false positives due to background contamination.

IX. Safe Drinking Water Act (SDWA) Right To Know Requirements

A. What are the Consumer Confidence Report requirements?

1. Proposal

A community water system (CWS) must prepare and deliver to its customers an annual Consumer Confidence Report (CCR) in accordance with requirements in 40 CFR part 141, subpart O. A CCR provides customers with information about their local drinking water quality as well as information regarding the water system's compliance with drinking water regulations. The EPA proposed that CWSs be required to report detected PFAS in their CCRs, specifically, PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS, and the Hazard Index for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS. The EPA also proposed adding paragraph (g) to 40 CFR 141.154 that would require health effects language be provided when any regulated PFAS is measured above the maximum contaminant level (MCL), in addition to those with an MCL violation.

2. Summary of Major Public Comments and EPA Responses

A few commenters requested clarification of the health effects language included in the CCR. Specifically, a couple of commenters said the proposed standard health effects language included in the CCR for a Hazard Index MCL exceedance was not clear. Commenters found some of the language regarding the Hazard Index MCL to be confusing and offered suggestions for clarification. The EPA has considered this input and revised the health effects language associated with PFAS exposure, including the Hazard Index.

A few of commentors raised concerns about requiring reporting of results below the practical quantitation level (PQL) in the CCR as these data may not be quantified with what they deem is appropriate precision. One commentor requested that any detected PFAS, not just the six regulated contaminants, be reported in the CCR. The EPA disagrees with commenters who voice concern over reporting measurements below the PQLs for PFOA and PFOS as ''detected'' contaminants in the CCR. Reporting these measurements in the CCR will allow customers to understand that the contaminant was detected in the water supply. While measurements below the PQL will not be used to calculate compliance with MCLs for the final rule, measurements lower than the PQL are achievable by individual laboratories, and therefore these measurements can be used for screening, to determine compliance monitoring frequency, and to educate consumers about the existence of PFAS (for further discussion of PQLs for regulated PFAS, please see section VII of this preamble). As such, the EPA believes that measurements below the PQL can reasonably be reported as ''detected'' for purposes of the CCR. This requirement is consistent with the CCR Rule in 40 CFR 141.153(d) which requires CWSs to report information on detected contaminants for which monitoring was required by the EPA or the state. The CCR reporting requirement includes unregulated contaminants for which monitoring is required pursuant to the Unregulated Contaminant Monitoring Rule (UCMR) as well as regulated contaminants in accordance with SDWA (Safe Drinking Water Act) 1414(c)(4). If the system has performed additional monitoring, the EPA strongly encourages them to include the results in the CCR, consistent with 40 CFR 141.153(e)(3).

3. Final Rule

As part of this action, the EPA has modified the trigger level value for quarterly monitoring from one-third of the MCL to one-half of the MCL in response to concerns that laboratories would not have the capacity to consistently measure as low as the threshold of one-third of the MCL (for further discussion of the EPA's trigger levels for the final rule, please see section VIII of this preamble). To reflect this change in the trigger level, the EPA has modified 40 CFR 141.151(d), which identifies what is considered detected

for purposes of reporting in CCRs consistent with SDWA 1414(c)(4). The EPA had also proposed adding a provision to require CWSs that detect any PFAS above the MCL to include health effects language for PFAS and stated in the preamble for the rule proposal that CWSs would be required to report detected PFAS as part of their CCRs. Because SDWA 1414(c)(4)(B) specifies that the Administrator may only require health effects language be reported in the CCR for situations other than an MCL violation for not more than three regulated contaminants, the EPA has removed the amendment to paragraph (g) of 40 CFR 141.154 included in the proposed rule from the final rule and has instead updated appendix O to part 141 for the final rule to only require CWSs that have violations of the PFAS MCLs to include health effects language for PFAS. Since systems must complete initial monitoring within three years of rule promulgation, systems will be required to report results and other required information in CCRs beginning with 2027 reports. As the MCL compliance date is set at five years following rule promulgation, systems will be required to report MCL violations in the CCR, accompanied by the required health effects language and information about violations, starting in 2029.

The EPA acknowledges the need to protect public health with clear and concise language that outlines the risks associated with exposures exceeding the MCLs and Hazard Index. The EPA's broad review of the most current research provides a comprehensive understanding of how exposure to PFAS may result in adverse impacts on the health of individuals. In response to commenter requests for plain language explanations of the Hazard Index, the EPA is adding the following definition of the *Hazard Index* in 40 CFR 141.153(c)(3)(v) of the CCR Rule to improve clarity and understandability for consumers (for more information on how the Hazard Index is calculated for this rule, please see table to paragraph (b) under 40 CFR 141.50):

Hazard Index or HI: The Hazard Index is an approach that determines the health concerns associated with mixtures of certain PFAS in finished drinking water. Low levels of multiple PFAS that individually would not likely result in adverse health effects may pose health concerns when combined in a mixture. The Hazard Index MCL represents the maximum level for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS allowed in water delivered by a public water system. A Hazard Index greater than one (1) requires a system to take action.

Additionally, in response to commenters' request for clearer mandatory health effects language, the final rule includes revised mandatory health effects language required as part of CCRs, in cases when MCL violations have occurred.[10] Identical mandatory health effects language is also required for public notification (PN) under the final rule (PN requirements are described further in section IX.B of this preamble). The mandatory health effects language in the final rule reads as follows:

Health effects language for PFOA: Some people who drink water containing PFOA in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including kidney and testicular cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for PFOS: Some people who drink water containing PFOS in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including liver cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOS in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for PFHxS: Some people who drink water containing PFHxS in excess of the MCL over many years may have increased health risks such as immune, thyroid, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFHxS in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for PFNA: Some people who drink water containing PFNA in excess of the MCL over many years may have increased health risks such as elevated cholesterol levels, immune effects, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFNA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for HFPO–DA: Some people who drink water containing HFPO–DA in excess of the MCL over many years may have increased health risks such as immune, liver, and kidney effects. There is also a potential concern for cancer associated with HFPO–DA exposure. In addition, there may be increased risks of developmental effects for people who drink water containing HFPO–DA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for Hazard Index PFAS: Per- and polyfluoroalkyl substances (PFAS) can persist in the human body and exposure may lead to increased risk of adverse health effects. Low levels of multiple PFAS that individually would not likely result in increased risk of adverse health effects may result in adverse health effects when combined in a mixture. Some people who consume drinking water containing mixtures of PFAS in excess of the Hazard Index (HI) MCL may have increased health risks such as liver, immune, and thyroid effects following exposure over many years and developmental and thyroid effects following repeated exposure during pregnancy and/or childhood.

B. What are the Public Notification (PN) requirements?

1. Proposal

As part of SDWA, the PN Rule ensures that consumers will know if there is a problem with their drinking water. Notices alert consumers if there is risk to public health. They also notify customers: if the water does not meet drinking water standards; if the water system fails to test its water; if the system has been granted a variance; or if the system has been granted an exemption (that is, more time to comply with a new regulation).

All public water systems (PWSs) must give the public notice for all violations of National Primary Drinking Water Regulations (NPDWRs) and for other situations. Under the EPA's PN Rule, the public notice requirements for each violation or situation are determined by the tier to which it is assigned. The EPA specifies three categories, or tiers, of PN requirements, to take into account the seriousness of the violation or situation and any potential adverse health effects that may occur (USEPA, 2000f). The

[10] The EPA has developed the existing mandatory health effects language to communicate accurate, clear health information to a non-technical audience. Although the EPA believes additional detail is not necessary to include in the mandatory health effects language which is required only where MCL violations have occurred, the EPA also recognizes that, in general, a single exposure at a critical time in development may produce an adverse developmental effect (see USEPA, 1991a).

EPA proposed that violations of the three MCLs in the proposal be designated as Tier 2 and as such, PWSs would be required to comply with 40 CFR 141.203. Per 40 CFR 141.203(b)(1), notification of an MCL violation should be provided as soon as practicable but no later than 30 days after the system learns of the violation. The proposed rule also designated monitoring and testing procedure violations as Tier 3, which would require systems to provide notice no later than one year after the system learns of the violation. The system would then be required to repeat the notice annually for as long as the violation persists.

2. Summary of Major Public Comments and EPA Responses

Many commenters support the Tier 2 PN requirement for MCL violations. Commenters assert that Tier 2 notification is appropriate and consistent with other MCLs for chemicals with chronic effects. Conversely, many commenters suggest that the PN tiering be raised from Tier 2 to Tier 1 or that the EPA consider other PN approaches given concerns about health impacts resulting from exposure on timescales shorter than chronic exposure. Commenters assert that raising PN for MCL violations from Tier 2 to Tier 1 would ensure that consumers are informed of potential harm associated with elevated PFAS levels in a timelier manner so they can make informed risk management decisions. Additionally, a few commenters request the EPA re-categorize repeat MCL violations to Tier 3 due to the expected length of time needed for a PWS to design and construct treatment. Commenters argue that quarterly PN would not offer added value and could possibly result in confusion for consumers.

The EPA agrees with commenters that Tier 2 PN is appropriate for MCL violations based on analysis of a wide range of scientific studies that shows that long-term exposure may have adverse health effects. The EPA disagrees with commenters who recommend issuing Tier 1 notification for MCL violations. Tier 1 notices must ''be distributed as soon as practicable, but no later than 24 hours, after the public water system learns of the violation'' pursuant to section 1414(c)(2)(C)(i) of SDWA. The PN Rule preamble characterizes contaminants with violations routinely requiring a Tier 1 notice as those with ''a significant potential for serious adverse health effects from short-term exposure'', stating that other violations do not require Tier 1 notice because elevated levels of these contaminants are not ''strongly or consistently linked to the occurrence of the possible acute health effects'' (USEPA, 2000f). The EPA has not characterized health risks resulting from acute exposure (*i.e.,* < or = 24 hours) to PFAS and the EPA believes that issuing Tier 2 PN for MCL violations constitutes a health protective approach given that the MCLG values are based on health effects that occur after chronic exposure to PFAS (*i.e.,* cancer). Based on the available health effects information, the EPA has characterized developmental effects, including immune impacts, associated with developmental PFAS exposure in addition to health effects that occur after chronic exposure. The agency considers it reasonable to notify consumers within 30 days of a PWS learning of an MCL violation because it generally provides protection of the adverse health effects that may occur from exposure to PFAS during sensitive lifestages such as gestation. The EPA typically reserves Tier 1 notifications for acutely toxic contaminants. For example, nitrate, nitrite, or total nitrate and nitrite require Tier 1 notice because exceedances can result in immediate life-threatening health impacts for infants (*i.e.,* methemoglobinemia). Based on the currently available information, the developmental and chronic effects associated with exposure to these PFAS are not known to represent immediate acute health effects. For more information on the EPA's characterization of health effects resulting from PFAS exposure, please see (USEPA, 2024c; USEPA, 2024d). This approach is also consistent with the PN requirements for other synthetic organic contaminants regulated under SDWA. The EPA acknowledges that there may be instances in which it is appropriate to elevate the tiering of PN on a case-by-case basis. Under the existing PN Rule in 40 CFR 141.202(a), a violation that routinely requires a Tier 2 notice but poses elevated risk from short-term exposure may be elevated to Tier 1 at the discretion of the primacy agency (USEPA, 2000f). Additionally, the EPA will develop appropriate implementation guidance to assist in the understanding of PN requirements among other final rule requirements.

The EPA disagrees with commenters that recommended reclassifying ongoing MCL violations to Tier 3 for repeat notices. The EPA believes there is sufficient flexibility in the existing PN Rule 40 CFR 141.203(b)(2) that allows primacy agencies to allow a less frequent repeat notice on a case-by-case basis for unresolved violations, but no less than once per year, and the determination must be in writing. The EPA believes repeat notices are valuable to consumers that may not receive the initial notice and allow water systems to provide any updates to consumers, such as actions being taken to resolve the situation and estimated timelines.

A few commenters recommended that the EPA update the proposed PN health effects language. Commenters stated that the proposed health effects language was confusing and needed to be clarified as it did not sufficiently explain the health effects resulting from PFAS exposure. Additionally, commenters stated that further clarifying the health effects language would mitigate confusion from customers when receiving PN from their water system.

The EPA agrees with commenters that additional explanation of the health effects of PFAS exposure will more effectively communicate risk to consumers when they receive PN from their water system. The EPA has considered this input and has revised health effects language for the final rule to further clarify the health effects associated with PFAS exposure.

3. Final Rule

The final rule requires the PN of violations of all MCLs promulgated under this final rule to be designated as Tier 2 and as such, PWSs would be required to comply with 40 CFR 141.203. The final rule also designates monitoring and testing procedure violations as Tier 3, requiring systems to provide notice no later than one year after the system learns of the violation. Systems are also required to repeat the notice annually for as long as the violation persists. As systems must comply with initial monitoring requirements within three years of rule promulgation, systems will be required to provide Tier 3 notification for monitoring and testing procedure violations starting in 2027. As the MCL compliance date is set at five years following rule promulgation, systems will be required to provide Tier 2 notification for MCL violations starting in 2029. However, the EPA acknowledges that primacy agencies have the authority in the existing PN Rule (table 1 to § 141.201) to require systems to provide notices to consumers prior to the MCL compliance date. The EPA encourages primacy agencies to use this flexibility to require systems to provide notices to consumers for PFAS detections that precede the date that MCL compliance will take effect, as they deem appropriate. By encouraging systems to provide timely notification, it

allows customers to take actions to protect their health, such as using a filter, while systems take necessary steps to apply treatment.

With respect to violations and reporting associated with the individual MCLs and Hazard Index MCL, the EPA recognizes that a utility may have two or more of these PFAS present that, over the course of four quarterly samples, may result in violation of multiple MCLs. For example, if, following four quarterly samples, a utility has PFHxS and HFPO–DA present and the RAA is above their respective MCLs and HBWCs of 10 ng/L, the system would be in violation of both the individual MCLs for PFHxS and HFPO–DA, as well as the Hazard Index MCL. Issuing multiple notifications (three in this example) for these violations may cause public confusion as the adverse health effects and exposure concern in this instance is not meaningfully different from either a Hazard Index or individual MCL perspective. To simplify implementation of PN in this scenario, the EPA is finalizing requirements in appendix A to subpart Q of part 141 such that utilities who violate the Hazard Index MCL and one or more individual MCLs because of the same compounds can issue one notification to satisfy the PN requirements for the multiple violations.

The EPA has also made edits to clarify the mandatory health effects language required in the PN of an MCL violation, as well as the CCR. The mandatory health effects language required for both PN and CCRs is summarized in section IX.A.3 of this preamble above.

X. Treatment Technologies

Section 1412(b)(4)(E) of the Safe Drinking Water Act (SDWA) requires that the agency ''list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL],'' which are referred to as best available technologies (BATs). The EPA generally uses the following criteria for identifying ''feasible'' BATs: (1) The capability of a high removal efficiency; (2) a history of full-scale operation; (3) general geographic applicability; (4) reasonable cost based on large metropolitan water systems; (5) reasonable service life; (6) compatibility with other water treatment processes; and (7) the ability to bring all the water in a system into compliance. Section 1412(b)(4)(E)(ii) of SDWA requires that the agency identify small system compliance technologies (SSCTs), which are affordable treatment technologies, or other means that can achieve compliance with the maximum contaminant level (MCL).

In the proposed rule, the EPA requested comments on: technologies designated as BATs, costs associated with nontreatment options; whether employing these treatment technologies are sound strategies to address PFAS as well as whether the BATs could feasibly treat to below the proposed MCLs; the type of assistance that would help public water systems (PWSs); potential benefits from co-removal; treatment residual disposal estimates; the capacity to address the increased demand for BATs as well as residuals disposal or reuse; impacts that PFAS residuals disposal may have in communities adjacent to the disposal facilities; the most appropriate disposal means for PFAS contaminated residuals and waste the systems may be generating; and SSCT selection as well as national affordability analysis, specifically on the methodologies.

A. What are the best available technologies?

1. Proposal

The agency proposed GAC, AIX, NF, and RO as BATs for the six PFAS under consideration in the proposed rule. The EPA also acknowledged that there are nontreatment options which may be used for compliance such as replacing a PFAS-contaminated drinking water source with a new uncontaminated source. The EPA also stated that conventional and most advanced water treatment methods are ineffective at removing PFAS.

2. Summary of Major Public Comments and EPA Responses

The vast majority of comments germane to the BAT designations support the EPA's designation of granular activated carbon (GAC), anion exchange resins (AIX), and high-pressure membranes (nanofiltration (NF) and reverse osmosis (RO)) as BATs that are technologically feasible for treating drinking water to the proposed standards or below. Many commenters shared practical experience with installed treatment including successes, costs, implementation considerations, challenges, and other areas. The EPA agrees that GAC, AIX, RO, and NF are BATs and consistent with the criteria outlined in the BAT/SSCT document for identifying ''feasible'' treatment for PFAS in this rule, and the comments providing information on practical full-scale experience with these technologies further support for this finding.

A few commenters suggested either that the designated BATs could not treat to or below the MCL or that not enough data was available to support the conclusion that the BATs could treat to at or below the proposed MCL. The EPA disagrees with these commenters based on the history of full-scale use as documented in the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024l), the information in the rule preamble, and in the comments that provided full-scale data as well as case studies. For example, commenters highlighted more than 45 military installations that have treated PFAS, including those in this rule, successfully for more than 15 years, a major water treatment company provided information on over 150 successful installations they had performed, and comments supported that there are significant numbers of industrial users successfully treating PFAS, including those in this rule. One commenter noted the example of the Chemours Fayetteville facility which used GAC to eliminate PFAS, including those in this rule, as high as 345,000 ng/L and has reduced PFAS in effluent to non-detect levels for several PFAS. Finally, the Water Quality Association reviewed proprietary performance data from its accredited laboratory demonstrating that this standard is feasible for the BATs selected to effectively remove the PFAS regulated in this rule from drinking water.

Many commenters pointed out site-specific issues with particular BATs. The EPA acknowledges that not every BAT represents the best treatment option for an individual system and site-specific considerations can limit BAT selection. For instance, residuals management considerations can limit the choice of RO/NF; particularly in states with limited water resources. While many commenters agreed that high pressure membranes such as RO and NF can remove the six PFAS included in the proposal, many commenters also suggested that high pressure membranes may not be the most feasible treatment option for some systems because of residual management considerations, which are discussed in the residuals management section. There are, however, documented RO/NF facilities for treating PFAS in California, Illinois, North Carolina, and Alabama (USEPA, 2024l). In response to public comment and residual management concerns surrounding high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to 0% in the EA. While the EPA

does not estimate any water systems will elect to install RO/NF to comply with the PFAS rule, it remains a BAT for water systems to consider. For additional details on the EPA's EA, please see section XII.

The EPA also acknowledges that due to technical site-specific considerations, some BATs may not be the best choice for particular water types. PFAS treatment option selection should consider conditions for a given utility including water quality, available space, disposal options, and currently installed unit operations. AIX may be the preferred technology for some utilities based on expected treatment needs, while others may select GAC or other technologies. However, as many commenters indicated, the BAT designations are appropriate for water systems across the country.

Several commenters pointed out that GAC may release arsenic at levels exceeding arsenic's MCL temporarily when installed and upon changing media, deleteriously impacting finished water quality. While the EPA has documented challenges surrounding GAC and arsenic (USEPA, 2024l), the EPA disagrees that the arsenic release poses an exposure concern so long as appropriate procedures are followed. Those procedures include discarding the initial bed volumes (BVs) after installation or replacement of media. A bed volume is the volume of liquid contained within a GAC contactor, it is the container volume minus the solids volume and void space. The quantity of treated water discarded can be significant (*e.g.,* as high as 350 BVs as one commenter noted). However, this amount of discarded water is low in comparison to the normal service life between GAC replacement, which is approximately 84,000 BVs or approximately about 0.5% of the total treated volume. The total water volume discarded is also low in comparison to water loss through leaks across the United States, which account for about 15% of treated water or what would be approximately 12,600 BV equivalents for this system. While conserving water is a significant issue, the water discarded due to GAC applications is relatively low. Systems can reduce water discard associated with BAT implementation by using acid washed and/or prerinsed GAC or using buffered/pre-flushed resins for AIX. Any treatment technology can create problems if improperly maintained and operated. Finally, GAC has been statutorily designated as ''feasible for the control of synthetic organic chemicals,'' such as PFAS, in SDWA section 1412(b)(5).

The EPA received many suggestions for additional BATs including powdered activated carbon (PAC), alternative sorbents, and new destructive technologies. However, these alternative BATs proposed, except for PAC, currently lack demonstrated full-scale removal of the six PFAS under consideration. The EPA notes that there are some reports of PAC use on a temporary basis and that it can reduce PFAS concentrations in drinking water. PAC may be an appropriate choice of technology in certain circumstances, however, its efficacy for trace removal tends to be variable due to factors such as carbon particle size, background organics, and plant efficiency. Therefore, PAC is not as effective as GAC overall, and the agency has not designated it as a BAT. The EPA periodically reevaluates treatment technologies and may add additional technologies based on updated information. It is important to note that water systems may use any technology or practice to meet the PFAS MCLs and are not limited to the BATs in this rule. Other technologies may be chosen in lieu of BAT because they may be more cost effective or better suited to the specific operating conditions of the particular site to meet the MCL. Electing not to use a BAT, however, means that a system will not be eligible for a variance under SDWA section 1415(a)(1)(A). For example, if a facility does not install GAC where it is the designated BAT, but uses PAC instead, and fails to meet the MCL, the facility would not be eligible for a variance under SDWA section 1415(a)(1)(A). On the other hand, the same facility may be eligible for an exemption under SDWA section 1416 if, for example, GAC could not be installed due to an inability to obtain financing and PAC was used instead, and the facility failed to meet the MCL.

Many commenters pointed out the need for increased research, technological innovation, and guidance in treating drinking water for PFAS. The available information is sufficient to finalize the BATs as proposed but the EPA agrees that more research may be beneficial (USEPA, 2022c). With respect to the EPA's request for public comment on additional guidance materials that would be helpful to support successful technical implementation of the rule, the EPA received many comments related to the need for technical materials to support rule implementation. The agency plans to collaborate with states, technical assistance providers, industry associations and interested stakeholders, including small systems, following the rule promulgation to provide technical materials that can assist water systems in complying with the regulations. The EPA is currently funding many technical assistance efforts associated with PFAS, including supporting treatment infrastructure projects through the Drinking Water State Revolving Fund (DWSRF) and the Emerging Contaminant grant program as designated and funded through the Bipartisan Infrastructure Law (BIL).

Many commenters supplied information related to capital as well as operations and maintenance costs. Many commenters expressed concerns over potential costs and capacity while some commenters expressed the opposite opinion. These issues are further addressed in the EPA cost analysis in section XII and within the EPA's *Response to Public Comments on the Proposed PFAS NPDWR* (USEPA, 2024k). For additional discussion regarding the feasibility of the final MCLs, please see section V of this preamble above.

Many comments pointed to potential supply chain issues in both material and technical capacity such as qualified personnel, including certified operators. While there may be some supply chain issues in the short-term, comments from BAT suppliers indicate excess capacity as well as investment in production. Furthermore, while there may be temporary difficulties in supply chain and technical capacity, the structural demand increase is expected to lead to supply increases as well as innovation such as proposed technologies which were not designated as BATs. This has been historically demonstrated multiple times in prior drinking water rules. For example, activated alumina was listed as one of the BATs and a SSCT for arsenic removal in the Arsenic Rule (USEPA, 2001), and acknowledgement was given to granular ferric hydroxide media as a developing technology. While the granular ferric hydroxide media was not selected as a BAT/SSCT at the time due to lack of full-scale demonstration, these media became the predominant approach to addressing arsenic: Rubel (2003) stated that new iron-based materials could be ''employed economically on a spent media basis without the incorporation of pH adjustment chemicals and equipment.'' McCullough et al. (2005) cited over a dozen demonstration sites across the US implementing granular iron media treatment technologies, providing further supporting evidence that new technologies evolved in the wake of the Arsenic rule to provide more efficient and economical treatment

systems. Additionally, the present statutory standard for ''best available technology'' under 1412(b)(4)(D) represents a change from the provision prior to 1986, which required the EPA to judge feasibility on the basis of ''best technologies generally available'' (BTGA). The 1986 Amendments to the SDWA changed BTGA to BAT and added the requirement that BAT must be tested for efficacy under field conditions, not just under laboratory conditions. The legislative history explains that Congress removed the term ''generally'' to assure that MCLs ''reflect the full extent of current technology capability'' [S. Rep. No. 56, 99th Cong., 1st Sess. at 6 (1985)]. Read together with the legislative history, the EPA has concluded that the statutory term ''best available technology'' is a broader standard than ''best technology generally available,'' and that this standard allows the EPA to select a technology that is not necessarily in widespread use, as long as its performance has been validated in a reliable manner. Indeed, the 1991 Lead and Copper Rule stated, ''as long as it has been tested beyond the laboratory under full-scale conditions for other contaminants, and the performance of the technology for lead and copper may reasonably be projected based upon other available treatment data (*i.e.,* laboratory or pilot scale), the EPA believes the technology can be established as BAT.''

With respect to the challenges raised by commenters surrounding capital improvement, the EPA has provided compliance flexibility by providing a two-year capital improvements extension of the MCL compliance deadline allowed by section 1412(b)(10) of SDWA. Additionally, the EPA will continue its research as well as outreach efforts to help develop technical and operator capacities. For comments and additional information regarding the implementation timeframe for this rule, please see section XI.D.

Many commenters stated that permitting needs to be streamlined and that more assistance should be proffered to primacy agencies, utilities, and other interested stakeholders. While SDWA does not require permits, state and local authorities often require permits for the installation of treatment facilities at water systems. The EPA has developed supporting rule documents such as the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024l) that can be used to help permitting authorities develop more familiarity with these technologies over time. After finalization of the PFAS National Primary Drinking Water Rule (NPDWR), the EPA also intends to work with stakeholders to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

3. Final Rule

In the final rule, the EPA is codifying GAC, AIX, NF, and RO as BATs. The record does not support including additional BATs at this time. A BAT designation is informational, and while installation of the BAT is a condition of a variance under section 1415(a)(1)(A), systems without a variance are not required to use a BAT for MCL compliance. The owner/operator of a PWS will need to consider site specific circumstances as well as technical, economic, and local regulatory considerations when choosing a compliance technology for this rule. To address the challenges raised by commenters surrounding capital improvement, the EPA has provided a two-year compliance extension for capital improvements which is discussed in greater detail in section XI (*Rule Implementation and Enforcement*) and will continue its research efforts. The two-year capital improvement extension should also provide time for development of technical capacities and qualified personnel including certified operators. In response to public comment and in acknowledgement of residuals management concerns surrounding high pressure membrane separation technologies, the EPA is lowering RO/NF's technology projection compliance forecast in the EA. For comments and additional information related to the EPA's cost analysis, please see section XII. For comments and additional information regarding the implementation timeframe for this rule, please see section XI.D.

B. PFAS Co-Removal

1. Proposal

The EPA stated that AIX and GAC are effective at removing PFAS and there is generally a linear relationship between PFAS chain length and removal efficiency shifted by functional group. The EPA also notes that perfluoroalkyl sulfonates (PFSA), such as PFOS, are removed with greater efficiency than the corresponding perfluoroalkyl carboxylic acid (PFCA), such as PFOA, of the same carbon backbone length. Additionally, the compounds with longer carbon chains display a smaller percentage decrease in average removal efficiency over time (McCleaf et al., 2017). These same technologies also remove other long-chain and higher carbon/higher molecular weight PFAS as well as total organic carbon (TOC, DBP precursors). RO and NF may also remove other contaminants including arsenic, TOC, and chromium-VI. In short, the EPA noted that this regulation, if finalized, would result in a reduction of the six PFAS proposed for regulation, other co-occurring PFAS, and other co-occurring contaminants.

2. Summary of Major Public Comments and EPA Responses

A significant majority of commenters supported the EPA's position that treatment technologies which remove PFAS provide ancillary benefits by removing other known or potential contaminants. One commenter disputed the ability of these technologies to provide ancillary benefits, and others suggested that the EPA's proposed regulation would provide only limited protection against the many PFAS not under consideration in the rule. The EPA disagrees with the commenters who state that the proposed regulation would not result in a reduction in co-occurring PFAS and other contaminants. Burkhardt et al. (2023) used a theoretical approach [11] to estimate that all but one of the PFAS that are quantified by EPA Methods 533 and 537.1 could be economically removed by GAC in typical water qualities and that of 428 PFAS evaluated, 76–87 percent could be cost-effectively treatable. The co-removal benefits are well documented in the scientific literature and in the evidence submitted by public comment. The *Best Available Technologies and Technologies and Cost* support documents summarize literature demonstrating the co-removal capabilities of treatment technologies.

Some commenters stated that treatment for one PFAS does not inherently imply removal of other PFAS. The EPA agrees, as discussed in the proposed rule preamble. In general, there is an inverse relationship between treatability and toxicity which is tied to the carbon backbone (Bellia et al., 2023). Generally, the longer the carbon backbone length, the more easily the PFAS is removed by a given treatment technology. For example, if PFOA (C8) is targeted for removal by the water system, perfluorodecanoic acid (PFDA, C10) would most likely be removed as well. However, the converse would not

[11] While PFAS are often discussed as a group, the individual PFAS species can have a range of different removal efficacies using GAC. A theoretical approach for PFAS fills information gaps where analytical methods do not exist for all PFAS and testing is expensive and time consuming

be true (*i.e.,* a system targeting PFNA (C9) removal would reduce PFHxA (C6) to a lesser extent).

Some commenters suggested that co-removal would decrease the removal efficiency of GAC or AIX and that removal efficiency of non-target contaminants is lower than it could otherwise be. The EPA agrees that the removal of non-targeted contaminants by GAC or AIX can lower the PFAS removal efficiency; the agency has accounted for this uncertainty in appendix N of the EA (USEPA, 2024e). The EPA also agrees that targeting contaminants for removal will be more effective than relying on other non-targeted removal. For example, a GAC facility designed to remove PFAS will not be as effective at removing DBP precursors as a facility designed for that; however, there will still be co-removal of DBP precursors which may lead to a reduction in DBPs. Ultimately, treatment facilities operate best when tailored to specific contaminants or mixture of contaminants unique to that location. For additional information on the EPA's co-benefit analysis, please see section XII.

Some commenters expressed concern about co-removal taking beneficial ions from water, specifically fluoride ions, and suggested that would be an added cost to the rule. The EPA notes that fluoride has a legally enforceable MCL of 4.0 mg/L, and a non-enforceable secondary standard of 2.0 mg/L to prevent mild or moderate dental fluorosis. The EPA also notes that while some PFAS do contain organic fluorine bound to carbon, fluorine and fluoride are not the same. The BATs identified for the removal of PFAS for drinking water are not optimized for the removal of fluoride and do not necessarily provide effective removal of naturally occurring fluoride. For example, GAC is ineffective for fluoride removal at environmentally relevant pHs (USEPA, 2024o).

Some commenters suggested that co-removal may make it more difficult to dispose of materials left over from the drinking water treatment processes, known as treatment residuals. For example, GAC may remove and concentrate radon or other contaminants to such an extent that the spent media is considered hazardous. The EPA believes that removing hazardous constituents from drinking water is generally beneficial even though it could complicate residual management. More details on treatment residuals, are discussed in part C of this section.

Some commenters also suggest more research may be beneficial to understanding co-removal. The EPA agrees (USEPA, 2022c).

3. Final Rule

GAC, AIX, NF, and RO are codified in the final rule as BATs. As discussed elsewhere in the record for this final rule, because of PFAS co-occurrence and the ability for treatment technologies to co-remove co-occurring PFAS and other contaminants, the EPA anticipates the final rule will result in significant co-removal public health benefits in addition to those benefits from removing the six PFAS being directly regulated by this action.

C. Management of Treatment Residuals

1. Proposal

As part of the BAT evaluation, the EPA reviews full-scale studies that fully characterize residual waste streams and disposal options. The EPA found that the most likely management options for spent material containing PFAS is reactivation for GAC, incineration for spent IX resin, and for disposal of RO/NF retentate, treatment and discharge via a NPDES compliant facility to surface water or, sanitary sewer, or in limited circumstances, underground injection. Large volumes of spent GAC and AIX containing PFAS are periodically generated and must be removed which does not lend itself to on-site storage over time. The EPA stated that the disposal options identified in the 2020 *Interim PFAS Destruction and Disposal Guidance* (USEPA, 2020d) are landfill disposal, thermal treatment, and in limited circumstances, underground injection.

The EPA recognizes that future actions through statutory authorities other than SDWA may have direct or indirect implications for the residuals from drinking water treatment. Future hazardous waste listings for certain PFAS may limit disposal options for spent drinking water treatment residuals containing PFAS and/or potentially increase costs. A CERCLA designation as a hazardous substance does not restrict, change, or recommend any specific activity or type of waste (USEPA, 2022l). The EPA evaluated the potential impact on PWS treatment costs to PWSs associated with hazardous residual management should PFAS be listed as a hazardous waste in the future. For comments and additional information related to the EPA's cost analysis, please see section XII.

2. Summary of Major Public Comments and EPA Responses

While some commenters stated that more research can be beneficial to further our understanding of managing PFAS treatment residuals, others urged the EPA to proceed with this rulemaking as expeditiously as possible in the interest of public health. Others argued that the EPA should delay this action until the *PFAS Destruction and Disposal Guidance* is updated. The National Defense Authorization Act for Fiscal Year 2020, Public Law 116–92, section 7361, directs the EPA to revise the *PFAS Destruction and Disposal Guidance* triennially; the new destruction and disposal guidance is anticipated to be released approximately concurrently with this rule and further revisions may be expected before the effective dates for this rule. The EPA disagrees that the projected significant and direct public health protections for drinking water consumers in this rule should be delayed for the revision of guidance on management of PFAS waste streams.

Many commenters expressed concern that not enough was being done to manage spent drinking water treatment residuals containing PFAS at the end of their useful working life and that residual management amounted to media shifting (*i.e.,* taking PFAS from water via sorption media then landfilling that media does nothing to reduce the overall amount of PFAS). Many commenters stated that landfills and thermal treatment facilities can potentially be PFAS sources as the BATs in this rule are separative as opposed to destructive technologies.

The EPA notes that from a mass balance perspective, PFAS removal from drinking water is generally anticipated to result in lower concentrations of PFAS in the environment. With appropriate controls, landfills, and thermal treatment of PFAS contaminated media can minimize PFAS releases to the environment (USEPA, 2020d). Sorptive media can be incinerated or reactivated. There is also ongoing research into destructive and sequestration technologies that may help quantify the extent to which PFAS may be destroyed some of which is funded by the EPA (USEPA, 2022c).

Furthermore, it is also important to distinguish between a potential environmental release and a direct exposure. A PFAS release does not inherently imply human exposure and a release is not inherently risky to specific populations. From a risk management perspective, while the EPA acknowledges that while each destruction and disposal technology has limitations, a potential environmental release under point source management is anticipated to be a more health

protective alternative than human exposure through drinking water.

Some commenters recommended the EPA consider additional destruction and disposal technologies. The EPA notes that disposal and destruction technologies are currently available to manage drinking water residuals. The EPA appreciates the example destructive technologies, and while beyond the scope of finalizing this NPDWR, the agency intends to consider additional destruction and disposal technologies in future destruction and disposal guidance.

Many commenters, including destruction and disposal trade associations, stated there would be difficulties managing spent residuals containing PFAS generated from drinking water treatment. In contrast, other commenters stated that there was existing national capacity and at least one company stated they were actively evaluating investment for additional capacity to handle residuals. The record demonstrates that there is existing national capacity to handle spent drinking water residuals containing PFAS in a manner that minimizes risk to human health. Destruction and disposal of PFAS-containing materials is currently not subject to certain hazardous waste regulation and therefore the materials may be managed in non-hazardous and hazardous waste treatment and disposal systems (USEPA, 2020d). Hazardous waste is regulated pursuant to RCRA authority 42 U.S.C. 6921–6939 (also known as RCRA ''Subtitle C''). The regulatory definition of hazardous waste is found in 40 CFR 261.3. PFAS are currently not a listed hazardous waste or characterized as a hazardous waste, but a PFAS-containing waste may meet the regulatory definition of hazardous waste if PFAS is mixed with a listed hazardous waste or if a PFAS-containing mixture exhibits a hazardous characteristic (*e.g.,* corrosivity or another characteristic stemming from the material that is mixed with PFAS). PFAS which are commingled with hazardous substances and/or hazardous wastes will be subject to the appropriate rules and regulations and may be included as Applicable or Relevant and Appropriate Requirements on a site-specific basis. Not all disposal sites may be appropriate for spent drinking water treatment residuals containing PFAS and the EPA strongly encourages owners and operators of treatment facilities to refer to appropriate and up-to-date guidance on treatment residual management such as the *2020 Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances* (USEPA, 2020d) and subsequent updates.

The EPA anticipates approximately 226,500 short tons of spent drinking water media such as activated carbon and AIX resin to be generated annually as a result of this rule; in calendar year 2018 alone, the U.S. generated about 290 million short tons of waste (USEPA, 2022m). The increase in total waste caused by this action is approximately 0.08% of the total U.S. waste produced. This is a minor change in aggregate waste produced; the same amount as a pound contributes to a ton. Even if PFAS were to be designated in the future as regulatory hazardous waste, there is existing capacity to handle these waste streams through existing hazardous waste facilities in every state. Some water systems may have to ship hazardous wastes significant distances; however, the main cost driver is disposal fees not transportation. The EPA rejects the assertion that it has not evaluated if sufficient capacity exists for disposal and storage of PFOA and PFOS contaminated materials. The EPA also acknowledges that CERCLA section 104(c)(9) does not allow the agency to initiate a remedial action, unless the state first enters into a state Superfund State Contract or Cooperative Agreement (CA) that assures the availability of adequate capacity to manage hazardous wastes generated in the state for 20 years following the date of the response agreement. The EPA's rulemaking designating PFOA and PFOS as CERCLA hazardous substances, if finalized, does not impose any capacity concerns that require further action under section 104(c)(9). In that action, the EPA is designating PFOA and PFOS as CERCLA hazardous substances. No PFAS are currently listed, or being proposed to be listed, as hazardous wastes under RCRA. The 2021 *Biennial Report Summary Results* indicate about 18 million tons of hazardous wastes are normally generated annually. Drinking water treatment materials then would constitute about a 1.26% increase in hazardous wastes generated annually. Since there is over twenty years' capacity, the relatively small magnitude of the increase indicates that waste management capacity is sufficient in the short term should PFAS be designated as regulatory hazardous wastes.

Many commenters conveyed concern over the cost of drinking water residuals management resulting from finalizing this rule. The EPA conducted an EA to help address these concerns. For comments and additional information related to the EPA's cost analysis, please see section XII.

While no PFAS are currently listed as regulatory hazardous wastes under RCRA, in response to stakeholder feedback, the EPA included a sensitivity analysis to determine the impact on water systems should they be required to handle and dispose of PFAS treatment materials as hazardous waste in the future. The results of this analysis can be found in the EA for this rule (USEPA, 2024g). Some commenters suggested that accounting for future potential regulations is uncommon, and trying to account for all potential future contingencies would make economic analyses impossible. The EPA strongly agrees and has not attempted to do so here; this analysis was limited to looking at a hypothetical future hazardous waste listing situation because that has been of particular concern in this rule. Some commenters stated that the EPA should account for the public health benefits of treating PFAS as hazardous wastes, not just additional costs incurred. The EPA agrees and has modified the analysis to include a qualitative statement about the public health benefits which could potentially arise from treating PFAS as hazardous wastes. Many commenters stated that the EPA hazardous waste cost would drive the total cost higher than the 3–5% estimated by the EPA. After considering public comment, the EPA has revised the final cost estimates in this rule. The EPA estimated increased cost would be approximately $99M at the 2% discount rate. The increased cost was driven by updating the dollar year of cost curves from 2021 to 2022 which increased waste management unit costs by approximately 12%; implementing a cap on media life even if not indicated; changing the technology compliance forecast by eliminating RO/NF while increasing GAC and AIX (thereby increasing spent media volume); and increasing occurrence estimates for the final rule compared to the proposed rule, triggering more systems into treatment. The increased costs were not driven by changes to unit cost estimates for hazardous waste management. The EPA believes its assessment is accurate; the total cost encompasses capital costs, maintenance, design, and operations, including waste management. Waste management costs are thus a subset of operational cost which in turn is a subset of total costs; generally, changes in the cost of one subcomponent would not significantly influence total costs, and the record does not reflect that a change in waste disposal costs would

have a significant impact on total costs under this rule. These estimates are discussed in greater detail in the HRRCA section of this rule and in appendix N of the EA (USEPA, 2024e).

Many commenters suggested that regulations under other statutes, particularly a potential CERCLA hazardous substance designation, will increase disposal costs. The EPA disagrees that, if finalized, the CERCLA hazardous substance designation for PFOA and PFOS will increase disposal costs for water treatment facilities. The designation of PFOA and PFOS as CERCLA hazardous substances would not require waste (*e.g.,* biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any specific particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. Along with other release notification requirements, CERCLA designation would require that any person in charge of a vessel or facility report a release of PFOA and/or PFOS of one pound or more within a 24-hour period. The EPA does not expect spent drinking water treatment residuals containing PFAS to be released into the environment at or above the reportable quantity as a part of standard residuals management practices used by water systems. This is because the PFAS loading onto sorptive media is very small. The weight percent of PFAS onto GAC under normal treating scenarios will vary widely; however, a reasonable order of magnitude estimate is 1×10^{-5} grams PFAS per gram of sorbent in full-scale applications. High pressure membranes split water into a treated stream and concentrated waste stream. The concentrated waste stream will contain about 5–12 times more PFAS than the influent which is likely to still be in the ng/L scale. A drinking water facility which takes reasonable precautions is unlikely to release enough low concentration residuals to release one pound of PFOA and/or PFOS within a 24-hour period. At the concentrations discussed above, to exceed a one-pound threshold, a facility using sorptive techniques would have to release approximately 50 tons of sorbent, within a 24-hour period. A one-pound uncontrolled release from RO or NF facilities, assuming 500 ng/L of PFAS in the reject water, would require approximately 240 million gallons of high-pressure membrane concentrate to be released within 24 hours. Additionally, neither a release nor a report of a release automatically requires any response action under CERCLA. The EPA makes CERCLA response decisions based on site-specific information, which includes evaluating the nature, extent, and risk to human health and/or the environment from the release. Hazardous substance designations do not automatically result in CERCLA liability for any specific release. Whether an entity may be subject to litigation or held liable under CERCLA are site-specific and fact-dependent inquiries. Likewise, CERCLA affords the Federal Government broad discretion as to whether or how to respond to a release. For those reasons, the EPA cannot assess with reasonable certainty what litigation or liability outcomes may indirectly result from this designation since those outcomes are often linked to the EPA's discretionary decisions with respect to CERCLA response actions as well as site-specific and fact-dependent court rulings.

Many commenters suggested that high pressure membranes, which separate PFAS from one stream and concentrate it in another stream, may not be feasible as a BAT because utilities treating and discharging reject water from high pressure membranes typically require a NPDES permit. The EPA disagrees because there are currently full-scale facilities which use this technology to treat PFAS and high-pressure membranes may be the best viable option in a multi-contaminant setting. The brine may undergo further pre-treatment as part of a process train to enable discharge, such as GAC or AIX treatment. Some RO/NF applications discharge directly to surface water or through an interconnection to a wastewater treatment plant. The EPA, however, does agree that brine treatment or disposal may be challenging and in 2022, the EPA issued memorandum that recommended NPDES and POTW pretreatment program permitting conditions for PFAS discharges (USEPA, 2022d; USEPA, 2022e). In conclusion, in limited applications, high pressure membranes may still serve as a viable treatment strategy, such as for facilities with access to brine treatment or disposal.

Some commenters suggested that reactivation was not permissible under the *2020 Interim PFAS Destruction and Disposal Guidance* or that interim storage was required. Commenters are incorrect in their interpretation of the plain language in that guidance. The guidance does not state that reactivation or thermal treatment are prohibited. The guidance does acknowledge a need for further refinement and research and that interim storage may be an option if the immediate dispensation of PFAS-containing materials is not imperative. However, nowhere does that guidance mandate interim storage or prohibit other forms of PFAS destruction and disposal.

3. Final Rule

The final rule does not specifically require any specific destruction or disposal practices for spent media containing PFAS. The EPA has considered residual waste streams and disposal options and found that management options exist for treatment residuals containing PFAS.

D. What are Small System Compliance Technologies (SSCTs)?

1. Proposal

Section 1412(b)(4)(E)(ii) requires that the agency identify SSCTs, which are affordable treatment technologies, or other means that can achieve compliance with the MCL. The EPA identified SSCTs using the affordability criteria methodology developed for drinking water rules (USEPA, 1998b) and proposed the following table which shows which of the BATs listed above are also affordable for each small system size category listed in section 1412(b)(4)(E)(ii) of SDWA.

Table 23: Proposed SSCTs for PFAS Removal

System Size (Population Served)	GAC	IX	RO/NF	Point of Use (POU) RO/NF [1]
25-500	Yes	Yes	No	Yes
501-3,300	Yes	Yes	No	Yes
3,301-10,000	Yes	Yes	Yes	not applicable [2]

Notes:

[1] POU RO is not currently listed as a compliance option.

[2] Implementing and maintaining a large-scale POU program is likely to be impractical.

Point-of-use (POU) and point-of-entry (POE) were not listed as compliance options because the regulatory options under consideration require treatment to concentrations below the current NSF International/American National Standards Institute (NSF/ANSI) certification standard for POU device removal of PFAS. As the EPA has determined that affordable SSCTs are available, the agency is not proposing any variance technologies.

2. Summary of Major Public Comments and EPA Responses

Many commenters stated that the POU/POE water treatment industry may already have multiple products that can reduce PFAS chemicals to below the proposed MCL. Additionally, some commenters stated that the influent used (*i.e.,* the challenge water) to test these POU/POE products often contains much higher concentrations of PFAS than would normally be found in most source waters. Commenters also pointed out that under NSF/ANSI, 53 and 58 certifications exist for total PFAS (PFOA, PFOS, PFHxS, PFHxA, and PFDA), as well as PFHpA, PFHxS, and PFNA individually. However, SDWA section 1412(b)(4)(E)(ii) requires that SSCTs achieve compliance with the MCL or treatment technique. While devices certified to the NSF/ANSI standards must be demonstrated to significantly reduce PFAS concentrations and, in many cases, can reasonably be expected to treat below this rule's MCLs, the current standards and certification procedures do not assure compliance with this rule. In particular, PFBS and HFPO–DA, have no certification standards at this time and the certification standards for PFOA, PFOS, and PFHxS are above this rule's MCL. The certification standards for PFOA, PFOS, and PFHxS are 20 ng/L, compared to the MCLs of 4.0 ng/L for PFOA and PFOS, as well as 10 ng/L for PFHxS; the total PFAS certification standard is 20 ng/L effluent comprised of PFOA, PFOS, PFHxS, PFHxA, and PFDA compared to a Hazard Index of 1 for mixtures of PFHxS, PFNA, HFPO–DA and PFBS. Since the NPDWR has standards that NSF/ANSI are currently unable to verify, POE/POU technologies could potentially not achieve compliance contrary to SDWA section 1412(b)(4)(E)(ii) which requires that SSCTs achieve compliance with the MCL. While POU/POE technologies may provide significant levels of protection, and the EPA anticipates they will eventually comply with the NPDWR, there is not yet a systematic verification process in place for the level of protection provided by these devices. As mentioned in the proposal, the EPA is aware that the NSF/ANSI Drinking Water Treatment Unit Joint Committee Task Group is in the process of updating their standards; should these future standards meet the NPDWR, the EPA could revise the SSCT list to include POE/POU.

Many commenters also correctly pointed out numerous challenges surrounding POU/POE as a compliance option for some PWSs such as resident cooperation, operation and maintenance, monitoring, and implementation of distributed treatment approaches. The EPA agrees implementation of POU/POE as a compliance option for any NPDWR can be challenging for some PWSs but also agrees with commenters who noted that POU/POE can provide flexibility and compliance options to very small water systems or certain NTNCWS such as schools, factories, office buildings, and hospitals that provide their own water.

The EPA received many comments that other POU devices other than RO/NF should be acceptable ways to meet the MCLs for small systems. For instance, commenters noted that a combination GAC/AIX device with filters could reduce PFAS concentrations to below the MCL values. The EPA agrees and has changed wording in the final rule preamble and related supporting documents that implied that only RO/NF POU devices would be able to meet a future certification standard. The EPA notes that for small systems, as long as the proposed POU/POE devices are certified by an appropriate third-party certifier (*e.g.,* ANSI/NSF) to meet the regulatory MCL, they would meet the requirements of this regulation. The EPA also received many requests to change the way data was displayed in tables 20 and 22 of the proposed rule which summarized proposed SSCTs for PFAS removal and total annual cost per household for candidate technologies. In the proposal, the EPA wrote that this data was ''Not Applicable'' because of the economies of scale for centralized treatment. While the EPA still believes that a POU program that large is likely to be impractical, the EPA has changed the way this is displayed by replacing the term ''Not Applicable'' with ''Data Unavailable.'' The EPA notes that neither of these changes imposes nor relieves any rule requirements and only serve to recharacterize the way the EPA reports available technologies.

The EPA asked for comment on the national level analysis of affordability of SSCTs and specifically on the potential methodologies presented in the EA for the proposed rule section 9.12. A couple of commenters recommended the EPA not use median household income (MHI) in the affordability analysis. The EPA decided to retain the MHI measure of income in its primary national level SSCT affordability methodology, and specifically use 2.5% of the MHI as the affordability threshold, given the value is easily understandable and available, providing a central tendency for income which is representative of a whole community's ability to pay and is not unduly influenced by outlier values. However, in this rule, the EPA

recognizes the value in examining alternative measures of a community's ability to afford an SSCT, so the agency chose to include supplemental analyses that use alternative metrics, specifically 1% of MHI, 2.5% of lowest quintile income (LQI), and an analysis accounting for financial assistance. See chapter 9.13.2 of the EA for more details. These supplemental analyses help to characterize affordability when considering the marginal impact, disadvantaged community groups, and subsidization.

Some commenters stated that the data the EPA used to inform current water rates from the 2006 Community Water System Survey (CWSS) is outdated. While dated, the data from the 2006 CWSS remains the best available dataset for this national level analysis and affordability determination for the following reasons: (1) the CWSS survey used a stratified random sample design to ensure the sample was representative and (2) these responses can be extrapolated to national estimates since the survey has a known sampling framework; and the data can be organized by system size, source, and ownership (USEPA, 2020e).

Some commenters recommended the EPA extend the affordability analysis to medium and large systems. The EPA disagrees with this recommendation, as the purpose of this analysis is to determine if available SSCTs are affordable, per SDWA section 1412(b)(4)C(ii). Therefore, the EPA chose to continue to analyze small system technologies rather than include medium and large systems.

Some commenters specifically disagreed with one of the EPA's supplemental affordability analyses that examined the impact of the rule when accounting for the financial assistance through BIL and other sources that are generally available to small systems. These commenters stated that the EPA should not assume that this funding will be available or enough to cover the small system capital costs associated with the rule. The EPA conducted this supplemental analysis in response to the recommendations of the SAB, which stated, ''[i]f this funding is readily available to many or most systems facing affordability problems, it seems appropriate to take the availability of this funding into account in determining national level affordability.'' (USEPA, 2002b) The EPA disagrees with these commenters as this significant funding will be generally available, and the EPA continues its efforts to help PWSs access it. It is therefore reasonable to consider the burden reduction in the supplemental affordability analysis.

Some commenters disagreed with the EPA's affordability determination because they stated it was based on inaccurate treatment cost information. A couple of commenters presented their own estimates for small system household costs and compared these estimates to the EPA's affordability threshold and concluded the rule is unaffordable. The EPA disagrees with many of the underlying assumptions in the commenters' cost estimates which, on whole, result in overestimated household costs, see section XII.A. These commenters cited cost information that is not representative of the range of treatment costs nationally, and the EPA disagrees with the commenter's cost model that systematically overestimates capital operation and treatment costs. The EPA updated the affordability analysis for the national affordability determination using the updated treatment cost curves (discussed in section XII.D) and found for systems serving between 25 and 500 people, that the upper bound estimated annual household treatment costs for GAC exceed the expenditure margin. Lower bound estimated annual household treatment costs for GAC do not exceed the expenditure margin; for more information see section XII. These exceedances are primarily driven by capital costs and attributable to the use of high-cost materials (*e.g.,* stainless steel) in the upper bound estimates. Systems using low-cost materials, but with source water characteristics otherwise set to the upper bound (*e.g.,* influent PFAS at approximately 7,000 ng/L, influent TOC at 2 mg/L), would fall below the expenditure margin. Although costs increase in some scenarios, the increases are not significant enough to change the conclusions about affordability. The small system compliance technologies available to meet the requirements of the final rule are affordable for all small systems when the technologies do not use the high-end materials. Technologies that do not use high end materials may be less durable but nonetheless are available for small systems and can meet the requirements of the final rule. For more information on the EPA's response to comments on treatment costs see section XII. The EPA also disagrees that there are no affordable compliance technologies for small systems as the EPA has demonstrated that SCCTs are available below the affordability threshold using the best available peer reviewed information to support the agency's cost estimates.

3. Final Rule

The final rule includes sorptive devices as well as combination devices, should they meet third party verification standards and the MCL. In USEPA, 2024l, the EPA also changed the way data are presented by replacing the term ''Not Applicable'' with ''Data Unavailable'' in response to public comment. Finally, the final affordability analysis reflects updates made to the unit cost curves after considering public comments. The EPA has determined that affordable SSCTs are available that meet the requirements of the final rule (see table 6 to paragraph (e) of 40 CFR 141.61).

The EPA's affordability determination for the final rule, using long standing EPA methodology and supplemental affordability analyses can be found in the EA chapter 9.12.

The EPA notes that POU RO devices are not currently listed as a SSCT because the NPDWR requires treatment to concentrations below the current NSF International/American National Standards Institute (NSF/ANSI) certification standard for POU device removal of PFAS. However, POU treatments are reasonably anticipated to become a compliance option for small systems in the future if NSF/ANSI develop a new certification standard that mirrors or is more stringent than the final regulatory standards. Other third-party entities including NSF can independently certify drinking water treatment units (DWTUs) that meet these standards. NSF/ANSI is considering lowering its current standard to levels closer to final standards in this NPDWR. Based on efficacy of reverse osmosis technology, RO POU devices can reasonably be anticipated to remove the majority of PFAS when they are properly designed and maintained. Other POU devices (*e.g.,* activated carbon) may also meet future EPA PFAS regulatory limits. These devices would also need third-party testing and certified against the regulatory standards. Further, the EPA notes that water systems may use any technology or practice to meet the MCLs promulgated in this NPDWR and are not limited to the BATs nor SSCTs discussed in this section. Other technologies or nontreatment options may be chosen in lieu of a BAT or SSCT because they may be more cost effective or better suited to the specific operating conditions of the particular site to meet any MCL.

XI. Rule Implementation and Enforcement

A. What are the requirements for primacy?

1. Proposal

SDWA section 1413 establishes requirements that primacy agencies (states, Tribes and territories) must meet to have primary enforcement responsibility (primacy) for its PWSs. These include: (1) adopting drinking water regulations that are no less stringent than Federal NPDWRs in effect under sections 1412(a) and 1412(b) of SDWA; (2) adopting and implementing adequate procedures for enforcement; (3) keeping records and making reports available on activities that the EPA requires by regulation; (4) issuing variances and exemptions (if allowed by the state) under conditions no less stringent than allowed by SDWA sections 1415 and 1416; and (5) adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations. The regulations in 40 CFR part 142 set out the specific program implementation requirements for states to obtain primacy for the Public Water System Supervision (PWSS) Program, as authorized under section 1413 of the Act.

Under 40 CFR 142.12(b), all primacy agencies are required to submit a revised program to the EPA for approval within two years of promulgation of any final PFAS NPDWR or request an extension of up to two years in certain circumstances. To be approved for a program revision, primacy agencies are required to adopt revisions at least as stringent as the revised PFAS-related provisions. To obtain primacy for this rule, primacy applications must address the general requirements specified in subpart B of part 142. The EPA proposed special primacy requirements for the PFAS NPDWR (§ 142.16(r)), to outline additional requirements for a primacy agency related to identifying its plan for implementing the initial monitoring requirements.

2. Summary of Major Public Comments and EPA Responses

The EPA received one comment that most of the initial monitoring may occur before primacy applications will be submitted, which are not due until two years after final rule promulgation. A couple of commenters assert that it is unclear why states are required to include an initial monitoring plan in their primacy application and that states will not be able to implement and demonstrate that this monitoring plan is enforceable under state law until state regulations have been promulgated. The EPA recognizes that some initial monitoring by water systems may occur prior to a state, territory, or Tribe receiving the EPA approval for primacy and agrees with the commentor that for states to develop a monitoring plan that addresses when systems will be scheduled to conduct initial monitoring is not a necessary requirement for a primacy application. However, where states are approved for primacy before the compliance date for the water systems, primacy agencies should have procedures for evaluating whether data that a CWS or NTNCWS submits to satisfy the initial monitoring requirements are acceptable. It is therefore appropriate to require primacy agencies to include in their primacy application a description of their procedures for reviewing water system's use of pre-existing data to meet initial monitoring requirements, including the criteria that will be used to determine if the data are acceptable and the primacy agency's procedures for ensuring water system compliance within the required timeframes. The compliance deadline for this initial monitoring by systems is three-years from promulgation, by which time primacy agencies should have primacy or interim primacy. To address the possibility that a state, Tribe, or territory may get an extension to apply for primacy, the final rule provides that these special primacy requirements are not applicable after the initial monitoring deadline (*i.e.,* three years after publication of the rule in the **Federal Register**). When a primacy agency does not yet have primacy for a new drinking water rule, an NPDWR is nonetheless applicable to water systems and may be enforced by the EPA following the compliance dates specified in § 141.900(b).

3. Final Rule

The EPA is revising the requirements for primacy as proposed in 40 CFR 142.16(r) by removing the requirements to develop an initial monitoring plan, although the EPA is finalizing the proposed requirement for primacy agency procedures for ensuring all systems complete the initial monitoring period requirements, including for determining whether pre-existing data are acceptable, but clarifying that these requirements would not apply after the deadline for initial monitoring has passed (*i.e.,* three years after publication of the rule in the **Federal Register**). The EPA also corrected two grammatical errors. In the final rule, the EPA requires that a PWS complete the initial monitoring by three years following date of promulgation (for additional discussion on monitoring and compliance requirements, please see section VIII of this preamble). It is the EPA's expectation that primacy agencies will have completed the requirements for primacy within the two years (*i.e.,* without an extension) and in that case, they will have the authority in place to ensure that systems comply with the initial monitoring requirements. If a primacy agency is applying for primacy after the deadline for initial monitoring has passed, then the requirement is no longer applicable. In that case, an NPDWR is nonetheless applicable to water systems and implementation would be overseen and enforced by the EPA consistent with any agreements with the state pursuant to the primacy application extension approval.

B. What are the record keeping requirements?

1. Proposal

The current regulations in 40 CFR 142.14 require primacy agencies to keep records of analytical results to determine compliance, system inventories, sanitary surveys, state approvals, vulnerability and waiver determinations, monitoring requirements, monitoring frequency decisions, enforcement actions, and the issuance of variances and exemptions. The primacy agency record keeping requirements remain unchanged and would apply to PFAS as with any other regulated contaminant.

2. Summary of Major Public Comments and EPA Responses

The EPA received a few comments about the record keeping that primacy agencies must maintain for compliance determinations and reporting, storing PWS facility data, tracking monitoring schedules, and keeping the public informed of the quality of their drinking water. As noted in the comments, most primacy agencies rely on SDWIS, developed by the EPA, to support this record keeping requirement. It was recommended that the EPA develop a data system, either SDWIS or a replacement, that is capable of fully managing the data associated with the proposed rule. Further, it was recommended that the EPA develop data management solutions such as a mechanism for migrating UCMR data into SDWIS State to reduce or eliminate the burden of ensuring compliance with the initial monitoring. The EPA agrees that appropriate data management solutions are needed to effectively comply with SDWA requirements; however, the agency does not believe

these systems must be available at the time of rule promulgation. Additionally, while beyond the scope of this rulemaking itself, the EPA is actively working on PFAS data management solutions, including DW–SFTIES support and potentially updating the SDWIS suite of applications to manage data reported from this rule.

3. Final Rule

The primacy agency record keeping requirements in 40 CFR 142.14 remain unchanged and would apply to PFAS as with any other regulated contaminants. Water system recordkeeping requirements are referenced within subpart Z in § 141.904. In the final rule, the EPA updated this regulatory text to cross-reference the record retention provisions in § 141.33. The EPA is developing the Drinking Water State-Federal-Tribal Information Exchange System (DW–SFTIES) that will support all SDWA drinking water rules. The EPA plans to continue to provide support for necessary updates to SDWIS State, including for reporting requirements for new rules, until the DW–SFTIES is in production and in use by primacy agencies. SDWIS State support and updates will continue until the DW–SFTIES Board recommends a sunset date after DW–SFTIES is in production and in use by primacy agencies. The EPA will evaluate the migration of UCMR data into the suite of SDWIS applications.

C. What are the reporting requirements?

1. Proposal

Under 40 CFR 142.15, primacy agencies must report to the EPA information regarding violations, variances and exemptions, enforcement actions, and general operations of state PWS programs. The primacy agency reporting requirements remain unchanged and would apply to PFAS as with any other regulated contaminant. The water system reporting requirements are mentioned in § 141.904 and cross-reference the reporting timeframes and provisions in § 141.31.

2. Summary of Major Public Comments and EPA Responses

A few commenters recommended that the EPA provide Data Entry Instructions within six months of the promulgation of the rule to allow primacy agencies, particularly those that do not use SDWIS State, to implement their data systems for reporting to the EPA, prepare their PWS, and train staff. The EPA acknowledges this comment and will work to develop Data Entry Instructions as soon as possible. One commentor recommended that the EPA provide separate tracking of reporting and monitoring violations. The EPA acknowledges this comment and will consider this as data reporting tools are developed. A couple of commentors recommended that the reporting and recordkeeping requirements for compliance within the rule should provide an option for not requiring the RAA to be reported by the laboratories if the primacy agency performs the RAA calculations for the water system. In addition, one commenter requested that the primacy agency calculate the RAA, and another commentor inquired whether the EPA intended to allow the water systems not to perform the RAA calculations if the primacy agency performs the RAA calculations. The EPA disagrees with these comments. To ensure that the water system has immediate knowledge of their compliance status, the final rule requires that water systems calculate the RAA and report this to the primacy agency. Primacy agencies or laboratories may also calculate the RAA, to confirm the results of the water system, but it is not a required reporting element under this regulation. Lastly another commentor suggested that utilities be required to report the occurrence and concentration of other PFAS listed in the method (preferably 533) to facilitate data collection and to better inform water treatment objectives. The EPA notes that many water systems are currently collecting samples and reporting monitoring data for 29 PFAS that can be measured with EPA Methods 533 and 537.1 under UCMR 5 where EPA has the regulatory authority.

3. Final Rule

The reporting requirements for primacy agencies under 40 CFR 142.15 remain unchanged and apply to PFAS as with any other regulated contaminant. The EPA intends to develop and provide access to Data Entry Instructions within one year after rule publication. The EPA will follow the usual protocol of engaging with a State-EPA workgroup for drafting the Data Entry Instructions. In this process, the EPA will consider the use of separate monitoring and reporting violation codes, like is used for the Revised Total Coliform Rule (RTCR). In this final regulation, the cross-reference to the water system reporting timeframes and provisions in § 141.31 at the start of § 141.904 is retained, and, at 40 CFR 141.904(b), table 2, the EPA requires water systems to report PFAS RAAs to their primacy agency. As a general process, the laboratory will conduct the analysis of the sample and the system will use the result to calculate their RAA; the RAA calculation may subsequently be completed by the primacy agency as a compliance check. The EPA does recognize that state laboratories often directly report results to the state as allowed in 40 CFR 141.31(c) and that electronic reporting tools, such as the Compliance Monitoring Data Portal (CMDP), may be used by systems to comply with this reporting requirement.

D. Exemptions and Extensions

1. Proposal

Pursuant to SDWA section 1412(b)(10), the EPA proposed that all systems must comply with the NPDWR three years after rule promulgation. The EPA's proposal acknowledged that a primacy agency or the EPA may grant an extension of up to two additional years to comply with an NPDWR's MCL(s) if the primacy agency or the EPA determines an individual system needs additional time for capital improvements. The EPA stated that ''[a]t this time, the EPA does not intend to provide a two-year extension nationwide.'' 88 FR 18689. The proposal also discussed how a state which has primary enforcement responsibility may exempt any individual system facing compelling factors, such as economic factors, additional time to comply with any requirement respecting an MCL of any applicable NPDWR under SDWA section 1416 (USEPA, 2023f).

2. Summary of Major Public Comments and EPA Responses

SDWA section 1412(b)(10) requires that a ''NPDWR shall take effect ''3 years after the date on which the regulation is promulgated unless the administrator determines that an earlier date is practicable.'' Section 1412(b)(2) also authorizes ''the Administrator, or a State (in the case of an individual system), may allow up 2 additional years to *comply with a maximum contaminant level* . . . if the Administrator or the State . . . determines that additional time is necessary for capital improvements'' (emphasis added). Congress intended the extension under this provision to allow for a total of five years to comply with the MCL. Thus, if the EPA provides a two-year extension of the MCL compliance deadline for all systems based on the need for capital improvements, a state cannot provide an additional two-year extension under section 1412(b)(10) for capital improvements but may grant exemptions under section 1416

consistent with applicable requirements.

Many commenters, including utilities and state primacy agencies, expressed difficulty in meeting the three-year compliance deadline. Commenters expressed that it will be very challenging to both conduct initial monitoring and take actions (*e.g.,* installing treatment) to comply with the MCL within three years. Many of these commenters shared their on-the-ground experience in managing facilities that required capital improvements and provided evidence that additional time is needed to procure, design, pilot, permit, and ultimately construct treatment systems. Additionally, several commenters provided evidence of on-going labor and workforce challenges as well as recent experience with supply chain difficulties to obtain materials necessary to design and construct treatment facilities, which many attributed as a direct or indirect result of the COVID-pandemic residual impacts (AWWA, 2023).

The agency has evaluated the data and information shared by commenters regarding their experience with the time it takes to implement capital improvement projects. The EPA estimates that approximately 4,100–6,700 systems will be impacted by the MCLs in this final rule. Based on the EPA's initial compliance forecast, the agency anticipates that many of these systems will be installing advanced treatment technologies to meet the final PFAS standards (for additional discussion on the compliance forecast, please see section XII). The treatment technologies listed as BAT for the final rule include GAC, ion exchange resins, and centralized RO/NF (please see section X for more information). To ensure cost effective compliance with the PFAS MCLs, systems often need to evaluate their treatment technology options as a first step. Several commenters have noted that this planning step may include pilot studies with potential treatment systems, or it may be limited to an evaluation of the raw water characteristics. Further, some commenters have submitted data and project management plans for systems choosing to conduct pilot testing, indicating that it may take a year or more to contract with vendors and to perform pilot testing. Once the planning step is completed, systems must design and construct the treatment systems. Several commenters submitted information to the EPA indicating that the design and permitting of the treatment systems can take an additional year or longer, and construction of the treatment system can take another year or longer. Because systems will also need time to obtain funding, obtain local government approval of the project, or acquire the land necessary to construct these technologies, many commenters contend that systems will need additional time beyond the three-year effective date to comply with the MCLs.

While the EPA stated in the proposed rule that the agency did not intend to provide a two-year extension nationwide necessary for capital improvements, the EPA finds that the evidence submitted by commenters strongly supports that a significant number of systems covered by this rule will need two additional years to make capital improvements to meet the MCL. Specifically, the EPA reviewed data from applicants seeking DWSRF funding for capital improvement projects (*e.g.,* installation of advanced treatment technologies such as GAC or IX) and confirmed that these projects, on average, take about three or more years to complete (which excludes the time and activities that may occur to ensure these capital improvement projects are implemented successfully, such as the time it may take to secure funding or to conduct pilot testing). This evidence along with the breadth of practicable experience shared by utilities and primacy agencies demonstrate that additional time is necessary for a significant number of system sizes and types located throughout the country to make capital improvements. Additionally, the EPA notes that the number of systems estimated to be impacted by the MCLs are greater than what the agency anticipated in the proposal (*i.e.,* an increase from 3,400–6,300 systems to 4,100–6,700 systems nationally). This increase provides further evidence that a capital improvement extension is warranted as the agency expects that many of these systems will be installing advanced treatment technologies to meet the final PFAS standards. The agency also agrees with commenters that on-going labor and workforce challenges exist and can limit the ability to design, construct and operate treatment facilities. These workforce challenges facing water utilities and other sector organizations support the need for a capital improvement extension as a sufficient availability of qualified personnel is necessary to implement and sustain capital improvement projects. These issues may be attributed as a direct or indirect result of the recent COVID–19 pandemic and are clearly documented in data submitted to the agency as part of the public comment process (AWWA, 2023). Based upon these considerations, the EPA determined, in accordance with section 1412(b)(10) of SDWA, that the compliance date for the PFAS MCLs, regardless of system size, will be 5 years from the date of promulgation of the standard.

Some commenters recommend the EPA to follow a staggered implementation timeframe similar to what was done in some previous NPDWRs where compliance deadlines were staggered based on system size (USEPA, 2001; USEPA, 2006a). In these prior examples, larger systems typically conducted their monitoring and implemented the MCL first, followed by smaller systems. Upon consideration of information submitted by commenters, particularly issues related to supply chain complications that are directly or indirectly related to the COVID–19 pandemic residual challenges, the EPA has determined that a significant number of systems subject to the rule, including large systems, will require two additional years to complete the capital improvements necessary to comply with the MCLs for PFAS regulated under this action. For this reason, the EPA disagrees with commenters that staggered implementation based on system size is warranted for this rule. While large systems may have greater resources to implement capital improvements (*e.g.,* engineering and construction management staff to manage the projects), they still require time to design, pilot, permit, and construct treatment facilities.

Some commenters note that it will be challenging for systems to conduct their initial monitoring and install treatment within three years, particularly for those systems not conducting UCMR 5 monitoring that is ongoing until 2026. The EPA notes that the agency is finalizing a flexibility for systems to use previously acquired monitoring data from UCMR 5 or an equivalent state-led monitoring program for their initial monitoring which is intended to alleviate the burden placed on water systems in collecting additional data (see section VIII of this preamble for additional information on monitoring). While the agency agrees that systems need an additional two years to make capital improvements, the EPA finds that it is practicable for most systems to complete their initial monitoring within three years because all systems serving greater than 3,300 people will have appropriate monitoring data from UCMR 5. Many systems smaller than 3,300 people will also have appropriate monitoring data from state-led

monitoring programs that may be eligible to meet the rule's initial monitoring requirements, and some will have UCMR 5 or other data. If systems find elevated levels of PFAS, these systems have an additional two years to comply with the MCL. If a system does not have eligible previously collected monitoring data and are concerned about insufficient time to install capital improvements, the EPA encourages these facilities to collect monitoring data as soon as possible after rule promulgation, allowing them the bulk of the five-year period to plan for and install any capital improvements if necessary.

Some commenters point to concerns regarding laboratory capability and capacity in supporting the proposed three-year compliance timeline. Additionally, a couple of commenters noted that if additional time were allowed, water systems that are close to the MCL may have time to identify and address sources of PFAS in their watersheds rather than investing resources on treatment initially. Finally, a couple of commenters recommend the EPA consider implementation flexibilities for small and rural water systems and suggest that these types of utilities may not have staff capacity nor expertise to compete for funding to implement the rule. The EPA notes that these issues are not directly related to capital improvements and thus were not the basis for the EPA's decision to extend the compliance date for the PFAS MCLs. Although the EPA disagrees with assertions about insufficient laboratory capacity and capability at this time to support implementation of the NPDWR, to the extent there are initial implementation issues just after promulgation, extending the compliance date will also provide ancillary benefits toward addressing any such laboratory capability and capacity issues and may provide opportunities for systems who are close to exceeding the MCLs to investigate sources of contamination. Additionally, the extended compliance deadline may give smaller and rural water utilities more time to apply for funding under BIL (please see section II of this preamble above for a discussion on BIL). Further, other assistance programs such as the Environmental Justice Thriving Communities Technical Assistance Centers may provide additional fundamental training and capacity building activities for underserved and overburdened communities toward navigating Federal grant applications and managing funding opportunities.

The EPA requested comment as to whether there are specific conditions, in addition to the statutory conditions, that should be mandated for systems to be eligible for exemptions from the PFAS NPDWR under SDWA section 1416. Several commenters requested the EPA provide additional guidance to primacy Agencies on when exemptions are appropriate under SDWA section 1416 similar to what was done for the final Arsenic NPDWR (USEPA, 2002c). The EPA is not issuing additional guidance around implementation of SDWA section 1416 at this time but may consider it in the future. The EPA notes primacy agencies who have adopted the 1998 *Variance and Exemptions Regulation* (USEPA, 1998c) may choose to grant exemptions consistent with the requirements under this regulation to encourage systems facing compelling circumstances to come into compliance with the MCLs in an appropriate period of time.

3. Final Rule

Pursuant to SDWA section 1412(b)(10), the final PFAS NPDWR is effective June 25, 2024. The compliance date for the PFAS NPDWR, other than the MCLs, is April 26, 2027. As discussed above and upon consideration of information submitted by commenters, the EPA is exercising its authority under SDWA section 1412(b)(10) to implement a nationwide capital improvement extension to comply with the MCLs. All systems must comply with the MCLs by April 26, 2029. All systems must comply with other requirements of the NPDWR, including initial monitoring, by April 26, 2027.

Systems must comply with initial monitoring requirements within three years of rule promulgation and will be required to summarize PFAS monitoring results and applicable information beginning with CCRs delivered in 2027. As the MCL compliance date is set at five years from rule promulgation, systems must report MCL violations in the CCR, accompanied by the required health effects language and information about violations, starting in 2029. Monitoring and testing procedure violations require Tier 3 notification: systems must provide notice no later than one year after the system learns of the violation. Systems must repeat the notice annually for as long as the violation persists. Systems must comply with initial monitoring requirements within three years of rule promulgation and systems must provide Tier 3 notification for monitoring and testing procedure violations starting in 2027. As the MCL compliance date is set at five years from rule promulgation, systems must provide Tier 2 notification for MCL violations, starting in 2029. For more information on SDWA Right-to-Know requirements, please see section IX of this preamble above.

The agency notes that SDWA section 1416(a) and (b)(2)(C) describe how the EPA or states may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. PWSs that meet the minimum criteria outlined in the SDWA may be eligible for an exemption from the MCLs for up to three years. For smaller water systems (≤3,300 population), exemptions can provide up to six additional years to achieve compliance with the MCLs. States exercising primacy enforcement responsibility must have adopted the 1998 *Variance and Exemption Regulation* (USEPA, 1998c) for water systems in those jurisdictions to be eligible for an exemption.

XII. Health Risk Reduction and Cost Analysis

This section summarizes the final rule Health Risk Reduction and Cost Analysis (HRRCA) supporting document (USEPA, 2024g) for the per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR), which is prepared in compliance with section 1412(b)(3)(C) of the Safe Drinking Water Act (SDWA) and under Executive Order (E.O.) 12866. Section 1412(b)(3)(C)(i) lists the analytical elements required in a HRRCA applicable to an NPDWR that includes a Maximum Contaminant Level (MCL). The prescribed HRRCA elements include:

(1) Quantifiable and nonquantifiable health risk reduction benefits;

(2) quantifiable and nonquantifiable health risk reduction benefits from reductions in co-occurring contaminants;

(3) quantifiable and nonquantifiable costs that are likely to occur solely as a result of compliance;

(4) incremental costs and benefits of each alternative MCL considered;

(5) effects of the contaminant on the general population and sensitive subpopulations including infants, children, pregnant women, the elderly, and individuals with a history of serious illness;

(6) any increased health risks that may occur as a result of compliance, including risks associated with co-occurring contaminants; and

(7) other relevant factors such as uncertainties in the analysis and factors with respect to the degree and nature of the risk.

Based on this analysis, the Administrator confirms the finding

made at proposal under section 1412(b)(4)(C) of SDWA that the quantified and nonquantifiable benefits of the MCLs justify the costs. The complete HRRCA for the final NPDWR is commonly referred to as the ''Economic Analysis'' (or EA) in this final rule and can be found in the docket at USEPA (2024g).

Because this NPDWR is promulgated in 2024 and provides a 2-year nationwide extension of the date for MCL compliance, the EA assumes that capital improvements (*i.e.,* installation of treatment technologies) for systems taking action under the rule will be completed by five years from the date promulgated, or in 2029. All other requirements, including initial monitoring, are assumed to be completed within three years of rule promulgation, or by 2027. Based on an assumed mean human lifespan of 80 years, the Environmental Protection Agency (EPA) evaluates costs and benefits under the final rule through the year 2105.

The EPA selected this period of analysis to capture health effects from chronic illnesses that are typically experienced later in life (*i.e.,* cardiovascular disease [CVD] and cancer). Capital costs for installation of treatment technologies are spread over the useful life of the technologies. The EPA does not capture effects of compliance with the final rule after the end of the period of analysis. Costs and benefits discussed in this section are presented as annualized present values in 2022 dollars. The EPA determined the present value of these costs and benefits using a discount rate of 2 percent, which is the discount rate prescribed by the Office of Management and Budget (OMB; OMB, 2023). All future cost and benefit values are discounted back to the initial year of the analysis, 2024, providing the present value of the cost or benefit.

Estimates of PFAS occurrence used for cost-benefit modeling rely on a Bayesian hierarchical estimation model of national PFAS occurrence in drinking water (Cadwallader et al., 2022) discussed in section VI.E. of this preamble. The model was fitted using sample data from systems participating in PFAS sampling under the third Unregulated Contaminant Monitoring Rule (UCMR 3) and included all systems serving over 10,000 customers and a subset of 800 smaller systems. A best-fit model was selected using sample data to define occurrence and co-occurrence of perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), and perfluorohexane sulfonic acid (PFHxS [12]) in water systems stratified by system size and incorporating variations within and among systems. Sample data were derived from state-level datasets as well as from UCMR 3. For more information on the EPA's occurrence model, please see section VI.E. of this preamble.

In the EA, the EPA analyzes the costs and benefits of the final rule, which includes MCLs for PFOA and PFOS at 4.0 ng/L each and MCLs for PFHxS, perfluorononanoic acid (PFNA), and hexafluoropropylene oxide dimer acid (HFPO–DA) at 10 ng/L each and a unitless Hazard Index (HI) of 1 for any mixtures of PFHxS, PFNA, HFPO–DA, and PFBS. The EPA also analyzed the costs and benefits for several regulatory alternatives. The EPA analyzed the costs and benefits of setting individual MCLs for PFOA and PFOS at 4.0 ng/L, 5.0 ng/L, and 10.0 ng/L, referred to as regulatory alternative MCLs under option 1a, option 1b, and option 1c, respectively. The EPA assessed these regulatory alternative MCLs in the EA to understand the impact of less stringent PFOA and PFOS MCLs. Additionally, the EPA has separately estimated national level marginal costs associated with the individual MCL for PFHxS if this MCL were to be promulgated in the absence of the Hazard Index; see chapter 5.1.3 of the EA for details. The EPA has also estimated the marginal costs for the individual PFNA and HFPO–DA MCLs if there were no Hazard Index in the sensitivity analysis found in appendix N.4. The EPA notes that the costs for the individual PFHxS, PFNA, and HFPO–DA MCLs have been considered in this final rule.

Section A summarizes public comments received on the EA for the proposed rule and the EPA's responses to comments. Section B summarizes the entities which would be affected by the final rule and provides a list of key data sources used to develop the EPA's baseline water system characterization. Section C provides an overview of the cost-benefit model used to estimate the national costs and benefits of the final rule. Section D summarizes the methods the EPA used to estimate costs associated with the final rule. Section E summarizes the nonquantifiable costs of the final rule.[13] Section F summarizes the methods the EPA used to estimate quantified benefits associated with the final rule. Section G provides a summary of the nonquantifiable benefits associated with reductions in exposure to both PFOA and PFOS expected to result from the final rule. Section H provides a qualitative summary of benefits expected to result from the removal of PFAS included in the Hazard Index component of the final rule and additional co-removed PFAS contaminants. Section I of this preamble summarizes benefits expected to result from the co-removal of disinfection byproducts (DBPs). Section J provides a comparison of cost and benefit estimates. Section K summarizes and discusses key uncertainties in the cost and benefit analyses. Quantified costs and benefits for the final rule and regulatory alternative MCLs under options 1a-1c are summarized in section XII.J, specifically Tables 68–71. Tables 72–73 summarize the non-quantified costs and benefits and assess the potential impact of nonquantifiable costs and benefits on the overall cost and benefit estimates for the final rule.

A. Public Comment on the Economic Analysis for the Proposed Rule and EPA Response

1. Methods for Estimating Benefits

a. Methods for Estimating Benefits in the Proposed Rule

In the EA for the proposed rule, the EPA presented quantified and nonquantifiable health benefits expected from reductions in PFAS exposures. Quantified benefits are assessed as avoided cases of illness and deaths (or morbidity and mortality, respectively) associated with exposure to some of the regulated PFAS contaminants. The EPA provided a quantitative estimate of CVD, birth weight, and renal cell carcinoma (RCC) avoided morbidity and mortality associated with reductions in PFOA and PFOS consistent with the proposed rule. The EPA also developed a quantitative analysis for reductions in bladder cancer morbidity and mortality that stem from removal of DBP precursors as a function of PFAS treatment. Adverse human health outcomes associated with PFAS exposure that cannot be quantified and valued are assessed as nonquantifiable benefits.

The EPA qualitatively summarized potential health benefits associated with reduced exposure to PFAS other than PFOA and PFOS in drinking water. In the proposal, the EPA discussed non quantified benefits associated with health endpoints including developmental effects, cardiovascular effects, hepatic effects, immune effects,

[12] The EPA notes that perfluoroheptanoic acid (PFHpA) is not included in the proposed or final PFAS NPDWR; however, it was included in the occurrence model because of its UCMR 3 occurrence data availability; please see *Cadwallader et al., 2022* for additional details.

[13] This section includes costs with generally greater uncertainty that the EPA assesses in quantified sensitivity analyses.

endocrine effects, metabolic effects, renal effects, reproductive effects, musculoskeletal effects, hematological effects, other non-cancer effects, and COVID–19.

b. Summary of Major Public Comments on Method for Estimating Benefits and EPA Responses

Overestimation of Quantified Benefits

The EPA received comments from industry groups and organizations representing water utilities about the EPA's methodology for estimating quantitative benefits associated with the NPDWR. While some commenters supported the EPA's analysis, a few commenters stated that the agency overestimated quantified benefits. These commenters asserted that the EPA overstated the benefits of the rule and that the HRRCA is flawed because the existing health evidence does not support the quantified benefits. The EPA disagrees with commenters that the existing evidence does not support the EPA's estimate of quantified benefits from avoided adverse health effects likely to occur as a result of treatment and that these benefits are overstated. Among other things, the EPA has used the best available science in three key respects: by (1) considering relevant peer-reviewed literature identified by performing systematic searches of the scientific literature or identified through public comment, (2) relying on peer-reviewed, published EPA human health risk assessment methodology (USEPA, 2022f), and (3) utilizing peer-reviewed methodologies to valuing and quantifying avoided adverse health outcomes. Specifically, the EPA identified the full range of expected human health outcomes, including quantified benefits associated with co-removal of co-occurring contaminants (*i.e.,* DBPs). This process was built upon multidisciplinary research, including hazard identification and dose-response analysis, exposure assessment, and economic valuation methods recommended by the EPA's *Guidelines for Preparing Economic Analyses* (USEPA, 2016e) and updated Circular A–4 Guidance (OMB, 2023) to enumerate all beneficial outcomes, identify beneficiaries, and determine human health endpoints that can be valued. The EPA notes that the benefits analysis contains uncertainties associated with the modeling inputs in each of the steps listed above. In accordance with OMB Circular A–4 guidance (OMB, 2023), the EPA characterizes sources of uncertainty in its quantitative benefits analysis and reports uncertainty bounds for benefits estimated for each health endpoint category modeled in the final rule. See Table 75 and also section 6.1 of the EA for the final rule (USEPA, 2024g) for the list of quantified sources of uncertainty in benefits estimates. The reported uncertainty bounds reflect the best available data on health effect-serum slope factors, baseline PFAS occurrence, population size and demographic composition, and the magnitude of PFAS concentration reductions. In addition, some model inputs did not have sufficient distributional data to be included in the quantitative uncertainty analysis, and there are also uncertainties that could not be assessed quantitatively. These sources of uncertainty are described in Table 62 and also in section 6.8 of the EA for the final rule (USEPA, 2024g). Although some imprecision in the estimated benefits may be expected due to the lack of perfect information, the EPA has demonstrated, using the best science and data available, that there is sufficient health evidence to support the estimation of quantified benefit values and that these values are not systematic overestimates of the welfare improvements derived from implementation of the NPDWR.

Another commenter claimed that ''for the large majority of health endpoints discussed, the EPA has not provided a factual basis by which to conclude that such benefits are likely to occur when the EPA decreases the levels of PFAS in drinking water.'' The EPA disagrees with the commenter's assertion that the agency has not provided a factual basis for the benefits that are likely to occur as a result of the rule, which is amply supported in the HRRCA by the best available peer-reviewed science, consistent with SDWA section 1412(b)(3). Moreover, the commenter did not provide any additional or contrary factual information for the EPA to consider.

One commenter stated that the EPA did not provide data to support the analysis of benefits predicted from the implementation of the Hazard Index MCL. The EPA disagrees with commenter that the EPA did not provide evidence to support Hazard Index MCL benefits. In section XII of the preamble and in section 6.2 of the EA (USEPA, 2024g), the EPA qualitatively summarized and considered the potential health benefits resulting from reduced exposure to PFAS other than PFOA and PFOS in drinking water. These qualitative potential health benefits are based on summaries of a significant body of peer reviewed science. As summarized in the EA, the qualitatively discussed health effects of the Hazard Index PFAS are considerable; reducing human exposure to the Hazard Index PFAS is expected to reduce the incidence of multiple adverse health impacts. The qualitative benefits discussion of the impacts of the four PFAS which are regulated through the Hazard Index, as well as their co-occurrence in source waters containing PFOA and/or PFOS and additive health concerns, supports the EPA's decision to regulate them through the Hazard Index in this rulemaking.

Additionally, the EPA evaluated the impacts of PFNA (one of the Hazard Index PFAS) on birthweight in quantitative sensitivity analyses (USEPA, 2024e). The EPA notes that new evidence since the release of the current, best available peer reviewed scientific assessment for PFNA (ATSDR, 2021) provides further justification for the EPA's analysis of potential economic benefits of PFNA exposure reduction and avoided birthweight effects. Specifically, this new evidence confirms that in instances where PFNA is present, the national quantified benefits may be underestimated; however, birth weight benefits are considered quantitatively as part of this EA in the sensitivity analysis and support the EPA's decision to regulate PFNA.

The EPA received a number of comments on the quantitative analysis for CVD risk reduction. These commenters disagree with the EPA's assessment that cardiovascular benefits are likely to occur as a result of PFOA and PFOS exposure reduction. One commenter stated that the associations with total cholesterol (TC) are not biologically significant and criticized the EPA's use of linear models in the CVD meta-analysis, stating that this approach biases the analysis by excluding higher-quality studies. The EPA disagrees with the commenter's statement that associations between PFOA/PFOS and TC are not biologically significant. Such serum lipid changes may or may not result in a concentration considered clinically elevated in a particular individual; however, given the distribution of individual concentrations within the population, small changes in average serum lipid concentrations can result in substantial adverse health effects at the population level (Gilbert and Weiss, 2006). The EPA disagrees with the commenter's suggestions that linear assumptions are inappropriate for use in this context. The EPA presents the exposure-response estimates evaluated considering all studies, studies with linear models only, and a variety of sensitivity analyses in appendix F of the

EA (Tables F–2 and F–3, USEPA, 2024e). Meta-analyses of studies reporting linear associations had statistically significant relationships. These relationships are supported by the EPA's review of epidemiological studies showing positive associations between PFOA/PFOS and TC. The EPA used data from peer-reviewed studies, and the assumption of linear exposure-response function to explain associations between PFAS and serum lipids such as TC which are supported by data from numerous studies, including those used in the meta-analysis. Other studies have explored log-linear or linear-log relationships between PFAS and serum lipids, while acknowledging only ''slight improvements'' in model fit, especially for serum lipids with least skewed distributions (Steenland et al., 2009).

A couple of commenters stated that the downward trend in decreasing total and low-density lipid cholesterol since the 1970s coupled with the decreasing PFOA and PFOS serum levels suggests that there is a substantial likelihood that the proposed MCLs for PFOA and PFOS are unlikely to result in benefits as great as those reported in the proposal. The EPA disagrees with these comments asserting that decreasing trends in cholesterol levels over time indicate that PFAS exposure is unlikely to contribute to a measurable increase in CVD risk. The EPA relied on recent National Health and Nutrition Examination Study (NHANES) data (2011–2016) to inform baseline cholesterol and blood pressure conditions in the population evaluated under the proposed rule. These data reflect the current population and do not reflect cholesterol conditions in the population between 1970 and 2010. Therefore, the CVD benefits analysis examines how the probability of the current population might benefit from reduced incidence of hard CVD events.[14]

The EPA received a comment stating that the benefits associated with high-density lipoprotein cholesterol (HDLC, often referred to as the 'good cholesterol') changes are not likely to accrue because the evidence of the relationship between PFAS and the health outcome is not conclusive, and that this endpoint should not have been quantified. The EPA disagrees; although the evidence of a relationship between PFAS exposure and HDLC is not conclusive, the SAB recommended that the EPA evaluate how the inclusion of HDLC effects would influence results. Thus, the EPA evaluated how benefits results are affected by the inclusion of HDLC effects in a sensitivity analysis presented in appendix K of the EA for the proposed (USEPA, 2023f) and final rule (USEPA, 2024e). Additionally, the same commenter and one other commenter challenged the EPA's quantification of PFOS and blood pressure, stating that the EPA's finding that PFOS might have ''the potential'' to affect blood pressure does not meet the SDWA standard for inclusion in a benefits analysis and that the ''rationale for including changes in BP in relation to PFOS is not clear.'' Another comment identified a study that utilized NHANES data and ''did not observe an association'' between PFOA and blood pressure. Finally, another commenter mentioned that ''neither the ATSDR nor the National Academy of Sciences (NAS) have found an association between PFOA/PFAS and increased blood pressure.'' While the EPA is aware of this previous work, in the EPA's own, more recent assessment, the strength of the evidence is determined both by the number but also the quality of studies investigating the relationship. One high confidence study conducted using U.S. general population data from NHANES showed a relationship between PFOS exposure and systolic blood pressure in humans (Liao et al., 2020). In addition, several *medium* and *low* confidence studies provided evidence for an association between PFOS and blood pressure and/or hypertension (Mitro et al., 2020; Bao et al., 2017; Mi et al., 2020; Liu et al., 2018). Because blood pressure is an important component of the Atherosclerotic Cardiovascular Disease (ASCVD) model used to estimate hard CVD event risk, and because epidemiology reports show consistent evidence of an association between PFOS and blood pressure in general adult populations (*i.e.,* the populations evaluated using the ASCVD model), the EPA included the relationship between PFOS exposure and blood pressure in the analysis. The EPA further notes that the Science Advisory Board recommended modeling the impacts of changes in all ASCVD model predictors (including blood pressure and HDLC) for which there is evidence of a likely causal relationship (USEPA, 2022i).

A few commenters questioned the evidence or stated that the evidence supporting an association between exposure to PFOA and PFOS and CVD is insufficient. The EPA disagrees with these comments. The agency's approach to estimating reductions in CVD risk was reviewed and supported by SAB panelists (USEPA, 2022i). Numerous studies have shown consistent associations between PFOA/PFOS exposure and changes in TC and blood pressure which are biomarkers for CVD risk. TC and blood pressure are well-established CVD risk biomarkers, are clearly associated with CVD events, and are important inputs to the ASCVD model that the EPA used to estimate CVD outcomes.

The EPA received public comments on the benefits analysis for developmental effects. A few commenters claimed that the studies used for developmental modeling did not provide sufficient evidence of an association between PFOA and PFOS exposure and stated that the studies which the EPA used to model the developmental effects relationship did not consider confounders including pregnancy hemodynamics and other chemical and non-chemical stressors, including other PFAS. One commenter stated that the EPA's findings are inconsistent with other regulatory agency findings that small decreases in birth weight are associated with maternal exposure to PFOA and PFOS but not increased risk of low birth weight. Other commenters stated that the EPA did not address these concerns and inappropriately used these studies to support quantitative analysis, and one commenter stated that because of the shortcomings of the studies used and the modeling uncertainties, peer review of the developmental effects modeling should be completed. Although there are some uncertainties in the developmental epidemiological effects data (*e.g.,* differences seen across biomarker sample timing), the EPA disagrees with these comments: the developmental benefits analysis is supported by a wide body of peer reviewed science (Verner et al., 2015; Negri et al., 2017; ATSDR, 2021; Waterfield et al., 2020; USEPA, 2016c; USEPA, 2016d; USEPA, 2024c; USEPA, 2024d). Specifically, birth weight was determined to be a critical effect based on findings in the EPA's health assessments (see USEPA, 2024c; USEPA, 2024d), and low birth weight is linked to a number of health effects that may be a source of economic burden to society in the form of medical costs, infant mortality, parental and caregiver costs, labor market productivity loss, and education costs.

Discussion regarding the selection of decreased birth weight as a critical effect, including the selection of specific studies for candidate RfD derivation and the evidence supporting associations between PFOA or PFOS and

[14] Hard CVD events include fatal and non-fatal myocardial infarction (*i.e.,* heart attack), fatal and non-fatal stroke, and other coronary heart disease mortality.

developmental effects, is available in sections 3.4.4 and 4.1 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024c; USEPA, 2024d). In estimating benefits of reducing PFOA and PFOS in drinking water, the agency selected results from Steenland et al. (2018) as the birth weight exposure-response function for PFOA and results from Dzierlenga et al. (2020) as the birth weight exposure-response function for PFOS. The agency chose the results from these studies because they include the most recent meta-analyses on PFOA- and PFOS-birth weight relationships, and they included a large number of studies, including multiple studies with first trimester samples (seven studies in Steenland et al., 2018 and eight studies in Dzierlenga et al., 2020). To provide insights into the potential effects of sample timing and pregnancy hemodynamics, the EPA also performed a sensitivity analysis considering only first trimester estimates from Steenland et al (2018) for PFOA and Dzierlenga et al. (2020) for PFOS in section K.4 of the EA appendices (USEPA, 2024e). While reports prior to 2019 found ''plausible'' or ''suggestive'' (USEPA, 2016d; ATSDR, 2018) evidence of relationships between PFOA and PFOS and developmental outcomes, the EPA's assessment found clear evidence of an association for PFOA and PFOS in both toxicological and epidemiological studies (USEPA, 2024h; USEPA, 2024i). The agency further disagrees with the commenter's statement that further peer review is needed, as the EPA relies extensively on peer-reviewed studies in its developmental benefits model. Furthermore, the EPA characterizes the uncertainty in the PFOA and PFOS exposure-response functions as described in appendix L of the EA (USEPA, 2024e). In short, the benefits analysis for developmental effects relies on a wide body of the best available, peer-reviewed science, and the epidemiological evidence provides a reliable basis for quantifying the risks of low birth weight.

A different commenter claimed that the EPA relied on equivocal epidemiological evidence to estimate developmental benefits, stating that the RfDs calculated from animal studies in the EPA's health assessment documents for PFOA and PFOS are significantly higher than those based on human studies used for benefits analysis and that the animal studies represent a more appropriate estimate of the risk of PFOA and PFOS exposure. The EPA disagrees with the commenter that the analysis relies on equivocal epidemiological evidence to estimate benefits. The systematic literature review and assessment conducted by the EPA, the most comprehensive evaluation of the current literature to date, concluded that there is moderate evidence for developmental effects based on consistent adverse effects for fetal growth restriction including birthweight measures which are the most accurate endpoint (USEPA, 2024c; USEPA, 2024d). One commenter raised concerns about the EPA's reliance on the study (Steenland et al., 2018) that the EPA uses to model PFOA dose response for benefits analysis, stating that the EPA's benefits analysis for PFOA and developmental effects is not supported by the underlying publication. The same commenter questioned the EPA's reliance on the study that is used to model PFOS dose response for benefits analysis (Dzierlenga et al., 2020), stating that the study found that there was no evidence of a relationship at the beginning of pregnancy. The commenter contended that the meta-analysis was not peer reviewed and thus the validity of the EPA's methods should be questioned. The EPA disagrees with the commenter's criticism of the studies used to assess dose response in developmental benefits analysis. The selected meta-analyses on the relationship between PFOA/PFOS exposure and birth weight produced statistically significant results, are based on recent data, and include a large number of studies in each meta-analysis.

One commenter stated that given the discussion about changes over time in infant mortality, a dataset containing only two years of data is insufficient to build infant mortality regression models. The EPA disagrees that two years of data is insufficient to build regression models relating infant birth weight to infant mortality. The EPA's regression analysis improves upon earlier analyses relating birth weight to infant mortality (Almond et al., 2005; Ma and Finch, 2010) by evaluating two years of recent data. Sample sizes among the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) linked birth/infant death data per year are large (n = approximately 3.8 million infants) and contribute to the overall statistical significance of regression results. As described in appendix E of the EA (section E.2, USEPA, 2024e), there has been a notable decline in U.S. infant mortality rates since the analyses reported in Ma and Finch (2010) and Almond et al. (2005). Using recent data from two CDC NCHS linked birth/infant death data cohorts results is a more accurate and conservative characterization of recent infant mortality trends than if the EPA had included older CDC NCHS data.

The EPA received comments on the benefits analysis for RCC. Two commenters expressed concerns with the EPA's use of Shearer et al. (2021) to estimate RCC risk in benefits analysis and claimed flaws in the study related to outliers in the RCC group and inconsistent evidence of an association across epidemiological studies. One commenter stated that given what they perceive as SAB concerns and uncertainties in the modeling, further peer review is warranted. The EPA disagrees with the comments critical of the agency's use of information from the Shearer et al (2021) study for purposes of PFOA health assessment and benefits analysis. As noted in section 3.5.1 of the Final Toxicity Assessment for PFOA (USEPA, 2024c), the EPA determined that Shearer et al. (2021) is a *medium* confidence study after conducting study quality evaluation consistent with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f). The biomonitoring measures of PFOA levels in Shearer et al. (2021) were reliable measures of PFOA exposure due to the chemical's well-established long half-life. The commenters failed to acknowledge multiple studies further supporting a positive association between PFOA exposure and RCC risk (Bartell and Vieira, 2021; Vieira et al., 2013; Steenland et al., 2022). Critically, the SAB PFAS Review Panel supported the *Likely to be Carcinogenic to Humans* designation for PFOA in its final report (USEPA, 2022i). Shearer et al (2021) has been sufficiently peer reviewed and it represents the best available science for purposes of health and benefits assessment in the PFAS NPDWR.

The EPA received comments on uncertainties associated with bladder cancer reductions. One commenter incorrectly stated that the ''EPA does not recognize the uncertainty that there is not always direct correlation between THM4 levels and TOC in all public water systems''. In response, the EPA notes that the THM concentrations in this co-removal analysis were not calculated based on TOC reduction. TOC was used to bin systems in the universe of PWSs using the fourth Six-Year Review (SYR4) database and PFAS occurrence model with the THM4 reduction calculated from the formation potential experiments before and after GAC treatment in the DBP Information Collection Rule Treatment Study Database. This dataset reflects the current best available data to determine THM4 reduction based on TOC removal

using GAC treatment. Another commenter stated that the causal link of DBPs and bladder cancer has not been established. The EPA notes that an extensive body of epidemiological studies have shown that increased exposure to chlorinated DBPs is associated with higher risk of bladder cancer and other adverse health outcomes (Cantor et al., 1998; Freeman et al., 2017). Weisman et al. (2022) found that approximately 8,000 of the 79,000 annual bladder cancer cases in the U.S. were potentially attributable to chlorinated DBPs in drinking water systems. While research has not established a causal link between THM4 and bladder cancer, there is strong evidence that there is a correlation between THM4 and bladder cancer.

One commenter stated that the DBP co-removal benefit analysis did not meet the standards required by SDWA for estimating benefits since it was not reviewed by the SAB. The commenter is incorrect. SDWA 1412(e) directs the EPA to request comments from the SAB prior to proposing an MCLG and NPDWR. The EPA sought and received comment from the SAB prior to proposing this NPDWR (see USEPA, 2022i). The statute does not dictate the precise level of scientific questions for which the EPA must seek comments from the SAB. The EPA sought SAB comment on the four most significant areas that informed derivation of the MCLGs for all six PFAS regulated by this action and for other parts of the benefits analysis that informed the overall development of the NPDWR. The EPA did seek additional peer review of its DBP co-removal benefit analysis prior to its inclusion in the EA for which it received overwhelmingly favorable comments from reviewers (see USEPA, 2023m). Furthermore, this rule is based on the EPA's consideration of a wide body of existing peer-reviewed science on this subject (*e.g.,* Regli et al., 2015; Weisman et al., 2022). In short, the EPA has used peer reviewed science and sought further peer review to support its DBP co-removal analysis, and as part of the supporting material for the rule proposal, the EPA included the comments from the expert peer reviewers as well as how each comment was addressed or the rationale for why it was not changed. Please see *Response to Letter of Peer Review for DBP Co-benefits* (USEPA, 2023m) for discussion of that peer review and the EPA's responses to peer reviewed comments.

Another commenter claimed that the EPA improperly quantified benefits of co-removed substances rather than co-occurring substances. The EPA disagrees with these assertions since the analysis of DBP co-removal is focused on co-occurring contaminants. As demonstrated elsewhere in the record for this action, PFAS commonly co-occur with each other. Additionally, in waters where disinfection is required, TOC (*i.e.,* a DBP precursor) and PFAS may co-occur. The DBP co-removal benefits analysis relied on DBP formation potential experiments that highlighted the changes to TOC with and without GAC treatment. Furthermore, as discussed above, the methodology to estimate THM4 reductions was externally peer reviewed by three experts in GAC treatment for PFAS removal and DBP formation potential.

A few commenters stated that the EPA already had initiatives to reduce THMs in drinking water and suggested that reduction of bladder cancer cases is better addressed through existing DBP rules. While the EPA agrees that there are existing DBP regulations to reduce DBP exposure and risks, this rule will provide additional health risk reduction benefits associated with enhanced DBP reduction. The EPA has considered those co-removal benefits as part of the EA. The EPA notes that it is required under the SDWA 1412(b)(3)(C)(i)(II) to assess quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL, excluding benefits resulting from compliance with other proposed or promulgated regulations. DBP reductions presented in the EPA's HRRCA are those that are anticipated to result solely from compliance with the PFAS MCLs. As required under the SDWA, any quantifiable and nonquantifiable benefits from future actions concerning DBPs in drinking water will be addressed at the time of those actions and are independent from benefits stemming as a result of the PFAS rulemaking. A couple of commenters supported the EPA's analysis of DBP benefits but recommended that the EPA also consider other co-removed contaminants. The EPA agrees with the commenters that multiple co-occurring contaminants will be removed as a result of this rule. Furthermore, the EPA acknowledges in the EA that additional co-removal benefits would be realized due to treatment for PFAS. With the exception of DBPs co-removed, the EPA has not quantified other co-removal benefits at this time because of data limitations, the agency included discussion of nonquantifiable benefits for multiple other PFAS and for other contaminants.

Nonquantifiable Benefits of PFAS Exposure Reduction

One commenter expressed that the EPA's characterization of benefits is inadequate and not supported by science. The commenter specifically discussed hepatic effects, endocrine effects, and musculoskeletal effects and asserted that the EPA's characterization is based on mixed findings and inconsistent evidence regarding PFAS exposures and specific health outcomes. The EPA disagrees with this comment, as the EPA has evaluated the best available peer reviewed science, as required under SDWA. The EPA did not quantify or monetize benefits where there are inadequate data. For hepatic effects, the EPA's toxicity assessments determined that there is moderate evidence supporting the association between exposure to PFOA/PFOS and hepatic toxicity in humans. However, the EPA did not quantify benefits for hepatic effects because although there will be benefits delivered by reducing PFOA and PFOS in drinking water, there is a lack of adequate data available to accurately quantify those benefits. Further information on health effects related to PFAS exposures is provided in the health assessments within the MCLG documents (USEPA, 2024c; USEPA, 2024d).

Conversely, some commenters expressed support for the quantification that the EPA has already performed, stated that the benefits of the rule are underestimated, and urged the EPA to quantify and monetize additional health endpoints, particularly mammary gland and lactational effects, immunotoxicity, and liver disease. These commenters also provided additional resources and information with the intention of the EPA using that information to update analyses regarding lactational effects, expand analyses to include immune effects, and adjust analyses to characterize hepatotoxicity as a quantifiable benefit, as opposed to a non-quantifiable one. Commenters also urged the EPA to quantify some of the benefit categories, even if monetization is not possible, and to highlight the magnitude of some of the qualitatively discussed benefits. The EPA agrees with these commenters that the quantified benefits of the rule are underestimated. Where appropriate, the EPA used medical cost information provided by the commenters to supplement qualitative discussion of adverse effects. Additionally, and based on these comments, the EPA considered

information in the record and added additional quantified benefits analysis in the sensitivity analysis evaluating the reductions in liver cancer cases expected by reducing concentrations of PFAS. This additional analysis was confirmatory of the EPA's previous analysis and did not result in changes to the NPDWR's requirements.

Some commenters also provided recommendations regarding the inclusion of additional costs and benefits beyond health endpoints. These included the opportunity cost of time, environmental benefits, and psychosocial benefits that are expected to result from the rule. The opportunity cost of time was suggested to be incorporated into morbidity estimates, while the other benefits were suggested to be encapsulated in a qualitative summary.

In the EA document, the EPA describes that the cost of illness (COI)-based approach does not account for the pain and suffering associated with non-fatal CVD events. Based on the above comments, for quantified cancer endpoints (*i.e.,* RCC and bladder cancers), the EPA has included a new sensitivity analysis using willingness to pay values for risk reductions which can inform the direction of benefits when opportunity cost is included. This additional analysis was confirmatory of the EPA's previous analysis and did not result in changes to the NPDWR's requirements.

c. Final Rule Analysis

For the final rule, the EPA retained the quantitative benefits analyses from the proposal for developmental, CVD, and cancer endpoints as well as the bladder cancer benefits from DBP exposure reduction as a result of the rule. In response to comments described above, the agency identified new information on willingness to pay values for non-fatal cancer risk reductions and added additional sensitivity analyses for RCC and bladder cancer in appendix K to the final rule EA (USEPA, 2024e). In light of new epidemiological studies on PFOS exposure and liver cancer that strengthened the weight of evidence and supported the toxicological information that was identified in the proposed rule, and comments received requesting that the EPA monetize additional health endpoints, the EPA developed a sensitivity analysis assessing the liver cancer impacts in appendix O of the final rule EA (USEPA, 2024e). The EPA estimates that PFOS liver cancer benefits would add $4.79 million annually to the national benefits estimates. The EPA retained discussion of nonquantifiable benefits associated with PFAS exposure reduction from the proposed rule for the final rule EA.

2. Treatment Costs

a. Treatment Cost Estimates in the Proposal

The EPA estimated costs associated with engineering, installing, operating, and maintaining PFAS removal treatment technologies, including treatment media replacement, and spent media destruction or disposal, as well as nontreatment actions that some PWSs may take in lieu of treatment, such as constructing new wells in an uncontaminated aquifer or interconnecting with and purchasing water from a neighboring PWS. To evaluate the treatment costs to comply with the proposed PFAS NPDWR, the EPA used the agency's Work Breakdown Structure (WBS) models, a spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs. The WBS models are extensively peer-reviewed engineering models for individual treatment technologies and discussed in section XII.D of this preamble. The EPA used PFAS occurrence outputs from a Bayesian hierarchical estimation model of national PFAS occurrence in drinking water (Cadwallader et al., 2022), to estimate the number of water systems exceeding the proposed MCLs, and therefore triggered into action to comply with the proposed MCLs.

b. Summary of Major Public Comments on Treatment Costs and EPA Responses

Many commenters state that the EPA has underestimated the treatment costs required to comply with the proposed MCLs. One commenter suggested that the EPA has not complied ''with its statutory requirements by conducting an analysis that fully captures these costs.'' The EPA disagrees with the few commenters that suggested the EPA has not met its requirements under SDWA, and the EPA emphasizes the agency has used the best available peer reviewed science to inform it cost estimates, including treatment costs, of the MCLs. Specific aspects of comments related to treatment costs and the EPA's response are discussed further in this section.

Many commenters cited rising costs in the drinking water sector and discussed the effects of inflation and the COVID–19 pandemic on the costs of labor, construction, and capital, among other materials related to compliance with the MCLs. These commenters emphasized the significant impacts felt from supply chain and workforce issues. The EPA recognizes these impacts, and as recommended by commenters, adjusted the cost estimates by escalating unit costs using indices including the Bureau of Labor Statistics producer price indices (USBLS, 2010). The EPA updated each unit cost using the change in the relevant price index from year 2020 to 2022. For example, the EPA applied the percent increase of the price of metal tanks and vessels (50 percent increase from 2020 to 2022) to the price of metal tanks and vessels in the WBS cost models. The EPA also collected new vendor price quotes for cost driver equipment components (*e.g.,* pressure vessels, treatment media) and made several other adjustments to WBS model assumptions, described further in this section. Taken together, these adjustments increased the system level capital cost estimates in the EPA's cost assessment by a percentage that varied depending on the system size and treatment technology. For small systems using GAC and IX, the increase ranged from approximately 40 percent to 110 percent. For medium systems, the increase was approximately 20 to 60 percent; for large systems, 10 to 40 percent. Additionally, while revising the SafeWater model to incorporate new information from public comments, the EPA identified and corrected a coding error related to the discounting of future operation and maintenance costs resulting in increased estimated annualized treatment costs. The result of these changes are increased cost estimates for the final rule.

Some commenters state that while BIL funding is available, it is not enough to cover the compliance costs of the rule. For example, one commenter noted that, ''[t]his amount of funding support, while crucial, will come nowhere near the cost to ratepayers that must be borne to implement necessary compliance actions for these MCLs.'' The EPA disagrees with the commenter that BIL funding will be nowhere near the cost'' necessary to implement compliance actions. The EPA estimates that the initial capital costs of the rule in undiscounted dollars is approximately $14.4 billion (see appendix P of the EA for more information). Given the BIL appropriations of $11.7 billion in DWSRF and an additional $5 billion for emerging contaminants, the EPA reasonably anticipates BIL funding is likely to be able support a substantial portion of the initial capital costs of the final rule. BIL funding appropriations began in the Federal Fiscal Year (FFY) 2022 and appropriations are anticipated to continue through FFY 2026.

Many commenters shared some information about the costs that they

have incurred or estimated they would incur at a system level to install, operate, and maintain treatment to remove PFAS. Some system level cost information provided by commenters fell within the ranges of costs presented in the EPA's supporting documentation for the proposal and other information provided by commenters exceeded the EPA's system level cost ranges. The EPA does not dispute the commenters stated experience of costs to install, operate and maintain treatment to remove PFAS; however, many of these comments lacked supporting details. Many of the comments cited preliminary or conceptual estimates and did not specify the methods and assumptions used to develop the estimate. Furthermore, most comments did not include information to confirm that all of the reported or estimated costs were or would be directly associated with PFAS treatment, as opposed to other infrastructure improvements (*e.g.,* capacity expansion, administrative facilities, distribution system improvements) that happened to be completed as part of the same project. Most commenters also did not include information to confirm that key design and operating parameters (*e.g.,* empty bed contact time, media replacement frequency) would be similar to the typical values assumed in the EPA's estimates. To fully evaluate the commenters' reported or estimated costs in comparison to WBS model results, the EPA would need itemized line-item cost details and engineering design parameters. To inform the cost estimates of the proposed and final PFAS NPDWR, the EPA conducted an extensive review of the literature. The EPA has further validated the unit costs in the PFAS rule with equipment cost information from 2023 from a major supplier of treatment media. While the EPA recognizes there are likely site-specific instances where costs exceed the EPA's cost ranges, there are also likely site-specific instances where costs are less than the EPA's cost ranges, and this level of accuracy is appropriate for a national level analysis.

Other commenters compared state-level costs to the EPA's national level cost estimates, noting that the EPA's estimates appeared too low. Utilizing this permit data and project cost data submitted by water systems in applications to the DWSRF, one state estimated that total capital costs for installation of PFAS treatment to meet the EPA's proposed standards across the state could be as high as $1.065 billion. The EPA's EA analysis, however, presents national level cost estimates that are annualized over the period of analysis and are therefore not directly comparable to a single year estimate of capital costs.

A few commenters stated that the EPA incorrectly omitted the costs associated with performance monitoring, which commenters believe will be necessary because a water system needs to know how often it needs to replace its media. The EPA disagrees that large amounts of additional samples in performance monitoring will be required, and the commenter provided no data to support their assertion that this would be necessary. The EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that the operational results from the pilot test will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. The EPA includes the costs of pilot testing, and sampling during that time, in the treatment capital cost estimates. In response to public comments, the EPA increased the estimated length of the pilot study and the frequency of sampling during the pilot study. Additionally, the EPA added a full year of confirmation sampling after full-scale installation to the estimated pilot study costs. Taken together, these changes doubled to more than tripled the pilot study costs included in the EPA's estimates.

In response to public comments about residual management concerns for high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to zero percent in the EA for the final rule. Therefore, the EPA assumes that RO/NF will not generally be used solely for the purpose of complying with the final rule. For more information on public comments on residuals management and the EPA's response please see section X.

A few commenters stated that the EPA underestimated or insufficiently incorporated contingency in its cost estimates. For example, one commenter stated that the EPA's contingency assumptions in the proposal were ''. . . inconsistent with recommended best practices for cost estimators and [are] expected to be a major contributor to the EPA WBS' failure to accurately capture costs for PFAS treatment facility implementation.'' In response to these comments, the EPA changed its approach and incorporated contingency for all systems, not just high-cost systems. The EPA also increased the complexity factor applied to estimate contingency for systems using GAC. Taken together, these changes result in a contingency factor of 5 to 10 percent depending on total project cost at all cost levels for systems installing treatment. Additionally, the EPA includes a miscellaneous allowance of 10 percent. This allowance can be viewed as either as a form of contingency or a method to increase the level of project definition (thus reducing the amount of contingency required).

One commenter stated that the EPA underestimated the costs associated with interconnection.[15] This commenter stated that it was ''unrealistic to assume that booster pumps are unlikely to be necessary. Pressure loss associated with friction could be significant, especially for an interconnection that may span 10,000 feet or more,'' and recommended that the EPA include booster pumps in the cost estimate. Commenters also pointed out that ''. . . systems considering interconnections will need to thoroughly investigate this option and determine if it is both cost effective and appropriate given the water quality impacts.'' In response to these comments, the EPA made several changes to the assumptions used to estimate costs for interconnection in the WBS model for nontreatment options. The EPA agrees that booster pumps may be needed and added the costs of booster pumps designed to account for friction loss in interconnecting piping. The EPA also agreed that there are many considerations for water systems pursuing interconnections including elevated water age, nitrification, and DBPs, as pointed out by commenters, and therefore the EPA increased the complexity factor applied to estimate contingency for systems using nontreatment options. Taken together with the escalation to 2022 dollars, these changes increased the system level capital costs for interconnection by approximately 60 to 100 percent.

Many commenters cited and expressed agreement with the conclusions of a study conducted by Black & Veatch on behalf of the American Water Works Association (AWWA) (hereafter referred to as AWWA's B&V report) (AWWA, 2023). The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions

[15] Interconnection is when a system replaces their contaminated water source by purchasing water from another nearby system that is in compliance. Booster pumps can be needed when the pressure from the supplying system is lower than required at the purchasing system and also to overcome pressure losses due to friction in interconnecting piping.

about the estimated national costs of the PFAS NPDWR. Tables 24–26 detail some of the key assumptions related to (1) PWSs that exceed the MCL, (2) capital costs and (3) operation and maintenance costs that overestimate national treatment costs in AWWA's B&V report and the EPA's response to those assumptions and resulting estimates. In combination, all these factors result in an overestimate of treatment costs. For example, AWWA's B&V report Table 6–1 reports an average capital cost per EP for the smallest size category of $900,000. Using AWWA's B&V report's (overestimated) design flow calculations, the treatment system design flow at each EP would be approximately 0.062 million gallons per day (mgd). For comparison, Forrester (2019) reports capital equipment costs of approximately $300,000 for a 1 mgd GAC PFAS treatment system. Even after adding indirect capital and building costs, the $900,000 estimate appears substantially overestimated, given that it is for a treatment system designed for approximately 1/16th of the flow of the system in the Calgon Carbon estimate (Forrester, 2019). When AWWA's B&V report's EP level results are aggregated nationally to an overestimated number of systems treating for PFAS, the overestimates are compounded at the national level.

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Table 24. EPA Response to assumptions about PWSs exceeding the MCLs in AWWA's B&V Report

Analytical Component	AWWA's B&V report	EPA response
PFAS occurrence estimates	Used an occurrence dataset comprised of UCMR 3 and information from state regulatory agencies. Estimates the following number of water systems will exceed 4.0 ng/L PFOA and/or PFOS: Serving 10,000 or less: 7,056 PWS (8,808 EP) Serving more than 10,000: 393 PWS (1,214 EP) Total PWSs: 7,449 PWSs (10,022 EP)	The dataset used is not appropriate for national extrapolation, for example, 90 percent of non-UCMR systems used in the report come from just 6 states. As a result, AWWA's B&V report likely overestimates the number of water systems exceeding the MCLs, particularly small water systems. After incorporating updated state monitoring data into its occurrence model, the EPA estimates the following number of water systems will exceed 4.0 ng/L of PFOA and/or PFOS (**mean** (5^{th} – 95^{th}) from chapter 4.4 of the EA): Serving 10,000 or less: **3,870** (2,795-5,097) PWS **5,115** (3,666-6,858) EP Serving more than 10,000: **1,266 (**1,203-1,328) PWS **3,878** (3,701-4,056) EP Total PWSs: **5,136** (4,018-6,441) PWSs **8,993** (7,497-10,711) EP AWWA's B&V report did not specify what measures, if any, were taken to ensure the data was nationally representative and this may be one cause of their overestimation of water systems exceeding the MCLs. The EPA used QC measures to ensure that the data represented finished drinking water and that the set of systems used to inform the model was nationally representative. Additional state data that were available at systems that were part of this nationally representative set of systems were used to fit the model. For more information see section VI of this preamble.

Number of EP installing treatment	Assumes every EP a system will require treatment regardless of whether a given EP exceeds the MCL.	This is an incorrect assumption and likely leads to a significant overestimate of national costs. A single water system often has EP that use different water sources, and therefore have different PFAS concentrations. The EPA conducted an EP-level cost analysis as compliance with the rule is determined at the EP-level and treatment is installed at the EP-level.
PWSs in states with existing PFAS regulations	Includes estimates of the costs to PWSs to comply with existing state PFAS regulations; and does not assume that PWSs are already in compliance with state standards.	This approach overestimates costs for water systems in states with existing state standards. The EPA adjusts the baseline by setting the maximum pre-regulation concentrations equal to the state MCL for systems in states with promulgated regulations. This allows the EPA to capture the incremental costs of the NPDWR MCLs more accurately.
Nontreatment options	Assumes all exceeding EP will install a treatment technology to comply with the MCLs.	This assumption overestimates costs, as the EPA is aware of a number of water systems that have elected to drill a new well to reduce PFAS concentrations in supplied water. Another commenter pointed out that Michigan expects up to 26 percent of water systems to interconnect with other systems to comply with their state standard. Other commenters pointed out the viability of interconnection and new wells as compliance options will vary regionally, and the EPA agrees. Nevertheless, the absence of these options entirely in AWWA's B&V report overestimates national costs.

Table 25. EPA Response to key capital cost assumptions in AWWA B&V Report

Analytical Component	AWWA B&V report	EPA response
Equipment lifespan	Assumes a fixed life cycle cost using a fixed 20-year lifespan for all capital equipment.	A 20-year lifespan may be reasonable for very small systems but based on the composite useful life of treatment systems derived from the useful lives of individual treatment system components and industry information, the EPA estimates that treatment system useful life can be 30 years or more for medium to larger systems using more durable materials of construction.
Contingency factors	Includes a contingency factor of 4 percent under contractor markup and an additional contingency factor of 30 percent under non-construction costs.	The inclusion of contingency twice is unusual and may not reflect actual realized contingency costs at project completion. A Construction Industry Institute (2001) study found that projects of $100 million or less incurred only 74 percent or less of the contingency initially budgeted. The EPA updated its approach to incorporate a contingency factor of 5 to 10 percent depending on total project cost at all cost levels for systems installing treatment. The EPA also included a miscellaneous allowance of 10 percent, which can be considered a form of contingency.
Building costs	Assumes a fixed unit cost of $200/square foot for buildings.	AWWA's fixed unit cost likely overestimates actual building costs, particularly for small systems that may not require complex or architecturally detailed buildings. The EPA estimates that building costs vary depending on building quality and square footage and range from $57/square foot to $204/square foot.
Pumping and backwash assumptions	Assumes that all GAC and IX treatment systems require a new influent pumping station, and all GAC and IX treatment systems require new backwash pumps. Except for the two smallest size categories, assumes all GAC and IX treatment systems require backwash recovery basins providing 20 feet of water depth.	AWWA's assumptions overestimate costs as many systems, including small groundwater systems, likely have sufficient existing influent pumping pressure to cover the additional head loss. Some systems using GAC (especially small systems) may not need a dedicated new backwash pump and may be able to accomplish backwash using existing influent or treated water pumps. In applications using PFAS-selective IX resins, periodic backwashing is not recommended (Berretta et al., 2021), so the need for these pumps is questionable and the assumption overestimates costs.

Capital equipment costs	The Association of Metropolitan Water Agencies (AMWA) and the AWWA surveyed its members to obtain recent cost data on installed PFAS treatment systems at drinking water treatment plants.	The EPA updated its equipment costs to 2022 dollars using current price indices. The EPA also collected new vendor price quotes for cost driver equipment components (e.g., pressure vessels, treatment media) and made several other adjustments to WBS model assumptions about pilot study costs and contingency costs that increased total capital costs. The B&V model, as presented in Figure 7-1 of AWWA's public comment letter, appears to overestimate costs for many of the case studies included in the B&V report. For example, it results in higher costs for 28 of the 32 case studies (88 percent) shown in Figure 7-1. The EPA assessed the WBS model results in comparison to the costs of GAC equipment packages from 2023 supplied by a nationally recognized vendor of GAC media and GAC treatment systems. Based on this assessment, the EPA concluded that the direct capital costs in the WBS model for comparable packages of equipment, excluding items the vendor does not supply, range from 23 percent lower to 19 percent higher than the vendor costs and with two exceptions, they are within 10 percent of the vendor costs.
Small system capital costs	Listed capital costs for small systems ranging from $900,000 to $5,300,000.	The EPA accounts for the use of package systems. AWWA appendix B, Table 3-1, indicates that their pressure GAC model accepts treatment capacity inputs from 1 to 12 mgd. It does not indicate how the model handles design flows less than 1 mgd. It is possible that the parametric estimates the model uses are not a good fit below this threshold and does not account for the use of package systems.
Average and design flow estimates	Service population data from SDWIS was used and the average flow for each PWS was assumed based on a per capita per day usage of 150 gallons. Peaking factors for different size systems from the EPA's *Cost and Technology Document for Final Groundwater Rule* were used.	Estimated design flow of a water system effects the size and cost of the capital equipment that will be installed on site. Average flow estimates are the driver for many operational costs. AWWA's approach to estimating design and average flow requirements overestimates the treatment system flow requirements, particularly for smaller systems. For the smallest systems, AWWA's approach overestimates flows by up to 30 percent. The EPA estimated the average daily flow and design flow for drinking water systems based on the empirical relationship between retail population served and flow. This relationship was derived using the data collected via the

		CWSS. It is reported in the EPA's *Geometries and Characteristics of Public Water Systems* report (USEPA, 2000g). As detailed in Table 4-34 of the EA for the final rule, water use efficiency has increased substantially since these relationships were developed, and therefore the trend of lower residential water use could result in lower flow per population and lower treatment costs as compared to predicted values in the EPA's analysis.

Table 26. EPA Response to key operation and maintenance cost assumptions in AWWA B&V Report

Analytical Component	AWWA B&V report	EPA response
Bed life	The BV values utilized for GAC were derived from data collected during a Black & Veatch GAC pilot study for Cape Fear Public Utility Authority (CFPUA). The values utilized for IX were derived partially from data collected during a Black & Veatch IX pilot study for CFPUA and partially from data collected during an IX pilot study for La Habra Height County Water District.	AWWA estimates bed life for all systems using parameters derived from one or two pilot studies. These site-specific pilot studies may not be representative of the range of water quality conditions experienced by systems across the country. For GAC in particular, using the parameters in AWWA's Table 5-9 results in estimated bed lives of less than 7,000 and 9,000 BVs for 90 percent removal of PFOA and PFOS, respectively. These short bed life estimates result in high annual operating costs and may be an artifact of the relatively high influent TOC in the CFPUA pilot study that is the basis of AWWA's estimates. Surface and groundwater systems with more moderate to low influent TOC would be expected to experience much longer GAC bed life and lower operating costs.
Disposal of treatment media	Assumed that spent GAC media would be incinerated "because of the unknown viability of GAC media reactivation under CERCLA." Replacement costs were therefore assumed to be virgin media.	The EPA has proposed PFOA and PFOS be designated as hazardous substances under CERCLA. If finalized, the designation of PFOA and PFOS as CERCLA hazardous substances would not require waste (e.g., biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any specific particular type of landfill. The designation also would not restrict, change, or recommend any specific activity or type of waste at landfills. This action should not result in limiting disposal options and how PFAS containing waste, including spent GAC or resin, is required to be managed. However, drinking water treatment operations may choose to send spent GAC and resin containing PFAS to facilities permitted to treat and/or dispose of hazardous wastes. Even where reactivation is not feasible, disposal in a RCRA permitted hazardous waste disposal facility is expected to be a more cost-effective option than incineration. Therefore, the assumption of incineration and replacement with virgin media overestimates the disposal costs in the B&V report.

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c. Treatment Costs in the Final Rule Analysis

The cost estimates in the EA for the final PFAS NPDWR reflects the adjustments made to the WBS curves and decision tree based on public comments discussed above as well as the additional occurrence information available since the publication of the proposed PFAS NPDWR. For detailed information on the EPA's occurrence analysis, see section VI of this preamble. For detailed information on the EPA's cost analysis and the EPA's estimates of the national annualized costs of the final MCLs, see section XII.D.

3. Primacy Agency Costs

a. Primacy Agency Cost Estimates in the Proposal

In the EA for the proposed rule, the EPA estimated the costs incurred by primacy agencies associated with the rule, including up front implementation costs as well as costs associated with system actions related to sampling and treatment.

b. Summary of Major Public Comments on Primacy Agency Costs and EPA Responses

Many commenters state that the EPA has underestimated the costs to primacy agencies required to comply with the rule. One commenter stated, ''EPA's analysis of primacy agency costs does not accurately capture all the activities that primacy agencies will undergo for PFAS implementation and underestimates the number of hours for the primacy tasks.'' Commenters recommend that the EPA use findings from ASDWA's PFAS Cost of State Transactions Study (PCoSTS) to reevaluate the primacy agency costs estimated in the EA. The EPA's response to specific recommendations is discussed here.

The EPA agrees with commenters on the burdens associated with regulatory start up; primacy package adoption; technical, managerial, and financial (TMF) assistance to water systems; and reviewing and approving treatment. Commenters pointed out activities not explicitly accounted for in the regulatory start up estimate in the EA for proposal including accreditation of laboratories for PFAS testing; SDWIS updates; monitoring schedule updates; time spent responding to questions from members of the public; inquiries from public officials; and media requests immediately following the final publication of the NPDWR. Commenters also pointed out that adopting primacy packages is a significant undertaking with ''specific and very detailed administrative procedures that must be adhered to in order to adopt water quality regulations'' and that ''some primacy agencies have requirements for robust public comment periods as a component of new rule adoption.'' As recommended by commenters, the EPA created a new cost item for primacy package adoption. Commenters stated the EPA's assumption in the proposal that the amount of time a primacy agency will need to review treatment plans directly correlates with the size of the water system was inaccurate. Commenters noted that ''. . . small systems often take the most time as they need significant assistance to navigate the process for the design and construction of new treatment and get into compliance.'' After considering these comments, the EPA agrees that reviewing and approving treatment for small systems is likely to take more time given the assistance needed for these systems. Because small systems often lack the technical, managerial, and financial capacity, it is likely that primacy agencies will spend more time assisting these systems in navigating compliance with the PFAS NPDWR. As such, the EPA adjusted burden estimates in the final rule to reflect the largest primacy agency burden per EP at the smallest systems and decreased burden hours with increasing system size, as commenters suggested.

Several commenters disagreed with the EPA's exclusion of additional costs to primacy agencies associated with reporting regarding violations, variances and exemptions, enforcement actions, and other compliance related primacy agency activities in the national cost analysis. One commenter estimated the PFAS NPDWR will likely result in hundreds of violations once in effect. The EPA recognizes that these activities do have an associated burden for primacy agencies but disagrees that these costs should be included in the EA. The EPA assumed 100 percent compliance for its national level analysis in the EA for the final rule because the EPA has determined that the final rule is feasible given known occurrence concentrations and efficacy of the technologies available. Further, this is consistent with the approach taken in EAs for other NPDWRs (USEPA, 2005c; USEPA, 2019c; USEPA, 2020f). Commenters recommended that the EPA include hours for additional annual reporting. The EPA disagrees and expects that adding PFAS results to already-required reports will have no discernable incremental burden for quarterly or annual reports to SDWIS Fed.

Commenters recommended that the EPA include the costs associated with various compliance activities. Given the EPA's assumption of 100 percent compliance for its national level analysis in the EA discussed above, the EPA disagrees and did not take commenters' recommendations to include the costs associated with assisting out of compliance systems and assisting systems to remain in compliance, pursuing enforcement actions, staff time checking in with system violations and reviewing system variances and exemptions. The EPA did include the costs associated with compliance activities for systems in compliance, including updating inspection SOPs and additional sanitary survey burden at water systems that have installed treatment to comply with the PFAS NPDWR.

c. Primacy Agency Costs in the Final Rule Analysis

After considering public comments on the burden hours associated with primacy agency activities, the EPA made the following changes. The EPA increased the estimate from 416 hours to ''read and understand the rule as well as adopt reg requirements'' to 4,000 hours per primacy agency to conduct a suite of regulatory start up activities. Per commenters' recommendation, the EPA included a new line item for primacy package adoption and estimated 300 hours per primacy agency. The EPA lowered the water system operator TMF training from 2,080 hours to 1,500 hours per primacy agency based on commenter recommendations. The EPA added a one-time burden estimate of 20 hours to inspection SOPs and an additional 2–5 burden hours for the primacy agency, by water system size, per sanitary survey per system installing treatment to comply with the rule. For more information see section XII.D.

4. Costs of the Hazard Index

a. Hazard Index Cost Estimates in the Proposal

In the EA for the proposed rule, the EPA estimated national costs associated with PFOA, PFOS, and PFHxS. Given available occurrence data for the other compounds in the proposed rule (PFNA, HFPO–DA, and PFBS) and the regulatory thresholds under consideration, the EPA did not use SafeWater to model national costs associated with potential Hazard Index (HI) exceedances as a direct result of these contaminants. To assess the potential impact of these compounds in the proposed rule, the EPA conducted an analysis of the additional, or

incremental, system level impact that occurrence of these contaminants would have on treatment costs. The EPA estimated that the Hazard Index would increase costs by 0–77 percent at the system level, with costs varying due to PFAS occurrence scenario and treatment technology used.

b. Summary of Major Public Comments on Hazard Index Costs and EPA Responses

A few commenters recommended that the EPA further consider the costs associated with compliance with the Hazard Index (HI) MCL. Specifically, commenters stated that the EPA's analysis of system level costs associated with the Hazard Index does not adequately characterize the overall costs that will be incurred due to the Hazard Index standard. One commenter stated that ''EPA should not move forward with the Hazard Index until it has satisfied its statutory and policy obligation to conduct a cost-benefit analysis.'' Some commenters voiced concern regarding the EPA's assumption that costs associated with compliance with the Hazard Index MCL are insignificant and asserted that these costs must be reexamined, stating that this assessment ''requires more knowledge on the nationwide occurrence of these compounds'' and that the EPA ''cannot assume that addressing the costs of PFOA and PFOS is sufficient when the additional four PFAS will be driving treatment decisions at some PWSs.'' Conversely, one commenter asserted that available occurrence data demonstrate that few systems will be required to install treatment to comply with the Hazard Index MCL that would not already be treating to comply with the PFOA and PFOS MCLs.

The EPA disagrees with commenters who state that the agency did not meet its requirements under SDWA, which requires the agency to analyze ''quantifiable and nonquantifiable costs . . . that are likely to occur solely as a result of compliance with the maximum contaminant level.'' In the proposal, the EPA analyzed the quantifiable costs of the Hazard Index at the system level, using the best available information at the time of publication, and analyzed the nonquantifiable costs of the Hazard Index by including a qualitative discussion of the national level impacts and therefore met the statutory requirements under SDWA 1412(b)(3)(C). After considering recommendations from the public comments to further analyze the costs of the Hazard Index and the data available to support a quantitative analysis of the costs of the Hazard Index, the EPA decided to conduct a sensitivity analysis of the costs of the Hazard Index at the national level. The results of the sensitivity analysis supported the EPA's assumption in the proposal that quantified national costs are marginally underestimated as a result of this lack of sufficient nationally representative occurrence data. The EPA's consideration of Hazard Index costs in the final rule analysis are discussed in the following subsection.

c. Hazard Index and PFHxS, PFNA, and HFPO–DA MCL Costs in the Final Rule Analysis

To estimate quantified costs of the final rule presented in the national-level summary tables, the EPA first estimated baseline PFAS occurrence using a Bayesian hierarchical model fitted with sampling data collected from systems participating in UCMR 3. The model included three of the six PFAS compounds regulated through this NPDWR: PFOA, PFOS, and PFHxS (see section VI of this preamble). This permitted the agency to quantify costs at a national level with a higher degree of confidence and precision for these three PFAS than if simple extrapolations had been used. Since there are some limitations with nationally representative occurrence information for the other compounds that were either not included in UCMR 3 (HFPO–DA) or did not have a sufficient number of observed values above the UCMR 3 reporting limits (PFNA, PFBS), the EPA has a lesser degree of confidence and precision for its quantified estimates of these three PFAS, which are informed by a significant amount of available state-level data. Therefore, the EPA presented the cost estimates for PFNA, HFPO–DA, and PFBS in a sensitivity analysis in the EA (*i.e.,* national-level sensitivity analysis, see appendix N.3) instead of including these costs in the summary tables of quantified national level costs.[16]

In the EA for the proposed PFAS NPDWR, the EPA used a model system approach[17] to illustrate the potential incremental costs for removing PFAS not included in the national economic model (*i.e.,* PFNA, HFPO–DA, and PFBS). After considering public comments on the incremental cost analysis, many of which encouraged the EPA to further evaluate and consider quantified costs of the Hazard Index MCL where feasible, the EPA updated and combined existing analyses contained in the rule proposal to evaluate the incremental costs associated with the Hazard Index MCL and individual MCLs for PFNA and HFPO–DA with a quantified national level sensitivity analysis in the final rule. The updated analysis for the final rule builds on the proposal analysis by combining information that was presented separately at proposal. The analysis in appendix N of the final EA utilizes the system level treatment cost information presented at proposal (See appendix N of USEPA, 2023n, 2023o) with updates to the cost models for the final rule detailed in section XII.A.2. These treatment costs were applied to the number of systems expected to exceed the standards based on PFNA, PFBS, and HFPFO–DA occurrence using the approaches for estimating occurrence of these compounds presented at proposal (see section 10.3 of USEPA, 2023l). This modified analysis was primarily conducted to ensure that the EPA has not, as some commenters claim, substantially underestimated the potential magnitude of these costs. The EPA notes the approach presented in appendix N for the final rule and summarized here, by connecting analyses for proposed rule, allows the agency to consider and compare the relative degree of the potential overall costs of these otherwise nonquantifiable costs of the Hazard Index and PFNA and HFPO–DA MCLs relative to overall national rule costs. This analysis confirms the EPA's findings at proposal that the Hazard Index costs (and those costs for regulating PFNA and HFPO–DA individually) make up a small portion of

[16] When available, nationally representative occurrence information is preferable for an economic analysis of national level costs and benefits. In the case of PFOA, PFOS, and PFHxS, the EPA has a sufficiently robust nationally representative dataset from UCMR 3. The EPA used additional state data that were available at systems that were part of this UCMR 3 set of systems to fit the national occurrence model that informed cost estimates for PFOA, PFOS, and PFHxS (see Cadwallader et al., 2022). In the case of PFNA, HFPO–DA, and PFBS, the EPA lacks the same level of precision as described above for PFOA, PFOS, and PFHxS. State-led data collection efforts provided valuable information about occurrence for PFNA, HFPO–DA, and PFBS, however they did not provide the nationally representative foundation provided by UCMR3 for PFOA, PFOS, and PFHxS to be incorporated into the MCMC national occurrence model.

[17] At proposal, the EPA used a model system approach for estimating potential incremental treatment costs associated with co-occuring PFAS at systems already required to treat in the national model framework and the potential per system costs for the set of systems triggered into treatment as a result of Hazard Index MCL exceedances not already captured in the national analysis. For further detail on the assumptions and findings of the EPA's analysis of incremental costs of other PFAS at rule proposal, please see appendix N.3 in the Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (USEPA, 2023n, 2023o).

the overall rule costs. Likewise, the EPA notes that while these costs are presented in appendix N because of the lesser degree of confidence and precision in the estimates, the EPA has considered these costs as part of this final regulation. It has done so by evaluating nonquantifiable costs and accounting for uncertainty, characterizing these otherwise nonquantifiable costs in appendix N to generate cost estimates that, while useful, are not as statistically robust as the national cost estimates presented in chapter 5 of the EA. Using this analysis, the agency has confirmed the Hazard Index and PFNA and HFPO–DA MCLs drive a relatively low percentage of the overall rule costs. The EPA has also considered these costs in the context that the Hazard Index and PFHxS, PFNA, and HFPO–DA MCLs are expected to deliver important nonquantifiable health benefits, including PFNA birth weight benefits [18] and other nonquantifiable benefits associated with the reduction of the Hazard Index PFAS (PFNA, PFHxS, HFPO–DA, and PFBS) [19] described in chapter 6.2 of the EA.

The proposed rule included a Hazard Index MCLG and MCL for any mixture of one or more of PFHxS, HFPO–DA, PFNA, and PFBS. The final rule includes a Hazard Index MCLG and MCL for any mixture of two or more of PFHxS, HFPO–DA, PFNA, and PFBS. The final rule also includes individual MCLGs and MCLs for PFHxS, PFNA, and HFPO–DA. The EPA's cost analysis at proposal considered the costs associated with the individual MCLs for PFHxS, PFNA, and HFPO–DA because the proposed Hazard Index MCL would function as individual MCLs when these contaminants occur in isolation. While the rule structure has changed in the final NPDWR, the costing framework used at proposal is still applicable in the final rule: what was considered a Hazard Index MCL exceedance at proposal would be an individual MCL exceedance under the final rule should those contaminants occur in isolation. Further, a Hazard Index exceedance in the final rule (defined as two or more of PFHxS, PFNA, HFPO–DA, and PFBS) is unchanged from a costing perspective to what the EPA proposed. Whether a system exceeds a Hazard Index MCL or individual MCL in the final rule, these costs are captured in the cost estimates the EPA considered and presented in appendix N.3 of the EA and summarized in this section. Specifically, if a system exceeds only one of the individual MCLs for PFHxS, PFNA, or HFPO–DA that exceedance is costed by estimating the removal needed to achieve compliance with a given individual MCL. If a system exceeds the Hazard Index MCL, that exceedance is costed by estimating the removal of the combination of contaminants needed to achieve compliance with the Hazard Index MCL. Therefore, the national level cost estimate for PFHxS is reflective of both the total national cost of the PFHxS individual MCL and instances of Hazard Index MCL exceedances where PFHxS is present above its HBWC while other Hazard Index PFAS are present.

To understand the totality of national-level cost impacts for the Hazard Index MCL, the EPA considered both the contribution of PFHxS (estimated as part of the national level cost analysis), as well as the costs for PFNA, HFPO–DA, and PFBS (estimated in the appendix N sensitivity analysis). Together, these provide information on the costs for the Hazard Index MCL and the individual MCLs for PFHxS, PFNA, and HFPO–DA, as a whole. Due to available data informing the Bayesian hierarchical occurrence model, the EPA was only able to quantify the portion of total costs for the Hazard Index MCL attributable to PFHxS [20] in the national level analysis. The EPA notes that this estimate also represents the national level quantified costs for the individual PFHxS MCL. The EPA acknowledges that this $11.6 million estimate is only a portion of the costs imposed by the Hazard Index MCL and also does not account for the costs imposed by the individual PFNA and HFPO–DA MCLs. The EPA accounted for those potential additional costs through the sensitivity analysis described in appendix N, in which the EPA found that costs of treating for PFNA, HFPO–DA, and PFBS to meet the Hazard Index MCL and individual MCLs for PFNA and HFPO–DA increased national costs by approximately 5 percent, from $1,549 million to $1,631 million. These costs represent the total costs of the final rule; in other words, this includes the costs associated with individual MCLs for PFOA, PFOS, PFHxS, HFPO–DA, and PFNA, as well as the Hazard Index MCL. Due to data limitations, the EPA has not separately estimated the costs of the Hazard Index in the absence of the individual MCLs. The sensitivity analysis demonstrates that the quantified national analysis cost estimate that includes only PFOA, PFOS, and PFHxS (where PFHxS represents only a portion of the Hazard Index costs) marginally underestimates total rule costs when also considering the potential cost impacts attributable to HFPO–DA, PFNA, and PFBS. The cost estimates stemming from both the quantified national estimate for PFOA, PFOS, and PFHxS, and from the sensitivity analysis conducted for PFNA, HFPO–DA, and PFBS together inform the impact of the Hazard Index MCL as required by the HRRCA under SDWA.

To fully weigh the costs and benefits of the action, the agency considered the totality of the monetized values, the potential impacts of the nonquantifiable uncertainties, the nonquantifiable costs and benefits, and public comments received by the agency related to the quantified and qualitative assessment of the costs and benefits. For the final rule, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the rule justify its quantified and nonquantifiable costs.

In light of the individual MCLs, the EPA has separately presented national level marginal costs associated with the individual MCLs for PFHxS, PFNA and HFPO–DA in the absence of the Hazard Index MCL; see chapter 5.1.3 and appendix N.4 of the EA for details. Therefore, the costs for the individual PFHxS, PFNA, and HFPO–DA MCLs have been considered both in the

[18] As discussed in appendix K.4, a 1 ppt reduction in both PFOA and PFOS for a system serving a population of 100,000 would result in $0.101 million in annualized birth weight benefits. If including a 1 ppt PFNA reduction, in addition to a 1 ppt reduction in both PFOA and PFOS, for a system serving a population of 100,000, the resulting annualized birth weight benefits would increase by $0.464 to $0.689 million, depending on the slope factor used for PFNA. The EPA estimates that 208 water systems may exceed the PFNA MCL.

[19] The EPA also anticipates additional substantial benefits to PWS customers associated with reduced exposure to Hazard Index compounds (PFHxS, HFPO–DA, PFNA, and PFBS) not included in the primary analysis. The nonquantifiable benefits impact categories include developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects. See chapter 6.2 of the EA for more information.

[20] The EPA notes that there are anticipated to be circumstances where PFHxS exceeds its individual MCL and HBWC where PFNA, PFBS, and HFPO–DA do not co-occur. While resulting in an exceedance of the PFHxS MCL, if PFHxS exceeds its HBWC without other Hazard Index PFAS present, this would not result in an exceedance of the Hazard Index MCL. At rule proposal, a single exceedance of any of the four Hazard Index PFAS would have resulted in an exceedance of the Hazard Index MCL. However, to improve rule implementation and to support effective risk communication, the EPA has structured the final rule such that a Hazard Index exceedance only occurs when there are two or more of the Hazard Index PFAS present. Therefore, while for purposes of informing its quantified cost analysis the EPA is assuming that every PFHxS exceedance of the MCL also causes an exceedance of the Hazard Index MCL, this approach results in the EPA overestimating PFHxS-attributable Hazard Index costs in its national cost analysis.

proposed and final rule. For more information on the agency's methodology, findings, and limitations of the EPA's updated analysis of costs associated with compliance with the Hazard Index, please see appendix N.3 of the EA (USEPA, 2024e).

5. Benefit-Cost Determination

a. Benefit-Cost Determination in the Proposal

When proposing an NPDWR, the Administrator shall publish a determination as to whether the benefits of the MCL justify, or do not justify, the costs based on the analysis conducted under section 1412(b)(3)(C). For the proposed rule, the Administrator determined that the quantified and nonquantifiable benefits of the proposed PFAS NPDWR justified the costs.

b. Summary of Major Public Comments on Benefit-Cost Determination and EPA Responses

Many commenters agreed with the Administrator's determination that the benefits of the rule justify its costs. Specifically, commenters asserted that the EPA's estimation of the net benefits of enacting the MCLs is reasonable, stating that ''even if the costs are very substantial, the benefits associated with the anticipated drinking water improvements justify such expenditures.'' Commenters also stated that it is likely that ''the analysis understates the benefits'' of the rule, particularly given the ''significant unquantified risk reduction benefits and co-benefits'' that are anticipated to result from the rule.

In response to these comments, the EPA agrees that its quantified benefits likely significantly understate the benefits of the rule due to the large share of nonquantifiable benefits that are expected to be realized as avoided adverse health effects, in addition to the benefits that the EPA has quantified. The EPA anticipates additional benefits associated with developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects beyond those benefits associated with decreased PFOA and PFOS that the EPA has quantified. In response to commenters urging the EPA to quantify additional health endpoints associated with PFAS exposure, the EPA has developed a quantitative sensitivity analysis of PFOS effects and liver cancer, further strengthening the justification for this determination. Due to occurrence, health effects, and/or economic data limitations, the EPA is unable to quantitatively assess additional benefits of the rule.

Conversely, several commenters stated that the EPA has failed to demonstrate that the benefits of the rule justify its costs. Specifically, commenters disagreed with this determination because the EPA's analysis ''significantly underestimates the costs of the proposed MCLs. . .and overestimates its benefits.'' Commenters asserted that the EPA needs to update its EA to more accurately reflect the true costs of compliance of the rule to make the determination that the rule's costs are justified by its benefits. A few commenters urged the EPA to consider whether the benefits of finalizing the rule at regulatory alternative MCLs (*e.g.,* 5.0 or 10.0 ng/L) would better justify the costs of the rule.

After considering public comments, the EPA has made a number of adjustments to the cost model and collectively these changes have increased the agency's estimated annualized costs. The EPA has used the best available peer reviewed science to inform the cost estimates, including treatment costs, of the final PFAS NPDWR. For more information on the EPA's responses to comments on the rule costs, see sections XII.A.2–XII.A.4 of this preamble. The EPA disagrees with commenters that the EPA has overstated the benefits. As discussed in section XII.A.1, the EPA has used the best available peer reviewed science to quantify the benefits of the rule. The EPA also disagrees with commenters that suggested the benefits ''better justify'' the costs of PFOA and PFOS standards at 5.0 or 10.0 ng/L. These commenters pointed to the quantified net benefits of the regulatory alternatives and noted that net benefits are positive at 3 and 7 percent discount rates for a standard of 10.0 ng/L for PFOA and PFOS. The commenters' sole reliance on the quantified costs and benefits of the rule to support their argument is incorrect, as SDWA requires the agency to consider both the quantifiable and nonquantifiable impacts of the rule in the determination. Under SDWA 1412(b)(4)(B), the EPA is required to set an MCL as close as feasible to the MCLG, taking costs into consideration. In other words, SDWA does not mandate that the EPA establish MCLs at levels where the quantified benefits exceed the quantified costs. This was many commenters' justification for the recommendation to promulgate a standard of 10.0 ppt each for PFOA and PFOS in lieu of the proposed rule, and the EPA therefore disagrees that quantified costs and benefits can or should be the sole determinant of an MCL value. The Administrator's assessment that the benefits of the proposed rule justified its costs was based on the totality of the evidence, specifically the quantified and nonquantifiable benefits, which are anticipated to be substantial, as well as the quantified and nonquantifiable costs. Other commenters incorrectly stated that SDWA requires the EPA to set an MCL at a level ''. . . that maximizes health risk reduction benefits at a cost that is justified by the benefits.'' This test is found in section 1412(b)(6)(A) of SDWA and applies only when the Administrator determines based on the HRRCA that the benefits of a proposed MCL developed in accordance with paragraph (4) would not justify the costs of complying with the level. In the case of the proposed PFAS NPDWR, the Administrator determined that the benefits justify the costs for MCLs set as close as feasible to the MCLGs. For more information on the EPA's response to comments on the regulatory alternative MCLs considered in this rule, see section V of this preamble.

c. Benefit-Cost Determination in the Final Rule Analysis

For the final rule, considering both quantifiable and nonquantifiable costs and benefits of the rule as discussed in the EA and EA Appendices, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the MCLs justify their costs.

B. Affected Entities and Major Data Sources Used To Develop the Baseline Water System Characterization

The entities potentially affected by the final rule are primacy agencies and PWSs. PWSs subject to final rule requirements are either CWSs or NTNCWSs. These water systems can be publicly or privately owned. PWSs subject to the rule would be required to meet the MCL and comply with monitoring and reporting requirements. Primacy agencies would be required to adopt and enforce the drinking water standard as well as the monitoring and reporting requirements.

Both PWSs and primacy agencies are expected to incur costs, including administrative costs, monitoring, and reporting costs, and in some cases, anticipated costs to reduce PFAS levels in drinking water to meet the final rule using treatment or nontreatment options. Section D of this preamble summarizes the method the EPA used to estimate these costs.

The systems that reduce PFAS concentrations will reduce associated

health risks. The EPA developed methods to estimate the potential benefits of reduced PFAS exposure among the service populations of systems with PFAS levels exceeding the final drinking water standard. Section E summarizes the method used to estimate these benefits.

In its *Guidelines for Preparing Economic Analyses,* the EPA characterizes the ''baseline'' as a reference point that reflects the world without the final regulation (USEPA, 2016e). It is the starting point for estimating the potential benefits and costs of the final NPDWR. The EPA used a variety of data sources to develop the baseline drinking water system characterization for the regulatory analysis. Table 27 lists the major data sources and the baseline data derived from them. Additional detailed descriptions of these data sources and how they were used in the characterization of baseline conditions can be found in chapter 4 of USEPA (2024g).

Table 27: Data Sources Used to Develop Baseline Water System Characterization

Data Source	Baseline Data Derived from the Source
SDWIS Federal version fourth quarter 2021 Q4 "frozen" dataset [1]	*Water System Inventory:* PWS inventory, including system unique identifier, population served, number of service connections, source water type, and system type. *Population and Households Served:* PWS population served. *Treatment Plant Characterization:* Number of unique treatment plant facilities per system, which are used as a proxy for EP when UCMR 3 sampling site data are not available.
UCMR 3 (USEPA, 2017)	*Treatment Plant Characterization*: Number of unique EP sampling sites, which are used as a proxy for EP. *Treatment Plant Characterization:* PFAS concentration data collected as part of UCMR 3.
Independent state sampling programs	*Treatment Plant Characterization:* PFAS concentration data collected by states. These data supplemented the occurrence modeling for systems included in UCMR 3.
Six-Year Review 4 Information Collection Request (SYR4 ICR) Occurrence Dataset (2012-2019)	*Treatment Plant Characterization:* TOC.
Geometries and Characteristics of Public Water Systems (USEPA, 2000g)	*Treatment Plant Characterization:* Design and average daily flow per system.
2006 CWSS (USEPA, 2009c)	*Public Water System Labor Rates:* PWS labor rates.

Notes:

[1] Contains information extracted on January 14, 2022.

C. Overview of the Cost-Benefit Model

The EPA's existing SafeWater Cost Benefit Model (CBX) was designed to calculate the costs and benefits associated with setting a new or revised MCL. Since the final rule simultaneously regulates multiple PFAS contaminants, the EPA developed a new model version called the SafeWater Multi-Contaminant Benefit Cost Model (MCBC) to efficiently handle more than one contaminant. SafeWater MCBC allows for inputs that include differing mixtures of contaminants based on available occurrence data as well as multiple regulatory thresholds. The model structure allows for assignment of compliance technology or technologies that achieve all regulatory requirements and estimates costs and benefits associated with multiple PFAS contaminant reductions. SafeWater MCBC is designed to model co-occurrence, sampling, treatment, and administrative costs, and simultaneous contaminant reductions and resultant benefits. The modifications to the SafeWater model are consistent with the methodology that was developed in the single MCL SafeWater CBX Beta version that was peer reviewed. More detail on the modifications to the SafeWater model can be found in section 5.2 of the EPA's EA.

The costs incurred by a PWS depend on water system characteristics; SDWIS

Fed provides information on PWS characteristics that typically define PWS categories, or strata, for which the EPA developed cost estimates in rulemakings, including system type (CWS, NTNCWS), number of people served by the PWS, the PWS's primary raw water source (ground water or surface water), the PWS's ownership type (public or private), and the state in which the PWS is located.

Because the EPA does not have complete PWS-specific data across the approximately 49,000 CWSs and 17,000 NTNCWSs in SDWIS Fed for many of the baseline and compliance characteristics necessary to estimate costs and benefits, such as design and average daily flow rates, water quality characteristics, treatment in-place, and labor rates, the EPA adopted a ''model PWS'' approach. SafeWater MCBC creates model PWSs by combining the PWS-specific data available in SDWIS Fed with data on baseline and compliance characteristics available at the PWS category level. In some cases, the categorical data are simple point estimates. In this case, every model PWS in a category is assigned the same value. In other cases, where more robust data representing system variability are available, the category-level data include a distribution of potential values. In the case of distributional information, SafeWater MCBC assigns each model PWS a value sampled from the distribution. These distributions are assumed to be independent.

For a list of PWS characteristics that impact model PWS compliance costs, please see chapter 5 of USEPA (2024g). These data include inventory data specific to each system and categorical data for which randomly assigned values are based on distributions that vary by category (*e.g.,* ground water and surface water TOC distributions or compliance forecast distributions that vary by system size category).

Once model PWSs are created and assigned baseline and compliance characteristics, SafeWater MCBC estimates the quantified costs and benefits of compliance for each model PWS under the final rule. Because of this model PWS approach, SafeWater MCBC does not output any results at the PWS level. Instead, the outputs are cost and benefit estimates for 36 PWS categories, or strata. Each PWS category is defined by system type (CWS and NTNCWS), primary water source (ground or surface), and size category. Note the EPA does not report state-specific strata although state location is utilized in the SafeWater MCBC model (*e.g.,* current state-level regulatory limits on PFAS in drinking water). The detailed output across these strata can be found in the chapter 5 of USEPA (2024g).

For each PWS category, the model then calculates summary statistics that describe the costs and benefits associated with final rule compliance. These summary statistics include total quantified costs of the final rule, total quantified benefits of the final rule, the variability in PWS-level costs (*e.g.,* 5th and 95th percentile system costs), and the variability in household-level costs.

D. Method for Estimating Costs

This section summarizes the cost elements and estimates total cost of compliance for the PFAS NPDWR discounted at 2 percent. The EPA estimated the costs associated with monitoring, administrative requirements, and both treatment and nontreatment compliance actions associated with the final rule (USEPA, 2024g).

1. Public Water System (PWS) Costs

a. PWS Treatment and Nontreatment Compliance Costs

The EPA estimated costs associated with engineering, installing, operating, and maintaining PFAS removal treatment technologies, including treatment media replacement and spent media destruction or disposal, as well as nontreatment actions that some PWSs may take in lieu of treatment, such as constructing new wells in an uncontaminated aquifer or interconnecting with and purchasing water from a neighboring PWS. The EPA used SafeWater MCBC to apply costs for one of the treatment technologies or nontreatment alternatives at each EP in a PWS estimated to be out of compliance with the final rule. For each affected EP, SafeWater MCBC selected from among the compliance alternatives using a decision tree procedure, described in more detail in USEPA (2024j). Next, the model estimated the cost of the chosen compliance alternative using outputs from the EPA's WBS cost estimating models. The WBS models are spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs.

Specifically, the EPA used cost equations generated from the following models (USEPA, 2024m):

- the GAC WBS model (USEPA, 2024p);
- the PFAS-selective IX WBS model (USEPA, 2024q); and
- the nontreatment WBS model (USEPA, 2024r).

The *Technologies and Costs* (T&C) document (USEPA, 2024m) provides a comprehensive discussion of each of the treatment technologies, their effectiveness, and the WBS cost models as well as the equations used to calculate treatment costs. In total, there are more than 2,600 individual cost equations across the categories of capital and operation and maintenance (O&M) cost, water source, component level, flow, bed life (for GAC and IX), residuals management scenarios (for GAC and IX), and design type (for GAC). These models are available on the EPA's website at *https://www.epa.gov/sdwa/drinking-water-treatment-technology-unit-cost-models* as well as in the docket for this rule.

b. Decision Tree for Technology Selection

For EP at which baseline PFAS concentrations exceed regulatory thresholds, SafeWater MCBC selects a treatment technology or nontreatment alternative using a two-step process that both:

- Determines whether to include or exclude each alternative from consideration given the EP's characteristics and the regulatory option selected, and
- Selects from among the alternatives that remain viable based on percentage distributions derived, in part, from data on recent PWS actions in response to PFAS contamination.

Inputs to SafeWater MCBC used in Step 1 include the following:

- Influent concentrations of individual PFAS contaminants in ng/L (ppt)
- EP design flow in MGD
- TOC influent to the new treatment process in mg/L.

The EPA relied on information from the national PFAS occurrence model to inform influent PFAS concentrations. The EPA relied on *Geometries and Characteristics of Public Water Supplies* (USEPA, 2000g) and SDWIS inventory information to derive EP design flow. SafeWater MCBC selects influent TOC using the distribution shown in Table 28.

Table 28: Frequency Distribution to Estimate Influent TOC in mg/L

Percentile	Surface Water	Ground Water
0.05	0.65	0.35
0.15	1.1	0.48
0.25	1.38	0.5
0.35	1.6	0.5
0.45	1.85	0.58
0.5	1.97	0.69
0.55	2.14	0.75
0.65	2.54	1
0.75	3.04	1.39
0.85	3.63	2.01
0.95	4.81	3.8

Source: The EPA's analysis of TOC concentrations in the SYR4 ICR database.

In Step 1, SafeWater MCBC uses these inputs to determine whether to include or exclude each treatment alternative from consideration in the compliance forecast. For the treatment technologies (GAC and IX), this determination is based on estimates of each technology's performance given available data about influent water quality and the regulatory option under consideration.

The EPA assumes a small number of PWSs may be able to take nontreatment actions in lieu of treatment. The viability of nontreatment actions is likely to depend on the quantity of water being replaced because the ability to purchase from another water system is limited by the seller water system's capacity and the ability to drill another well is limited by the ability to find an accessible, sufficiently large source. Therefore, SafeWater MCBC considers nontreatment only for EP with design flows less than or equal to 3.536 MGD. The EPA estimates approximately 2 percent of systems of this size will develop new wells and approximately 6–7 percent of systems will elect to interconnect with another system to achieve compliance.

In Step 2, SafeWater MCBC selects a compliance alternative for each EP from among the alternatives that remain in consideration after Step 1. Table 29 shows the initial compliance forecast that is the starting point for this step. The percentages in Table 29 consider data presented in the T&C document (USEPA, 2024m) on actions PWSs have taken in response to PFAS contamination.

To date, the majority of PWSs for which data are available have installed GAC (USEPA, 2024m). USEPA (2024m) includes data for 52 systems, 34 of which (65%) have installed GAC. The data in USEPA (2024m) also suggest that an increasing share of PWSs have selected IX in response to PFAS since the first full-scale system treated with PFAS-selective IX in 2017. Specifically, for systems installed prior to 2017, 78% used GAC. The EPA expects this trend to continue, so the initial percentages include adjustments to account for this expectation. In addition, the performance of GAC is affected by the presence of TOC, as further described in the cost chapter of the EA (USEPA, 2024g). Accordingly, the table includes adjusted distributions for systems with higher influent TOC. Finally, while central RO/NF remains a BAT for the final rule, the EPA does not anticipate water systems will select this technology to comply with the rule, largely due to the challenges presented by managing the treatment residuals from this process.

The list of compliance alternatives in Table 29 does not include POU devices for small systems. At this time, the EPA is not including POU devices in the national cost estimates because the final rule require treatment to concentrations below the current NSF/ANSI certification standard for POU devices. However, POU treatment is reasonably anticipated to become a compliance option for small systems in the future if independent third-party certification organizations, such as NSF or ANSI develop a new certification standard that mirrors the EPA's final regulatory standard. Therefore, the decision tree excludes POU devices from consideration.

Table 29: Initial Compliance Forecast

Compliance Alternative	Design flow less than 1 MGD		Design flow 1 to less than 10 MGD		Design flow greater than or equal to 10 MGD	
	TOC less than or equal to 1.5 mg/L	TOC greater than 1.5 mg/L	TOC less than or equal to 1.5 mg/L	TOC greater than 1.5 mg/L	TOC less than or equal to 1.5 mg/L	TOC greater than 1.5 mg/L
GAC	79%	62%	81%	52%	89%	52%
PFAS-selective IX	12%	29%	11%	40%	11%	48%
Central RO/NF	0%	0%	0%	0%	0%	0%
Interconnection	7%	7%	6%	6%	0%	0%
New Wells	2%	2%	2%	2%	0%	0%

Source: The EPA's analysis of TOC concentrations in the SYR4 ICR database.

If all the compliance alternatives remain in consideration after Step 1, the decision tree uses the forecast shown in Table 29 above. If Step 1 eliminated one or more of the alternatives, SafeWater MCBC proportionally redistributes the percentages among the remaining alternatives and uses the redistributed percentages.

The EPA's approach to estimating GAC and IX performance for the final rule and all alternatives considered is discussed in detail within the cost chapter of the EA (USEPA, 2024g).

c. Work Breakdown Structure Models

The WBS models are spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs. The EPA developed the WBS model approach as part of an effort to address recommendations made by the Technology Design Panel (TDP), which convened by the EPA in 1997 to review the agency's methods for estimating drinking water compliance costs (USEPA, 1997). The TDP consisted of nationally recognized drinking water experts from the EPA, water treatment consulting companies, public as well as private water utilities along with suppliers, equipment vendors, and Federal along with state regulators in addition to cost estimating professionals.

In general, the WBS approach involves breaking a process down into discrete components for the purpose of estimating unit costs. The WBS models represent improvements over past cost estimating methods by increasing comprehensiveness, flexibility, and transparency. By adopting a WBS-based approach to identify the components that should be included in a cost analysis, the models produce a more comprehensive, flexible, and transparent assessment of the capital and operating requirements for a treatment system.

Each WBS model contains the work breakdown for a particular treatment process and preprogrammed engineering criteria and equations that estimate equipment requirements for user-specified design requirements (*e.g.,* system size and influent water quality). Each model also provides unit and total cost information by component (*e.g.,* individual items of capital equipment) and totals the individual component costs to obtain a direct capital cost. Additionally, the models estimate add-on costs (*e.g.,* permits and land acquisition), indirect capital costs, and annual O&M costs, thereby producing the EPA's best estimates of complete compliance costs.

Primary inputs common to all the WBS models include design flow and average daily flow in MGD. Each WBS model has default designs (input sets) that correspond to specified categories of flow, but the models can generate designs for many other combinations of flows. To estimate costs for PFAS compliance, the EPA fit cost curves to the WBS estimates across a range of flow rates, which is described in chapter 5 of the EA (USEPA, 2024g).

Another input common to all the WBS models is ''component level'' or ''cost level.'' This input drives the selection of materials for items of equipment that can be constructed of different materials. For example, a low-cost system might include fiberglass pressure vessels and polyvinyl chloride (PVC) piping. A high-cost system might include stainless steel pressure vessels and stainless-steel piping. The component level input also drives other model assumptions that can affect the total cost of the system, such as building quality and heating and cooling. The component level input has three possible values: low cost, mid cost, and high cost. The components used in each of the estimated component/cost levels provide the treatment efficacy needed to meet the regulatory requirements. Note that the level of component (*e.g.,* plastic versus resin or stainless-steel piping and vessels) may impact the capital replacement rate but does not interfere with treatment efficacy. The EPA estimates the three levels of cost because it has found that the choice of materials associated with the installation of new treatment equipment often varies across drinking water systems. These systems may, for example, choose to balance capital cost with staff familiarity with certain materials and existing treatment infrastructure. Given this experience, the EPA models the potential variability in treatment cost based on the three component/cost levels. To estimate costs for PFAS treatment, the EPA generated separate cost equations for each of the three component levels, thus creating a range of cost estimates for use in national compliance cost estimates.

The third input common to all the WBS models is system automation, which allows the design of treatment systems that are operated manually or with varying degrees of automation (*i.e.,* with control systems that reduce the need for operator intervention). Cost

equations for system automation are described in chapter 5 of the EA (USEPA, 2024g).

The WBS models generate cost estimates that include a consistent set of capital, add-on, indirect, and O&M costs. Table 30 identified these cost elements, which are common to all the WBS models and included in the cost estimates. As described and summarized in Tables 31–34 the WBS models also include technology-specific cost elements. The documentation for the WBS models provides more information on the methods and assumptions in the WBS models to estimate the costs for both the technology-specific and common cost elements (USEPA, 2024p; USEPA, 2024q; USEPA, 2024r). WBS model accuracy as well as limitations and uncertainty are described in chapter 5 of the EA (USEPA, 2024g).

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Table 30: Cost Elements Included in All WBS Models

Cost Category	Components Included
Direct Capital Costs	Technology-specific equipment (e.g., vessels, basins, pumps, treatment media, piping, valves) Instrumentation and system controls Buildings Residuals management equipment
Add-on Costs	Land Permits Pilot testing
Indirect Capital Costs	Mobilization and demobilization Architectural fees for treatment building Equipment delivery, installation, and contractor's overhead and profit Sitework Yard piping Geotechnical Standby power Electrical infrastructure Process engineering Contingency Miscellaneous allowance Legal, fiscal, and administrative Sales tax Financing during construction Construction management
O&M Costs: Technology-specific	Operator labor for technology-specific tasks (e.g., managing backwash and media replacement) Materials for O&M of technology-specific equipment Technology-specific chemical usage Replacement of technology-specific equipment that occurs on an annual basis (e.g., treatment media) Energy for operation of technology-specific equipment (e.g., mixers)
O&M Costs: Labor	Operator labor for O&M of process equipment Operator labor for building maintenance Managerial and clerical labor
O&M Costs: Materials	Materials for maintenance of booster or influent pumps Materials for building maintenance
O&M Costs: Energy	Energy for operation of booster or influent pumps Energy for lighting, ventilation, cooling, and heating
O&M Costs: Residuals	Residuals management operator labor, materials, and energy Residuals disposal and discharge costs

The GAC model can generate costs for two types of design:

- Pressure designs where the GAC bed is contained in stainless steel, carbon steel, or fiberglass pressure vessel.
- Gravity designs where the GAC bed is contained in open concrete basins.

Table 31 shows the technology-specific capital equipment and O&M requirements included in the GAC model. These items are in addition to the common WBS cost elements listed in the Table 30 above.

Table 31: Technology-Specific Cost Elements Included in the GAC Model

Cost Category	Major Components Included
Direct Capital Costs	Booster pumps for influent water Contactors (either pressure vessels or concrete basins) that contain the GAC bed Tanks and pumps for backwashing the contactors GAC transfer and storage equipment Spent GAC reactivation facilities (if on-site reactivation is selected) Associated piping, valves, and instrumentation
O&M Costs: Labor	Operator labor for contactor maintenance (for gravity GAC designs) Operator labor for managing backwash events Operator labor for backwash pump maintenance (if backwash occurs weekly or more frequently) Operator labor for GAC transfer and replacement
O&M Costs: Materials	Materials for contactor maintenance (accounts for vessel relining in pressure designs, because GAC can be corrosive, and for concrete and underdrain maintenance in gravity designs) Materials for backwash pump maintenance (if backwash occurs weekly or more frequently) Replacement virgin GAC (loss replacement only if reactivation is selected)
O&M Costs: Energy	Operating energy for backwash pumps
O&M Costs: Residuals	Discharge fees for spent backwash Fees for reactivating spent GAC (if off-site reactivation is selected) Labor, materials, energy, and natural gas for regeneration facility (if on-site reactivation is selected) Disposal of spent GAC (if disposal is selected)

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For small systems (less than 1 MGD) using pressure designs, the GAC model assumes the use of package treatment systems that are pre-assembled in a factory, mounted on a skid, and transported to the site. These assumptions are based on common vendor practice for these technologies, for example, see Khera et al. (2013) which says ''. . . small systems are often built as packaged, pre-engineered, or skid-mounted systems.'' The model estimates costs for package systems by costing all individual equipment line items (*e.g.,* vessels, interconnecting piping and valves, instrumentation, and system controls) in the same manner as custom-engineered systems. This approach is based on vendor practices of partially engineering these types of package plants for specific systems (*e.g.,* selecting vessel size to meet flow and treatment criteria). The model applies a variant set of design inputs and assumptions that are intended to simulate the use of a package plant and that reduce the size and cost of the treatment system. USEPA (2024p) provides complete details on the variant design assumptions used for package plants.

To generate the GAC cost equations, the EPA used the following key inputs in the GAC model:

- For pressure designs, two vessels in series with a minimum total empty bed contact time (EBCT) of 20 minutes;
- For gravity designs, contactors in parallel with a minimum total EBCT of 20 minutes; and
- Bed life varying over a range from 5,000 to 75,000 BV.

The EPA generated separate cost equations for two spent GAC management scenarios:

- Off-site reactivation under current RCRA non-hazardous waste regulations;
- Off-site disposal as a hazardous waste in a RCRA Subtitle C landfill and replacement with virgin GAC (*i.e.,* single use operation).

The T&C document (USEPA, 2024m) provides a comprehensive discussion of

these and other key inputs and assumptions.

Table 32 shows the technology-specific capital equipment and O&M requirements included in the PFAS selective IX model. These items are in addition to the common WBS cost elements listed in the Table 30 above.

Table 32: Technology-Specific Cost Elements Included in the PFAS-Selective IX Model

Cost Category	Major Components Included
Direct Capital Costs	Booster pumps for influent water Pre-treatment cartridge filters Pressure vessels that contain the resin bed Tanks and pumps for initial rinse and (optionally) backwash of the resin bed Tanks (with secondary containment), pumps and mixers for delivering sodium hydroxide for use in post-treatment corrosion control (optional) Associated piping, valves, and instrumentation
O&M Costs: Labor	Operator labor for pre-treatment filters Operator labor for managing backwash/rinse events Operator labor for backwash pump maintenance (only if backwash occurs weekly or more frequently) Operator labor for resin replacement
O&M Costs: Materials	Replacement cartridges for pre-treatment filters Materials for backwash pump maintenance (only if backwash occurs weekly or more frequently) Chemical usage (if post-treatment corrosion control is selected) Replacement virgin PFAS-selective resin
O&M Costs: Energy	Operating energy for backwash/rinse pumps
O&M Costs: Residuals	Disposal of spent cartridge filters Discharge fees for spent backwash/rinse Disposal of spent resin

For small systems (less than 1 MGD), the PFAS-selective IX model assumes the use of package treatment systems that are pre-assembled in a factory, mounted on a skid, and transported to the site. The IX model estimates costs for package systems using an approach similar to that described for the GAC model, applying a variant set of inputs and assumptions that reduce the size and cost of the treatment system. USEPA (2024q) provides complete details on the variant design assumptions used for IX package plants.

To generate the IX cost equations, the EPA used the following key inputs in the PFAS-selective IX model:

- Two vessels in series with a minimum total EBCT of 6 minutes
- Bed life varying over a range from 20,000 to 260,000 BV

The EPA generated separate cost equations for two spent resin management scenarios:

- Spent resin managed as non-hazardous and sent off-site for incineration.
- Spent resin managed as hazardous and sent off-site for incineration.

The T&C document (USEPA, 2024m) provides a comprehensive discussion of these and other key inputs and assumptions.

USEPA (2024r) provides a complete description of the engineering design process used by the WBS model for nontreatment actions. The model can estimate costs for two nontreatment alternatives: interconnection with another system and drilling new wells to replace a contaminated source. Table 33 shows the technology-specific capital equipment and O&M requirements included in the model for each alternative.

Table 33: Technology-Specific Cost Elements Included in the Nontreatment Model

Cost Category	Major Components Included for Interconnection	Major Components Included for New Wells
Direct Capital Costs	Booster pumps or pressure reducing valves (depending on pressure at supply source) Concrete vaults (buried) for booster pumps or pressure reducing valves Interconnecting piping (buried) and valves	Well casing, screens, and plugs Well installation costs including drilling, development, gravel pack, and surface seals Well pumps Piping (buried) and valves to connect the new well to the system
O&M Costs: Labor	Operator labor for O&M of booster pumps or pressure reducing valves (depending on pressure at supply source) and interconnecting valves	Operator labor for operating and maintaining well pumps and valves
O&M Costs: Materials	Cost of purchased water Materials for maintaining booster pumps (if required by pressure at supply source)	Materials for maintaining well pumps
O&M Costs: Energy	Energy for operating booster pumps (if required by pressure at supply source)	Energy for operating well pumps

To generate the cost equations, the EPA used the following key inputs in the nontreatment model for interconnection:

- An interconnection distance of 10,000 feet
- Includes booster pumps designed to account for friction loss in interconnecting piping
- An average cost of purchased water of $3.35 per thousand gallons in 2022 dollars.

For new wells, the EPA used the following key inputs:

- A maximum well capacity of 500 gallons per minute (GPM), such that one new well is installed per 500 GPM of water production capacity required
- A well depth of 250 feet
- 500 feet of distance between the new wells and the distribution system.

The T&C document (USEPA, 2024m) provides a comprehensive discussion of these and other key inputs and assumptions.

d. Incremental Treatment Costs

The EPA has estimated the national level costs of the final rule associated with PFOA, PFOS, and PFHxS. As discussed in chapter 4 of the EA and detailed in the Technical Support Document for PFAS Occurrence and Contaminant Background chapter 10.1 and 10.3, there are limitations with nationally representative occurrence information for the other contaminants in the final rule (PFNA, HFPO–DA and PFBS). Specifically, HFPO–DA does not currently have a completed nationally representative dataset while PFNA and PFBS were not included in the national occurrence model because of limited results reported above the minimum reporting levels in UCMR 3. As described in the Technical Support Document for PFAS Occurrence and Contaminant Background chapter 10.3.2, non-targeted state monitoring datasets were used for extrapolation of PFNA, HFPO–DA, and PFBS in lieu of a nationally representative dataset. The EPA used conservative assumptions in this extrapolation to generate conservative cost estimates. As demonstrated in this analysis, the Hazard Index, PFNA, and HFPO–DA MCLs meaningfully increase public health protection at modest additional costs. Because of the increased uncertainty associated with PFNA, HFPO–DA and PFBS, the additional treatment cost from co-occurrence of PFNA, HFPO–DA, PFBS at systems already required to treat because of PFOA, PFOS, or PFHxS MCL and Hazard Index exceedances are not quantitatively assessed in the national cost estimates. These three PFAS' treatment costs are summarized here in this section and detailed in appendix N.3 of the EA (USEPA, 2024e). Likewise, treatment costs for systems that exceed the Hazard Index based on the combined occurrence of PFNA, HFPO–DA, PFBS, and PFHxS (where PFHxS itself does not exceed its HBWC of 10 ng/L) are not included in the national monetized cost estimates and are also summarized in this section and detailed in appendix N.3 of the EA (USEPA, 2024e).

In the EA for the proposed PFAS NPDWR, the EPA used a model system approach to illustrate the potential incremental costs for removing PFAS not included in the national economic model. After considering public comments on the incremental cost analysis, the EPA decided to further explore the incremental costs associated with the Hazard Index and MCLs with a national level sensitivity analysis for the final rule.

When the modeled occurrence data for PFNA, HFPO–DA, PFBS is incorporated into the SafeWater MCBC model, the estimated number of EP

exceeding one or more MCLs, and therefore required to treat or use a different water source, increases to 9,471 from 9,043. This results in an increase in the expected national costs. Under the primary analyses, the expected total national cost is $1,549 million over the EPA's period of analysis (2024–2105) for the PFOA, PFOS, and PFHxS MCLs. When considering the additional incremental national cost impacts of the Hazard Index MCL for, PFNA, HFPO–DA, and PFBS (and individual MCLs for PFNA and HFPO–DA) the expected national costs of the final rule increase to $1,631 million at, or approximately a 5 percent national cost increase.

For further detail on the assumptions and findings of the EPA's analysis of incremental costs of other PFAS, see appendix N.3 and section XII.A of this preamble.

e. PWS Implementation Administration Costs

The EPA estimated PWS costs associated with one-time actions to begin implementation of the rule including reading and understanding the rule and attending training provided by primacy agencies. The average unit costs for PWSs are based on the following burden assumptions: (1) The EPA anticipates that the majority of water systems will likely not read the entirety of the rule preamble (as they are not required to do so) but focus their time and attention on understanding the regulatory requirements through the CFR regulatory text, relevant portions of the preamble, the EPA provided fact sheets and small system guidance documents, and state provided summaries documents; (2) Additionally, the EPA anticipates that system staff will attend primacy agency PFAS rule trainings to reenforce the systems' understanding of the final rule. The EPA assumes that systems will conduct these activities during years one through three of the analysis period. Table 34 lists the data elements and corresponding values associated with calculating the costs of these one-time implementation administration actions.

Table 34: Implementation Administration Startup Costs ($2022)

Data element description	Data element value
The labor rate per hour for systems	$36.43 (systems ≤3,300) $38.84 (systems 3,301-10,000) $41.00 (systems 10,001-50,000) $42.81 (systems 50,001-100,000) $50.03 (systems >100,000)
The average hours per system to read and adopt the rule	4 hours per system
The average hours per system to attend one-time training provided by primacy agencies	16 hours per system (systems ≤3,300) 32 hours per system (systems >3,300)

Estimated national annualized PWS implementation and administration startup costs for the final rule are $1.33 million. National annualized PWS cost estimates are further summarized in Table 39.

f. PWS Monitoring Costs

The final rule requires initial and long-term monitoring. As Table 35 shows, surface and ground water systems serving greater than 10,000 people will collect one sample each quarter, at each EP, during the initial 12-month monitoring period. Surface water systems serving 10,000 or fewer people are also required to collect a quarterly sample at each EP during the initial 12-month period. Ground water systems that serve 10,000 or fewer people will be required to sample once at each EP on a semi-annual basis for the first 12-month monitoring period.

Long-term monitoring schedules are based on specific EP sampling results (*i.e.,* water systems can have different EP within the system on different monitoring schedules). Long-term monitoring requirements differ based on whether a system can demonstrate during the initial monitoring period or once conducting long-term monitoring that an EP is below the trigger levels for regulated PFAS. The trigger levels are set as one-half the MCLs: 2.0 ng/L for PFOA and PFOS, 5 ng/L each for PFHxS, PFNA, and HFPO–DA, and 0.5 for the Hazard Index. EP below the trigger level values during the initial 12-month monitoring period and in future long-term monitoring periods may conduct triennial monitoring and collect one triennial sample at that EP. For EP with concentration values at or above a trigger level, a quarterly sample must be taken at that EP following initial monitoring. EP that demonstrate they are ''reliably and consistently'' [21] below the MCLs following four consecutive quarterly samples are eligible to conduct annual monitoring. After three annual samples at that EP showing no results at or above a trigger level, the location can further reduce to triennial monitoring.

For any samples that are above detection, the system will analyze the FRB samples collected at the same time as the monitoring sample. Systems that have an MCL exceedance will collect one additional sample from the relevant EP to confirm the results.

[21] The definition of reliably and consistently below the MCL means that each of the samples contains regulated PFAS concentrations below the applicable MCLs. For the PFAS NPDWR, this demonstration of reliably and consistently below the MCL would include consideration of at least four quarterly samples at an EP below the MCL, but states will make their own determination as to whether the detected concentrations are reliably and consistently below the MCL.

Table 35: Modeled Initial and Long-Term Sampling Frequencies Per System EP

Initial Monitoring Period		Long-Term Monitoring[1]		
System Size Category	**Sample Number and Frequency**	**PFAS Detection ≥ MCLs**	**PFAS Detection ≥ trigger levels and < MCLs[2]**	**PFAS Detection < trigger levels**
≤ 10,000	Surface Water: 1 sample every quarter	1 sample every quarter	1 sample every year (following four consecutive quarterly samples reliably and consistently below the MCL)	1 triennial sample
	Ground Water: 1 sample every 6-month period			
>10,000	Surface Water and Ground Water: 1 sample every quarter	1 sample every quarter	1 sample every year (following four consecutive quarterly samples reliably and consistently below the MCL)	1 triennial sample

Notes:

[1] The EPA used the following thresholds to distinguish whether PFAS concentrations are reliably and consistently below the MCL: If after four consecutive quarterly samples, a system is below the MCLs (PFOA and PFOS – 4.0 ng/L, PFHxS, PFNA, HFPO-DA – 10 ng/L, Hazard Index – 1).

[2] Systems are not eligible for annual monitoring until after four consecutive quarterly samples are collected following initial monitoring.

For the national cost analysis, the EPA assumes that systems with either UCMR 5 data or monitoring data in the State PFAS Database (see section 3.1.4 in USEPA, 2024g) will not conduct the initial year of monitoring as allowed by the final rule. As a simplifying assumption for the cost analysis, the EPA assumes all systems serving a population of greater than 3,300 have UCMR 5 data and those with 3,300 or less do not. For the State PFAS Database, the EPA relied on the PWSIDs stored in the database and exempted those systems from the first year of monitoring in the cost analysis. Note these simplifying assumptions may result in a small underestimate of initial monitoring costs. Under UCMR 5, individual water systems would be able to request the full release of data from the labs for use in determining their compliance monitoring frequency. PWSs may be able to use these lab analyses to demonstrate a ''below trigger level'' concentration using the UCMR 5 analyses by following up with the lab for a more detailed results report.

The EPA used system-level distributions of PFOA, PFOS, and PFHxS, as described in Cadwallader et al. (2022), to simulate EP concentrations and estimate PFAS occurrence relative to the final rule MCLs and trigger levels. Based on these occurrence distributions, the EPA estimates that the large majority of water systems subject to the rule (approx. 52,000–57,000) will have EP with concentrations below the trigger levels and would conduct reduced monitoring on a triennial basis. The EPA estimates that the remainder of water systems subject to the rule (approx. 9,000–15,000) will have at least one or more EP exceed the trigger level and therefore would be required to conduct quarterly monitoring.

The EPA assumes that systems with an MCL exceedance will implement actions to comply with the MCL by the compliance date. The EPA assumes a treatment target,[22] for systems required to treat for PFAS, that includes a margin of safety so finished water PFAS levels at these systems are 80 percent of the MCLs. In the final rule, in order to reduce burden associated with monitoring, the EPA is adding an annual tier of sampling for any system with concentrations ''reliably and consistently'' [23] below the MCL but not consistently below the trigger level. The EPA believes this tier would likely

[22] A treatment target is a contaminant concentration that a PWS has designed and operated their water system to meet. The EPA assumes all PWS will target 80% of the MCLs.

[23] The definition of reliably and consistently below the MCL means that each of the samples contains regulated PFAS concentrations below the applicable MCLs. For the PFAS NPDWR, this demonstration of reliably and consistently below the MCL would include consideration of at least four quarterly samples at an EP below the MCL, but states will make their own determination as to whether the detected concentrations are reliably and consistently below the MCL.

apply to most systems treating their water for regulated PFAS, at least for the first three years of treatment. Therefore, in the model, the EPA assumes EP that have installed treatment will take one year of quarterly samples, then continue to sample on an annual basis after that. The final rule allows EP showing no results at or above a trigger level after three annual samples to further reduce to triennial monitoring. In the national cost analysis, the EPA does not model this possibility nor does the EPA model instances where water systems are triggered back into quarterly monitoring after installing treatment.

For all systems, the activities associated with the sample collection in the initial 12-month monitoring period are the labor burden and cost for the sample collection and analysis, as well as a review of the sample results. Table 36 presents the data elements and corresponding values associated with calculating sampling costs during the implementation monitoring period.

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Table 36: Sampling Costs ($2022)

Data Element Description	Data Element Value
The labor rate per hour for systems	$36.43 (systems ≤3,300) $38.84 (systems 3,301-10,000) $41.00 (systems 10,001-50,000) $42.81 (systems 50,001-100,000) $50.03 (systems >100,000)
The number of samples per EP per monitoring round for the initial monitoring in Year 1	2 samples (Ground Water systems ≤10,000) 4 samples (all systems) [1]
The number of samples per EP per long-term monitoring year for EPs that equal or exceed the MCLs	4 samples per year
The number of samples per EP per long-term monitoring year for EP < the MCLs and ≥ the trigger levels[2]	1 sample per year, following 4 quarterly samples reliably and consistently below the MCLs
The number of samples per EP per long-term monitoring round for EP < the trigger levels	1 sample every three years
The hours per sample to travel to sampling locations, collect samples, record any additional information, submit samples to a laboratory, and review results	1 hour
The laboratory analysis cost per sample for EPA Method 537.1	$309
The laboratory analysis cost per sample for the FRB under EPA Method 537.1	$273 [3]

Notes:

[1] Systems greater than 3,300 will rely on UCMR 5 data and a subset of other systems will rely on data in the State PFAS Monitoring Database discussed in USEPA, 2024g.

[2] The EPA used the following thresholds to distinguish whether PFAS concentrations are reliably and consistently below the MCL: If after four consecutive quarterly samples, a system is below the MCLs (PFOA and PFOS – 4.0 ng/L, PFHxS, PFNA, HFPO-DA – 10 ng/L, Hazard Index – 1).

[3] This incremental sample cost applies to all samples that exceed MDLs. The EPA used the Method 537.1 detection limits to apply this cost because Method 533 does not include detection limits.

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Estimated national annualized PWS sampling costs for the final rule have an expected value of $36.23 million. National annualized PWS cost estimates are further summarized in Table 39.

g. Treatment Administration Costs

Any system with an MCL exceedance adopts either a treatment or nontreatment alternative to comply with the rule. The majority of systems are anticipated to install treatment technologies while a subset of systems will choose alternative methods. The EPA assumes that systems will bear administrative costs associated with these treatment or nontreatment compliance actions (*i.e.,* permitting costs). The EPA assumes that systems will install treatment in the fifth year of the period of analysis. In addition, after installation of treatment, the EPA assumes that systems will spend an additional 2 hours per treating EP compiling data for and reviewing treatment efficacy with their primacy agency during their triennial sanitary survey. Table 37 presents the data elements and corresponding values associated with calculating treatment administration costs.

Table 37: Treatment Administration Costs ($2022)

Data element description	Data element value
The labor rate per hour for systems	$36.43 (systems ≤3,300) $38.84 (systems 3,301-10,000) $41.00 (systems 10,001-50,000) $42.82 (systems 50,001-100,000) $50.03 (systems >100,000)
The hours per EP for a system to notify, consult, and submit a permit request for treatment installation [a]	3 hours (systems ≤100) 5 hours (systems 101-500) 7 hours (systems 501-1,000) 12 hours (systems 1,001-3,300) 22 hours (systems 3,301-50,000) 42 hours (systems >50,000)
The additional hours per EP the system will spend every 3 years during a sanitary survey after PFAS related treatment is installed	2 hours, at EP that have installed treatment
The hours per EP for a system to notify, consult, and submit a permit request for source water change or alternative method[1]	6 hours

Notes:

[1] The EPA applied the cost per EP for this EA because the notification, consultation, and permitting process occurs for individual EP.

h. Public Notification (PN) Costs

The EPA's cost analysis assumes full compliance with the rule throughout the period of analysis and, as a result, the EPA does not estimate costs for the PN requirements in the final rule for systems with certain violations. The final rule designates MCL violations for PFAS as Tier 2, which requires systems to provide PN as soon as practical, but no later than 30 days after the system learns of the violation. The system must repeat notice every three months if the violation or situation persists unless the primacy agency determines otherwise. At a minimum, systems must give repeat notice at least once per year. The final rule also designates monitoring and testing procedure violations as Tier 3, which requires systems to provide public notice no later than one year after the system learns of the violation. The system must repeat the notice annually for as long as the violation persists. CWSs may deliver Tier 3 PNs in their CCR if the timing, content, and delivery requirements are met according to 40 CFR 141.204(d). Using the CCR to deliver Tier 3 PNs can minimize the burden on systems by reducing delivery costs. For approximate estimates of the potential burden associated with Tier 2 and 3 PNs, please see USEPA (2024g).

i. Primacy Agency Costs

The EPA assumes that primacy agencies will have upfront implementation costs as well as costs associated with system actions related to sampling and treatment. The activities that primacy agencies are expected to carry out under the final rule include:

- Reading and understanding the rule, providing internal primacy agency officials training for the rule implementation, updating sanitary survey standard operating procedures,
- Primacy package application, including making regulatory changes to the Federal rule where applicable,
- Providing systems with training and technical assistance during the rule implementation,
- Reporting to the EPA on an ongoing basis any PFAS-specific information under 40 CFR 142.15 regarding violations as well as enforcement actions and general operations of PWS programs,
- Performing inspection of PFAS related treatment during sanitary surveys every three years

- Reviewing the sample results during the implementation monitoring period and the SMF period, and
- Reviewing and consulting with systems on the installation of treatment technology or alternative methods, including source water change.

For the last three activities listed above, the primary agency burdens are incurred in response to action taken by PWSs; for instance, the cost to primacy agencies of reviewing sample results depends on the number of samples taken at each EP by each system under an agency's jurisdiction. Table 38 presents the data elements and corresponding values associated with calculating primacy agency costs.

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Table 38: Primacy Agency Costs ($2022)

Data element description	Data element value
The labor rate per hour for primacy agencies[1]	$59.69
The average hours per primacy agency to read and understand the rule, update sanitary survey standard operating procedures, and train internal staff.	4,020 hours per primacy agency
The average hours for a primacy agency to develop and adopt state-level regulations	300 hours per primacy agency
The average hours per primacy agency to provide initial training and technical assistance to systems	1,500 hours per primacy agency
The average hours per primacy agency to report annually to the EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of state PWS programs[2]	0
The hours per sample for a primacy agency to review sample results	1 hour
The hours per EP for a primacy agency to review and consult on installation of a treatment technology	80 hours (systems serving ≤3,300) 70 hours (systems serving 3,301 to 50,000) 50 hours (systems serving >50,000)
The additional hours per EP the primacy agency will spend every 3 years after PFAS-related treatment is installed during a sanitary survey	2 hours per EP that installs treatment every 3 years post installation
The hours per EP for a primacy agency to review and consult on a source water change	4 hours

Notes:

[1] In USBLS (2022), state employee wage rate of $33.91 from National Occupational Employment and Wage Estimates, United States, BLS SOC Code 19-2041, "State Government, excluding schools and hospitals - Environmental Scientists and Specialists, Including Health," hourly mean wage rate. May 2020 data (published in March 2021): https://www.bls.gov/oes/current/oes192041.htm. Wages are loaded using a factor of 62.2 from the Bureau of Labor Statistics (BLS) Employer Costs for Employee Compensation report, Table 3, March 2020. Percent of total compensation - Wages and Salaries - All Workers - State and Local Government Workers (https://www.bls.gov/news.release/archives/ecec_06182020.pdf). See worksheet BLS Table 3. The final loaded wage is adjusted for inflation.

[2] The EPA assumes that the final PFAS rule will have no discernable incremental burden for quarterly or annual reports to SDWIS Fed.

Estimated national annualized primacy agency costs for the final rule have an expected value of $4.65 million. National annualized cost estimates are further summarized in Table 39.

In addition to the costs described above, a primacy agency may also have to review the certification of any Tier 2 or 3 PNs sent out by systems. The EPA assumes full compliance with the final rule and therefore does not include this cost in national estimated cost totals but provides a brief discussion of the possible primacy agency burden associated with this component in USEPA (2024g).

In Table 39, the EPA summarizes the total annualized quantified cost of the final rule at a 2 percent discount rate expressed in millions of 2022 dollars. The first three rows show the annualized PWS sampling costs, the annualized PWS implementation and administrative costs, and the annualized PWS treatment costs. The fourth row shows the sum of the annualized PWS costs. The expected annualized PWS costs are $1,544 million. The uncertainty range for annualized PWS costs are $1,431 million to $1,667 million. Finally, annualized primacy agency implementation and administrative costs are added to the annualized PWS costs to calculate the total annualized cost of the final rule. The expected total annualized cost of the final rule is $1,549 million. The uncertainty range for the total annualized costs of the final rule is $1,436 million to $1,672 million. The EPA notes that treatment costs associated with the rule are the most significant contribution to overall rule costs for the final rule and the regulatory alternatives.

Table 39: National Annualized Costs, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	Expected Value	95th Percentile[1]
Annualized PWS Sampling Costs	$33.63	$36.23	$39.03
Annualized PWS Implementation and Administration Costs	$1.33	$1.33	$1.33
Annualized PWS Treatment Costs	$1,395.23	$1,506.44	$1,627.65
Total Annualized PWS Costs[2,3,4]	$1,431.00	$1,544.00	$1,667.10
Primacy Agency Rule Implementation and Administration Cost	$4.35	$4.65	$4.97
Total Annualized Rule Costs[2,3,4]	$1,435.70	$1,548.64	$1,672.10

Notes:

Detail may not add exactly to total due to independent rounding. 5th and 95th percentile values for total rule costs are not additive across cost categories as the categories are not completely correlated.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 74. This range does not include the uncertainty described in Table 43.

[2] The national level cost estimates for PFHxS are reflective of both the total national cost for PFHxS individual MCL exceedances, and Hazard Index MCL exceedances where PFHxS is present above its HBWC while one or more other Hazard Index PFAS is also present in that same mixture. Total quantified national cost values do not include the incremental treatment costs associated with the co-occurrence of PFNA, HFPO-DA, and PFBS. The EPA has considered the additional national costs of the Hazard Index and individual MCLs associated with HFPO-DA, PFBS, and PFNA occurrence in a quantified sensitivity analysis; see appendix N.3 of the EA (USEPA, 2024e) for the analysis and more information.

[3] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N.2 of the EA (USEPA, 2024e) for additional detail.

[4] See Table 72 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

In Tables 40, 41, and 42, the EPA summarizes the total annualized quantified cost of options 1a, 1b, and 1c, respectively.

Table 40: National Annualized Costs, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L; Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Annualized PWS Sampling Costs	$33.37	$35.98	$38.77
Annualized PWS Implementation and Administration Costs	$1.33	$1.33	$1.33
Annualized PWS Treatment Costs	$1,383.33	$1,495.14	$1,616.15
Total Annualized PWS Costs[2,3]	$1,419.20	$1,532.44	$1,654.80
Primacy Agency Rule Implementation and Administration Cost	$4.34	$4.63	$4.95
Total Annualized Rule Costs[2,3]	$1,423.60	$1,537.07	$1,660.30

Notes:

Detail may not add exactly to total due to independent rounding. 5th and 95th percentile values for total rule costs are not additive across cost categories as the categories are not completely correlated.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 74. This range does not include the uncertainty described in Table 43.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N.2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

Table 41: National Annualized Costs, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L; Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Annualized PWS Sampling Costs	$31.07	$33.29	$35.71
Annualized PWS Implementation and Administration Costs	$1.33	$1.33	$1.33
Annualized PWS Treatment Costs	$1,065.30	$1,153.31	$1,250.22
Total Annualized PWS Costs[2,3]	$1,098.40	$1,187.92	$1,286.50
Primacy Agency Rule Implementation and Administration Cost	$3.98	$4.21	$4.47
Total Annualized Rule Costs[2,3]	$1,102.60	$1,192.13	$1,291.40

Notes:

Detail may not add exactly to total due to independent rounding. 5th and 95th percentile values for total rule costs are not additive across cost categories as the categories are not completely correlated.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 74. This range does not include the uncertainty described in Table 4f3.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N.2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

Table 42: National Annualized Costs, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L; Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Annualized PWS Sampling Costs	$26.11	$27.48	$28.97
Annualized PWS Implementation and Administration Costs	$1.33	$1.33	$1.33
Annualized PWS Treatment Costs	$431.37	$467.12	$507.50
Total Annualized PWS Costs[2,3]	$459.50	$495.93	$537.21
Primacy Agency Rule Implementation and Administration Cost	$3.27	$3.37	$3.48
Total Annualized Rule Costs[2,3]	$462.87	$499.29	$540.68

Notes:

Detail may not add exactly to total due to independent rounding. 5th and 95th percentile values for total rule costs are not additive across cost categories as the categories are not completely correlated.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 74. This range does not include the uncertainty described in Table 43.

[2] PFAS- contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N.2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

j. Data Limitations and Uncertainties in the Cost Analysis

Table 43 lists data limitations and characterizes the impact on the quantitative cost analysis. The EPA notes that in most cases it is not possible to judge the extent to which a particular limitation or uncertainty could affect the cost analysis. The EPA provides the potential direction of the impact on the cost estimates when possible but does not prioritize the entries with respect to the impact magnitude.

Table 43: Limitations that Apply to the Cost Analysis for the Final PFAS Rule

Uncertainty/ Assumption	Effect on Quantitative Analysis	Notes
WBS engineering cost model assumptions and component costs	Uncertain	The WBS engineering cost models require many design and operating assumptions to estimate treatment process equipment and operating needs. Chapter 5 of the EA (USEPA, 2024g) addressed the bed life assumption. The *Technologies and Costs* document (USEPA, 2024m) and individual WBS models in the rule docket provide additional information. The component-level costs approximate national average costs, which can over- or under-estimate costs at systems affected by the final rule.
Compliance forecast	Uncertain	The forecast probabilities are based on historical full-scale compliance actions. Site-specific water quality conditions, changes in technology, and changes in market conditions can result in future technology selections that differ from the compliance forecast.
TOC concentration	Uncertain	The randomly assigned values from the two national distributions are based on a limited dataset. Actual TOC concentrations at systems affected by the final rule can be higher or lower than the assigned values.
Insufficient UCMR 3 data for PFBS and PFNA and no UCMR 3 data for HFPO-DA were available to incorporate into the Bayesian hierarchical occurrence model	Underestimate	The final rule regulates PFNA, HFPO-DA, and PFBS in addition to the PFAS modeled in the primary analysis. In instances when concentrations of PFBS, PFNA, and/or HFPO-DA are high enough to cause or contribute to Hazard Index exceedances or PFNA and/or HFPO-DA are high enough to cause individual MCL exceedances, the modeled costs in the primary analysis may be underestimated. If these PFAS occur in isolation at levels that affect treatment decisions, or if they occur in sufficient concentration to result in an exceedance when the concentration of PFHxS alone would be below the HBWC, then costs would be underestimated. Note that the EPA has conducted a sensitivity analysis of and considered the potential changes in treatment cost associated with the occurrence of PFNA, HFPO-DA, and PFBS using which is discussed in detail in appendix N.3 of the EA (USEPA, 2024e).

Uncertainty/ Assumption	Effect on Quantitative Analysis	Notes
POU not included in compliance forecast	Overestimate	If POU devices can be certified to meet concentrations that satisfy the final rule, then small systems may be able to reduce costs by using a POU compliance option instead of centralized treatment or source water changes.
Process wastes not classified as hazardous	Underestimate	The national cost analysis reflects the assumption that PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes. To address stakeholder concerns, including those raised during the SBREFA process, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. As part of this analysis, the EPA generated a second full set of unit cost curves that are identical to the curves used for the national cost analysis with the exception that spent GAC and spent IX resin are considered hazardous. If in the future PFAS-contaminated wastes require handling as hazardous wastes, the residuals management costs in the WBS treatment cost models are expected to be higher. See appendix N.2 of the EA (USEPA, 2024e) for a sensitivity analysis describing the potential increase in costs associated with hazardous waste disposal at 100 percent of systems treating for PFAS. The costs estimated in appendix N are consistent with the EPA OLEM's *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances* (USEPA, 2020d) and subsequent updates.
Population served held constant over time.	Uncertain	All PWS populations served were held constant over the period of analysis as not all locations have reliable information on population changes over time. If population served by affected PWSs increases (or decreases), then the estimated costs are likely underestimated (or overestimated).

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E. Nonquantifiable costs of the final rule

As described in section j. (*Data Limitations and Uncertainties in the Cost Analysis*) above, given the available occurrence data for the other compounds in the rule (PFNA, HFPO–DA, and PFBS) and the regulatory thresholds under consideration, the EPA considered national costs associated with potential Hazard Index exceedances as a direct result of these compounds in a sensitivity analysis; therefore, the additional treatment cost,

from co-occurrence of PFNA, HFPO–DA, PFBS, at systems already required to treat because of PFOA, PFOS, or PFHxS MCL and Hazard Index exceedances are not presented in the national cost estimates above. Nor are treatment costs for systems that exceed the Hazard Index based on the combined occurrence of PFHxS (where PFHxS itself does not exceed 10 ng/L), PFNA, HFPO–DA, and PFBS presented in the national monetized cost estimates above. Treatment costs for the individual PFNA and HFPO–DA MCLs are also not considered above. For further discussion of how the EPA considered the costs of the five individual MCLs and the HI MCL, see section XII.A.4 of this preamble. These potential additional costs are described in greater detail in section 5.3.1.4 of USEPA (2024g) and appendix N.3 of USEPA (2024e). When considering the national cost impacts of the Hazard Index MCL for PFNA, HFPO–DA, and PFBS (and individual MCLs for PFNA and HFPO–DA) the expected national costs increase from $1,549 million to $1,631 million, or approximately a 5 percent national cost increase.

PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns, including those raised during the Small Business Regulatory Enforcement Fairness Act (SBREFA) process, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. As part of this analysis, the EPA generated a second full set of unit cost curves that are identical to the curves used for the national cost analysis with the exception that spent GAC and spent IX resin are considered hazardous. If in the future PFAS-contaminated wastes require handling as hazardous wastes, the residuals management costs are expected to be higher. See appendix N.2 of the EA for a sensitivity analysis describing the potential increase in costs associated with hazardous waste disposal (USEPA, 2024e).

F. Method for Estimating Benefits

The EPA's quantification of health benefits resulting from reduced PFAS exposure in drinking water was driven by PFAS occurrence estimates, PK model availability, information on exposure-response relationships, and economic data to monetize the impacts. In the EA, the EPA either quantitatively assesses or qualitatively discusses health endpoints associated with exposure to PFAS. The EPA assesses potential benefits quantitatively if there is evidence of an association between PFAS exposure and health effects, if it is possible to link the outcome to risk of a health effect, and if there is no overlap in effect with another quantified endpoint in the same outcome group. Particularly, the most consistent epidemiological associations with PFOA and PFOS include decreased immune system response, decreased birthweight, increased serum lipids, and increased serum liver enzymes (particularly alanine transaminase, ALT). The available evidence indicates effects across immune, developmental, cardiovascular, and hepatic organ systems at the same or approximately the same level of exposure.

Table 44 presents an overview of the categories of health benefits expected to result from the implementation of treatment that reduces PFAS levels in drinking water. Of the PFAS compounds included in the final rule, the EPA quantifies some of the adverse health effects associated with PFOA and PFOS. These compounds have likely evidence linking exposure to a particular health endpoint and have reliable PK models connecting the compound to PFAS blood serum. PK models are tools for quantifying the relationship between external measures of exposure and internal measures of dose. Benefits from avoided adverse health effects of PFHxS, PFNA, HFPO–DA, and PFBS are discussed qualitatively in this section.

As Table 44 demonstrates, only a subset of the potential health effects of reduced PFAS in drinking water can be quantified and monetized. The monetized benefits evaluated in the EA for the final rule include changes in human health risks associated with CVD and infant birth weight from reduced exposure to PFOA and PFOS in drinking water and RCC from reduced exposure to PFOA. The EPA also quantified benefits from reducing bladder cancer risk due to the co-removal of non-PFAS pollutants via the installation of drinking water treatment, discussed in greater detail in USEPA (2024g). The EPA quantified benefits associated with PFOS effects on liver cancer and PFNA effects on birth weight in sensitivity analyses.

The EPA was not able to quantify or monetize other benefits, including those related to other reported health effects including immune, liver, endocrine, metabolic, reproductive, musculoskeletal, or other cancers. The EPA discusses these benefits qualitatively in more detail in this section, as well as in section 6.2 of USEPA (2024g).

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Table 44: Overview of Health Benefits Categories Considered in the Analysis of Changes in PFAS Drinking Water Levels

Health Outcome		PFAS Compound[a,b,d]		Benefits Analysis	
Category	**Endpoint**	**PFOA**	**PFOS**	**Discussed Quantitatively**	**Discussed Qualitatively**
Lipids	Total cholesterol (TC)	X	X	X	
	High-density lipoprotein cholesterol (HDLC)	X[c]	X[c]	X	
	Low-density lipoprotein cholesterol (LDLC)	X	X		X
CVD	Blood pressure (BP)		X	X	
Developmental	Birth weight	X	X	X	
	Small for gestational age (SGA), non-birth weight developmental	X			X
Hepatic	Alanine transaminase (ALT)	X	X		X
Immune	Antibody response (tetanus, diphtheria)	X	X		X
Metabolic	Leptin	X			X
Musculoskeletal	Osteoarthritis, bone mineral density	X			X
Cancer	Renal Cell Carcinoma (RCC)	X		X	
	Liver		X	X[e]	
	Testicular	X			X

Notes:

[a]Fields marked with "X" indicate the PFAS compound for which there is evidence of an association with a given health outcome in humans.

[b]Outcomes with indicative evidence of an association between a PFAS compound and a health outcome are assessed quantitatively unless (1) there is an overlap within the same outcome group (e.g., LDLC overlaps with TC and SGA overlaps with low birth weight), or (2) it is not possible to link the outcome to the risk of the health effect (e.g., evidence is inconclusive regarding the relationship between PFOS exposure, leptin levels and associated health outcomes). Such health outcomes are discussed qualitatively.

[c]Although evidence of associations between HDLC and PFOA and PFOS was mixed, certain individual studies reported robust associations in general adult populations. Based on comments and recommendations from the EPA SAB, the EPA assessed HDLC in a sensitivity analysis.

[d]Note that only PFOA and PFOS effects were modeled in the assessment of benefits under the final rule. For another PFAS in the rule, PFNA, the best available finalized analysis is based on studies published before 2018 (ATSDR, 2021). The EPA notes that new evidence since the release of the current, best available peer reviewed scientific assessment for PFNA (ATSDR, 2021) provides further justification for the EPA's analysis of potential economic benefits of PFNA exposure reduction and avoided birth weight effects. More recent epidemiological studies that evaluated PFNA and birth weight, including key studies modeled for PFOA and PFOS (Sagiv et al., 2018; Wikström et al., 2020), as well as a recently published meta-analysis of mean birth weight that indicates the birth weight results for PFNA are robust and consistent, even if associations in some studies may be small in magnitude (Wright et al., 2023). PFNA was modeled in a sensitivity analyses of birth weight benefits. This modeling relied on epidemiological studies published before 2018, representing the current, best available peer reviewed scientific assessment for PFNA (ATSDR, 2021) and the PFAS serum calculator developed by Lu and Bartell (2020) was used to estimate PFNA blood serum levels resulting from PFNA exposures in drinking water.

[e]Liver cancer benefits are not included in the national-level quantified benefits analysis. See appendix O of the EA for the liver cancer benefit analysis results.

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The EPA developed PK models to evaluate blood serum PFAS levels in adults resulting from exposure to PFAS via drinking water. To date, the EPA has developed PK models for PFOA and PFOS. The EPA used baseline and regulatory alternative PFOA/PFOS drinking water concentrations as inputs to its PK model to estimate blood serum PFOA/PFOS concentrations for adult males and females. For further detail on the PK model and its application in the EPA's benefits analysis, please see the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS* (USEPA, 2024c; USEPA, 2024d) and section 6.3 of USEPA (2024g).

1. Quantified Developmental Effects

Exposure to PFOA and PFOS is linked to developmental effects, including decreased infant birth weight (Steenland et al., 2018; Dzierlenga et al., 2020; Verner et al., 2015; USEPA, 2016c; USEPA, 2016d; USEPA, 2024c; USEPA, 2024d; Negri et al., 2017; ATSDR, 2021; Waterfield et al., 2020). The route through which infants are exposed prenatally to PFOA and PFOS is through maternal blood via the placenta. Most studies of the association between maternal serum PFOA/PFOS and birth weight report inverse relationships (Verner et al., 2015; Negri et al., 2017; Steenland et al., 2018; Dzierlenga et al., 2020). The EPA's PK model assumes that mothers were exposed to PFOA/PFOS from birth to the year in which pregnancy occurred.

The EPA quantified and valued changes in birth weight-related risks associated with reductions in exposure to PFOA and PFOS in drinking water. EP-specific time series of the differences between serum PFOA/PFOS concentrations under baseline and regulatory alternatives are inputs into this analysis. For each EP, evaluation of the changes in birth weight impacts involves the following key steps:

1. Estimating the changes in birth weight based on modeled changes in serum PFOA/PFOS levels and exposure-response functions for the effect of serum PFOA/PFOS on birth weight;

2. Estimating the difference in infant mortality probability between the baseline and regulatory alternatives based on changes in birth weight under the regulatory alternatives and the association between birth weight and mortality;

3. Identifying the infant population affected by reduced exposure to PFOA/PFOS in drinking water under the regulatory alternatives;

4. Estimating the changes in the expected number of infant deaths under the regulatory alternatives based on the difference in infant mortality rates and

the population of surviving infants affected by increases in birth weight due to reduced PFOA/PFOS exposure; and

5. Estimating the economic value of reducing infant mortality based on the Value of a Statistical Life and infant morbidity based on reductions in medical costs associated with changes in birth weight for the surviving infants based on the cost of illness.

The EPA also considered the potential benefits from reduced exposure to PFNA that may be realized as a direct result of the final rule. The agency explored the birth weight impacts of PFNA in a sensitivity analysis based on epidemiological studies published before 2018 cited in the current, best available final human health analysis of PFNA (ATSDR, 2021), as well as a recently published meta-analysis of mean birth weight that indicates the birth weight results for PFNA are robust and consistent, even if associations in some studies may be small in magnitude (Wright et al., 2023). The EPA used a unit PFNA reduction scenario (*i.e.,* 1.0 ng/L change) and the PFAS serum calculator developed by Lu and Bartell (2020) to estimate PFNA blood serum levels resulting from PFNA exposures in drinking water. To estimate blood serum PFNA based on its drinking water concentration, the EPA used a first-order single-compartment model whose behavior was previously demonstrated to be consistent with PFOA pharmacokinetics in humans (Bartell et al., 2010). In addition to the PFOA-birth weight and PFOS-birth weight effects analyzed in the EA, the EPA examined the effect of inclusion of PFNA-birth weight effects using estimates from two studies (Lenters et al., 2016; Valvi et al., 2017). The EPA found that inclusion of a 1.0 ng/L PFNA reduction increased annualized birth weight benefits by between a factor of 5.6 to 7.8, relative to the scenario that quantifies a 1.0 ng/L reduction in PFOA and a 1.0 ng/L reduction in PFOS only. The range of estimated PFNA-related increases in benefits is driven by the exposure-response, with smaller estimates produced using the slope factors from Lenters et al. (2016), followed by Valvi et al. (2017). The EPA notes that the PFNA slope factor estimates are orders of magnitude larger than the slope factor estimates used to evaluate the impacts of PFOA/PFOS reductions. The EPA also notes that the PFNA slope factor estimates in this analysis are not precise, with 95 percent CIs covering wide ranges that include zero (*i.e.,* serum PFNA slope factor estimates are not statistically significant at 5 percent level). Caution should be exercised in making judgements about the potential magnitude of change in the national benefits estimates based on the results of these sensitivity analyses, although conclusions about the directionality of these effects can be inferred. The EPA did not include PFNA effects in the national benefits estimates for the final rule because there was insufficient data above the UCMR 3 MRL to reasonably fit model parameters for PFNA. For the EPA's PFNA sensitivity analysis, see appendix K of USEPA (2024g).

To estimate changes in birth weight resulting from reduced exposure to PFOA and PFOS under the regulatory alternatives, the EPA relied on the estimated time series of changes in serum PFOA/PFOS concentrations specific to women of childbearing age and serum-birth weight exposure-response functions provided in recently published meta-analyses. For more detail on the evaluation of the studies used in these meta-analyses, please see the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS* (USEPA, 2024c; USEPA, 2024d) and section 6.4 of USEPA (2024g).

Changes in serum PFOA and PFOS concentrations are calculated for each PWS EP during each year in the analysis period. The EPA assumes that, given the long half-lives of PFOS and PFOA (with median half-lives of 2.7 and 3.5 years, respectively (Li et al., 2018)), any one-time measurement during or near pregnancy is reflective of a critical exposure window and not subject to considerable error. In other words, blood serum concentrations in a single year are expected to correlate with past exposures and are reflective of maternal exposures regardless of the timing of pregnancy. The mean change in birth weight per increment in long-term PFOA and PFOS exposure is calculated by multiplying each annual change in PFOA and PFOS serum concentration (ng/mL serum) by the PFOA and PFOS serum-birth weight exposure-response slope factors (g birth weight per ng/mL serum) provided in Table 45, respectively. The mean annual change in birth weight attributable to changes in both PFOA and PFOS exposure is the sum of the annual PFOA and PFOS-birth weight change estimates. Additional detail on the derivation of the exposure-response functions can be found in appendix D in USEPA (2024e). appendix K in USEPA (2024e) presents an analysis of birth weight risk reduction considering slope factors specific to the first trimester.

Table 45: Serum Exposure-Birth Weight Response Estimates

Compound	g /ng/mL serum (95% CI)
PFOA [a]	-10.5 (-16.7, -4.4)
PFOS [b]	-3.0 (-4.9, -1.1)

Notes:

[a] The serum-birth weight slope factor for PFOA is based on the main random effects estimate from Steenland et al. (2018).

[b] The serum-birth weight slope factor for PFOS is based on the EPA reanalysis of Dzierlenga et al. (2020).

The EPA places a cap on estimated birth weight changes in excess of 200 g, assuming that such changes in birth weight are unreasonable based on existing studies that found that changes to environmental exposures result in relatively modest birth weight changes (Windham and Fenster, 2008; Klein and Lynch, 2018; Kamai et al., 2019). Modest changes in birth weight even as a result of large changes in PFOA/PFOS serum concentrations may be due to potential bias from studies only including live births (Liew et al., 2015). Additionally, the magnitude of birth

weight changes may be correlated with other developmental outcomes such as preterm birth, gestational duration, fetal loss, birth defects, and developmental delays.

Low birth weight is linked to a number of health effects that may be a source of economic burden to society in the form of medical costs, infant mortality, parental and caregiver costs, labor market productivity loss, and education costs (Chaikind and Corman, 1991; Behrman and Butler, 2007; Behrman and Rosenzweig, 2004; Joyce et al., 2012; Kowlessar et al., 2013; Colaizy et al., 2016; Nicoletti et al., 2018; Klein and Lynch, 2018). Recent literature also linked low birth weight to educational attainment and required remediation to improve student outcomes, childhood disability, and future earnings (Jelenkovic et al., 2018; Temple et al., 2010; Elder et al., 2020; Hines et al., 2020; Chatterji et al., 2014; Dobson et al., 2018).

The EPA's analysis focuses on two categories of birth weight impacts that are amenable to monetization associated with incremental changes in birth weight: (1) medical costs associated with changes in infant birth weight and (2) the value of avoiding infant mortality at various birth weights. The birth weight literature related to other sources of economic burden to society (*e.g.,* parental and caregiver costs and productivity losses) is limited in geographic coverage, population size, and range of birth weights evaluated and therefore cannot be used in the EA of birth weight effects from exposure to PFOA/PFOS in drinking water (ICF, 2021).

Two studies showed statistically significant relationships between incremental changes in birth weight and infant mortality: Almond et al. (2005) and Ma and Finch (2010). Ma and Finch (2010) used 2001 NCHS linked birth/infant death data for singleton and multiple birth infants among subpopulations defined by sex and race/ethnicity to estimate a regression model assessing the associations between 14 key birth outcome measures, including birth weight and infant mortality. They found notable variation in the relationship between birth weight and mortality across race/ethnicity subpopulations, with odds ratios for best-fit birth weight-mortality models ranging from 0.8–1 (per 100 g birth weight change). Almond et al. (2005) used 1989–1991 NCHS linked birth/infant death data for multiple birth infants to analyze relationships between birth weight and infant mortality within birth weight increment ranges. For their preferred model, they reported coefficients in deaths per 1,000 births per 1 g increase in birth weight that range from -0.420 to -0.002. However, the data used in these studies (Almond et al., 2005 and Ma and Finch, 2010) are outdated (1989–1991 and 2001, respectively). Given the significant decline in infant mortality over the last 30 years (ICF, 2020) and other maternal and birth characteristics that are likely to influence infant mortality (*e.g.,* average maternal age and rates of maternal smoking), the birth weight-mortality relationship estimates from Almond et al. (2005) and Ma and Finch (2010) are likely to overestimate the benefits of birth weight changes.

Considering the discernible changes in infant mortality over the last 30 years, the EPA developed a regression analysis to estimate the relationship between birth weight and infant mortality using the *Period/Cohort Linked Birth-Infant Death Data Files* published by NCHS from the 2017 period/2016 cohort and the 2018 period/2017 cohort (CDC, 2017; CDC, 2018). These data provide information on infants who are delivered alive and receive a birth certificate. The EPA selected variables of interest for the regression analysis, including maternal demographic and socioeconomic characteristics, maternal risk, and risk mitigation factors (*e.g.,* number of prenatal care visits, smoker status), and infant birth characteristics. The EPA included several variables used in Ma and Finch (2010) (maternal age, maternal education, marital status, and others) as well as additional variables to augment the set of covariates included in the analyses. In addition, the EPA developed separate models for different race/ethnicity categories (non-Hispanic Black, non-Hispanic White, and Hispanic) and interacted birth weight with categories of gestational age, similar to Ma and Finch (2010). Appendix E of USEPA (2024e) provides details on model development and regression results.

Table 46 presents the resulting odds ratios and marginal effects (in terms of deaths per 1,000 births for every 1 g increase in birth weight) estimated for changes in birth weight among different gestational age categories in the mortality regression models for non-Hispanic Black, non-Hispanic White, and Hispanic race/ethnicity subpopulations. Marginal effects for birth weight among gestational age categories vary across different race/ethnicity subpopulations. The marginal effects for birth weight among different gestational age categories are higher in the non-Hispanic Black model than in the non-Hispanic White and Hispanic models, particularly for extremely and very preterm infants, indicating that low birth weight increases the probability of mortality within the first year more so among non-Hispanic Black infants than among non-Hispanic White and Hispanic infants.

The EPA relies on odds ratios estimated using the birth weight-mortality regression model to assess mortality outcomes of reduced exposures to PFOA/PFOS in drinking water under the regulatory alternatives. To obtain odds ratios specific to each race/ethnicity and 100 g birth weight increment considered in the birth weight benefits model,[24] the EPA averaged the estimated odds ratios for 1 g increase in birth weight over the gestational age categories using the number of infants (both singleton and multiple birth) that fall into each gestational age category as weights. Separate gestational age category weights were computed for each 100 g birth weight increment and race/ethnicity subpopulation within the 2017 period/2016 cohort and 2018 period/2017 cohort *Linked Birth-Infant Death Data Files.* The weighted birth weight odds ratios are then used in conjunction with the estimated change in birth weight and baseline infant mortality rates to determine the probability of infant death under the regulatory alternatives, as described further in section 6.4 of USEPA (2024g).

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[24] The birth weight risk reduction model evaluates changes in birth weight in response to PFOA/PFOS drinking water level reductions for infants who fall into 100 g birth weight increments (*e.g.,* birth weight 0–99 g, 100–199 g, 200–299 g. . . 8,000–8,099 g, 8,100–8,165 g).

Table 46: Race/Ethnicity and Gestational Age-Specific Birth Weight Marginal Effects and Odds Ratios from the Mortality Regression Models [1]

Race	Gestational Age Category [2]	Marginal Effect per 1,000 births (95% CI)	Odds Ratio (95% CI)
Non-Hispanic Black	Extremely Preterm	-0.20400 (-0.21910, -0.18890)	0.99817 (0.99802, 0.99832)
	Very Preterm	-0.04580 (-0.04820, -0.04340)	0.99816 (0.99804, 0.99827)
	Moderately Preterm	-0.01030 (-0.01080, -0.009850)	0.99852 (0.99846, 0.99857)
	Term	-0.00453 (-0.00472, -0.00434)	0.99856 (0.99851, 0.9986)
Non-Hispanic White	Extremely Preterm	-0.12160 (-0.13080, -0.11240)	0.99866 (0.99855, 0.99878)
	Very Preterm	-0.03290 (-0.03430, -0.03140)	0.9985 (0.99842, 0.99858)
	Moderately Preterm	-0.00677 (-0.00702, -0.00652)	0.99867 (0.99863, 0.99872)
	Term	-0.00228 (-0.00236, -0.00221)	0.99865 (0.99861, 0.99868)
Hispanic	Extremely Preterm	-0.15260 (-0.16770, -0.13750)	0.99835 (0.99817, 0.99853)
	Very Preterm	-0.03290 (-0.03510, -0.03070)	0.99846 (0.99835, 0.99858)
	Moderately Preterm	-0.00626 (-0.00659, -0.00592)	0.99856 (0.99849, 0.99862)
	Term	-0.00219 (-0.00229, -0.00208)	0.99849 (0.99844, 0.99855)

Notes:

[1] Data based on the *2016/17 and 2017/18 CDC Period Cohort Linked Birth-Infant Death Data Files* obtained from NCHS/National Vital Statistics System (NVSS). Marginal effects and odds ratios are estimated using a regression model that also includes covariates representative of infant birth characteristics in addition to birth weight, maternal demographic characteristics, and maternal risk factors. All effects were statistically significant at the 5 percent level. Additional details are included in appendix E to the EA.

[2] Gestational age categories defined as extremely preterm (<=28 weeks), very preterm (>28 weeks and <=32 weeks), moderately preterm (>32 weeks and <=37 weeks), and term (>37 weeks).

The EPA weighted the race/ethnicity-specific odds ratios in Table 46 by the proportions of the infant populations who fell into each gestational age within a 100 g birth weight increment, based on the 2016/17 and 2017/18 period cohort data, to obtain a weighted odds ratio estimate for each modeled race/ethnicity subpopulation and 100 g birth weight increment.

Based on reduced serum PFOA/PFOS exposures under the regulatory alternatives and the estimated relationship between birth weight and infant mortality, the EPA estimates the subsequent change in birth weight for those infants affected by decreases in PFOA/PFOS and changes in the number of infant deaths. The EPA evaluated these changes at each PWS EP affected by the regulatory alternatives and the calculations are performed for each race/ethnicity group, 100 g birth weight category, and year of the analysis. Additional detail on the calculations the EPA used to estimate changes in birth

weight, the affected population size, and infant deaths avoided, and the number of surviving infants is provided in chapter 6 of USEPA (2024g).

The EPA used the Value of a Statistical Life to estimate the benefits of reducing infant mortality and the cost of illness to estimate the economic value of increasing birth weight in the population of surviving infants born to mothers exposed to PFOA and PFOS in drinking water. The EPA's approach to monetizing benefits associated with incremental increases in birth weight resulting from reductions in drinking water PFOA/PFOS levels relies on avoided medical costs associated with various ranges of birth weight. Although the economic burden of treating infants at various birth weights also includes non-medical costs, very few studies to date have quantified such costs (Klein and Lynch, 2018; ICF, 2021). The EPA selected the medical cost function from Klein and Lynch (2018) to monetize benefits associated with the estimated changes in infant birth weight resulting from reduced maternal exposure to PFOA/PFOS.[25]

Using the incremental cost changes from Klein and Lynch (2018), the EPA calculates the change in medical costs resulting from changes in birth weight among infants in the affected population who survived the first year following birth, provided in Table 47.

[25] The Klein and Lynch (2018) report was externally peer reviewed by three experts with qualifications in economics and public health sciences. The EPA's charge questions to the peer reviewers sought input on the methodology for developing medical cost estimates associated with changes in birth weight. The agency's charge questions, and peer reviewer responses are available in the docket.

Table 47: Simulated Cost Changes for Birth Weight Increases ($2022) (Based on Klein and Lynch, 2018 Table 8)

Birth Weight[a,b]	Simulated Cost Changes for Birth Weight Increases, Dollars per Gram ($2022)[c]		
	+0.04 lb (+18 g)	+0.11 lb (+50 g)	+0.22 lb (+100 g)
2 lb (907 g)	-$131.66	-$117.44	-$113.82
2.5 lb (1,134 g)	-$98.72	-$88.07	-$85.35
3 lb (1,361 g)	-$74.03	-$66.04	-$64.00
3.3 lb (1,497 g)	-$62.29	-$55.56	-$53.85
4 lb (1,814 g)	-$41.63	-$37.13	-$35.99
4.5 lb (2,041 g)	-$31.21	-$27.84	-$26.98
5 lb (2,268 g)	-$23.41	-$20.88	-$20.23
5.5 lb (2,495 g)	-$0.97	-$0.88	-$0.87
6 lb (2,722 g)	-$0.95	-$0.86	-$0.86
7 lb (3,175 g)	-$0.92	-$0.83	-$0.83
8 lb (3,629 g)	-$0.89	-$0.81	-$0.80
9 lb (4,082 g)	$3.28	$2.99	$3.01
10 lb (4,536 g)	$3.69	$3.37	$3.39

Notes:

[a]Values for birth weight have been converted from lb to g.

[b]Note that simulated medical costs increase, rather than decrease, in response to increased birth weight changes among high birth weight infants (those greater than 8 lb). Among high birth weight infants, there is a higher risk of birth trauma, metabolic issues, and other health problems (Klein and Lynch, 2018).

[c]Values scaled from $2010 to $2022 using the medical care Consumer Price Index (USBLS, 2022).

Tables 48 to 51 provide the health effects avoided and valuation associated with birth weight impacts. The EPA estimated that, over the evaluation period, the final rule will result in annualized benefits from avoided reductions in birth weight of $209 million.

Table 48: National Birth Weight Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Increase in Birth Weight (Millions of Grams)	129.6	216.8	304.1
Number of Birth Weight-Related Deaths Avoided	781.9	1,301.7	1,823.6
Total Annualized Birth Weight Benefits (Million $2022) [2]	$124.85	$209.00	$292.78

Notes:

Detail may not add exactly to total due to independent rounding. Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 49: National Birth Weight Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Increase in Birth Weight (Millions of Grams)	128.8	215.6	302.1
Number of Birth Weight-Related Deaths Avoided	777.4	1,294.4	1,812.9
Total Annualized Birth Weight Benefits (Million $2022) [2]	$124.82	$207.82	$291.00

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 50: National Birth Weight Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Increase in Birth Weight (Millions of Grams)	111.3	185.6	260.3
Number of Birth Weight-Related Deaths Avoided	668.9	1,114.7	1,561.2
Total Annualized Birth Weight Benefits (Million $2022) [2]	$107.34	$178.97	$250.00

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 51: National Birth Weight Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Increase in Birth Weight (Millions of Grams)	62.1	102.0	142.4
Number of Birth Weight-Related Deaths Avoided	375.8	616.6	859.1
Total Annualized Birth Weight Benefits (Million $2022) [2]	$60.24	$98.97	$137.75

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

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2. Quantified Cardiovascular Effects

CVD is one of the leading causes of premature mortality in the United States (D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017). As discussed in the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS,* exposure to PFOA and PFOS through drinking water contributes to increased serum PFOA and PFOS concentrations and elevated levels of TC, as well as suggestive evidence of changes in levels of HDLC and elevated levels of systolic blood pressure (USEPA, 2024c; USEPA, 2024d). Changes in TC and blood pressure are associated with changes in incidence of CVD events such as myocardial infarction (*i.e.,* heart attack), ischemic stroke, and cardiovascular mortality occurring in populations without prior CVD event experience (D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017).

The EPA recognizes that the epidemiologic literature that provides strong support for an effect of PFOA and PFOS on cholesterol and blood pressure does not provide direct support for an effect of PFOA and PFOS on the risk of CVD. Therefore, the EPA uses the approach outlined here to link changes in CVD risk biomarkers (*i.e.,* cholesterol and blood pressure) to changes in CVD risk.

For each EP, evaluation of the changes in CVD risk involves the following key steps:

1. Estimation of annual changes in TC and blood pressure levels using exposure-response functions for the potential effects of serum PFOA/PFOS on these biomarkers;

2. Estimation of the annual incidence of fatal and non-fatal first hard CVD events, defined as fatal and non-fatal myocardial infarction, fatal and non-fatal ischemic stroke or other coronary heart disease death occurring in populations without prior CVD event experience (D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017), and post-acute CVD mortality corresponding to baseline and regulatory alternative TC and blood pressure levels in all populations alive during or born after the start of the evaluation period; and

3. Estimation of the economic value of reducing CVD mortality and morbidity from baseline to regulatory alternative levels, using the Value of a Statistical Life and cost of illness measures, respectively.

Given the breadth of evidence linking PFOA and PFOS exposure to effects on TC and blood pressure in general adult populations, the EPA quantified public health impacts of changes in these well-established CVD risk biomarkers (D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017) by estimating changes in incidence of several CVD events. Specifically, the EPA assumed that PFOA/PFOS-related changes in TC and blood pressure had the same effect on the CVD risk as the changes unrelated to chemical exposure and used the Pooled Cohort ASCVD model (Goff et al., 2014) to evaluate their impacts on the incidence of myocardial infarction, ischemic stroke, and cardiovascular mortality occurring in populations without prior CVD event experience.

The ASCVD model includes TC as a predictor of first hard CVD events. The EPA did not identify any readily available relationships for PFOA or PFOS and TC that were specifically relevant to the age group of interest (40–89 years, the years for which the ASCVD model estimates the probability of a first hard CVD event). Therefore, the agency developed a meta-analysis of studies reporting associations between serum PFOA or PFOS and TC in general populations (*e.g.,* populations that are not a subset of workers or pregnant women). Statistical analyses that combine the results of multiple studies, such as meta-analyses, are widely applied to investigate the associations between contaminant levels and associated health effects. Such analyses are suitable for economic assessments because they can improve precision and statistical power (Engels et al., 2000; Deeks, 2002; Rücker et al., 2009).

The EPA identified 14 studies from which to derive slope estimates for PFOA and PFOS associations with serum TC levels. Appendix F of USEPA (2024e) provides further detail on the studies selection criteria, meta-data development, meta-analysis results, and discussion of the uncertainty and limitations inherent in the EPA's exposure-response analysis.

The EPA developed exposure-response relationships between serum PFOA/PFOS and TC for use in the CVD analysis using the meta-analyses restricted to studies of adults in the general population reporting similar models. When using studies reporting linear associations between TC and serum PFOA or PFOS, the EPA estimated a positive increase in TC of 1.57 (95 percent CI: 0.02, 3.13) mg/dL per ng/mL serum PFOA (p-value=0.048), and of 0.08 (95 percent CI: -0.01, 0.16) mg/dL per ng/mL serum PFOS (p-value=0.064). Based on the systematic review conducted by the EPA to develop the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS,* the available evidence supports a positive association between PFOS and TC in the general population. For more information on the systematic review and results, see USEPA (2024c) and USEPA (2024d).

PFOS exposure has been linked to other cardiovascular outcomes, such as systolic blood pressure and hypertension (Liao et al., 2020; USEPA, 2024d). Because systolic blood pressure is another predictor used by the ASCVD model, the EPA included the estimated changes in blood pressure from reduced exposure to PFOS in the CVD analysis. The EPA selected the slope from the Liao et al. (2020) study—a high confidence study conducted based on U.S. general population data from NHANES cycles 2003–2012. The evidence on the associations between PFOA and blood pressure is not as consistent as for PFOS. Therefore, the EPA is not including effect estimates for the serum PFOA-blood pressure associations in the CVD analysis.

The EPA relies on the life table-based approach to estimate CVD risk reductions because (1) changes in serum PFOA/PFOS in response to changes in drinking water PFOA/PFOS occur over multiple years, (2) CVD risk, relying on the ASCVD model, can be modeled only for those older than 40 years without prior CVD history, and (3) individuals who have experienced non-fatal CVD events have elevated mortality implications immediately and within at least five years of the first occurrence. Recurrent life table calculations are used to estimate a PWS EP-specific annual time series of CVD event incidence for a population cohort characterized by sex, race/ethnicity, birth year, age at the start of the PFOA/PFOS evaluation period (*i.e.,* 2024), and age- and sex-specific time series of changes in TC and blood pressure levels obtained by combining serum PFOA/PFOS concentration time series with exposure-response information. Baseline and regulatory alternatives are evaluated separately, with regulatory alternative TC and blood pressure levels estimated using baseline information on these biomarkers from external statistical data sources and modeled changes in TC and blood pressure due to conditions under the regulatory alternatives.

The EPA estimated the incidence of first hard CVD events based on TC serum and blood pressure levels using the ASCVD model (Goff et al., 2014), which predicts the 10-year probability of a hard CVD event to be experienced by a person without a prior CVD history. The EPA adjusted the modeled

population cohort to exclude individuals with pre-existing conditions, as the ASCVD risk model does not apply to these individuals. For blood pressure effects estimation, the EPA further restricts the modeled population to those not using antihypertensive medications for consistency with the exposure-response relationship. Modeled first hard CVD events include fatal and non-fatal myocardial infarction, fatal and non-fatal ischemic stroke, and other coronary heart disease mortality. The EPA has also estimated the incidence of post-acute CVD mortality among survivors of the first myocardial infarction or ischemic stroke within 6 years of the initial event.

The estimated CVD risk reduction resulting from reducing serum PFOA and serum PFOS concentrations is the difference in annual incidence of CVD events (*i.e.,* mortality and morbidity associated with first-time CVD events and post-acute CVD mortality) under the baseline and regulatory alternatives. Appendix G of USEPA (2024e) provides detailed information on all CVD model components, computations, and sources of data used in modeling.

The EPA uses the Value of a Statistical Life to estimate the benefits of reducing mortality associated with hard CVD events in the population exposed to PFOA and PFOS in drinking water. The EPA relies on cost of illness-based valuation that represents the medical costs of treating or mitigating non-fatal first hard CVD events (myocardial infarction, ischemic stroke) during the three years following an event among those without prior CVD history, adjusted for post-acute mortality.

The annual medical expenditure estimates for myocardial infarction and ischemic stroke are based on O'Sullivan et al. (2011). The estimated expenditures do not include long-term institutional and home health care. For non-fatal myocardial infarction, O'Sullivan et al. (2011) estimated medical expenditures are $53,246 ($2022) for the initial event and then $33,162, $14,635, $13,078 annually within 1, 2, and 3 years after the initial event, respectively. For non-fatal ischemic stroke, O'Sullivan et al. (2011) estimated medical expenditures are $16,503 ($2022) for the initial event and then $11,988, $788, $1,868 annually within 1, 2, and 3 years after the initial event, respectively. Annual estimates within 1, 2, and 3 years after the initial event include the incidence of secondary CVD events among survivors of first myocardial infarction and ischemic stroke events.

To estimate the present discounted value of medical expenditures within 3 years of the initial non-fatal myocardial infarction, the EPA combined O'Sullivan et al. (2011) myocardial infarction-specific estimates with post-acute survival probabilities based on Thom et al. (2001) (for myocardial infarction survivors aged 40–64) and Li et al. (2019) (for myocardial infarction survivors aged 65+). To estimate the present discounted value of medical expenditures within 3 years of the initial non-fatal ischemic stroke, the EPA combined O'Sullivan et al. (2011) ischemic stroke-specific estimates with post-acute survival probabilities based on Thom et al. (2001) (for ischemic stroke survivors aged 40–64, assuming post-acute myocardial infarction survival probabilities reasonably approximate post-acute ischemic stroke survival probabilities) and Li et al. (2019) (for ischemic stroke survivors aged 65+). The EPA did not identify post-acute ischemic stroke mortality information in this age group, but instead applied post-acute myocardial infarction mortality estimates for ischemic stroke valuation. Table 52 presents the resulting myocardial infarction and ischemic stroke unit values.

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Table 52: Cost of Illness of Non-Fatal First CVD Event Used in Modeling

Type of First Non-fatal Hard CVD Event	Age Group	Present Discounted Value of 3-Year Medical Expenditures ($2022, 2% discount rate)[a,b] Adjusted for Post-Acute Mortality[c]
MI	40-64 years	$110,040
	65+ years	$96,626
IS	40-64 years	$30,373
	65+ years	$27,954

Abbreviations: CVD – cardiovascular disease; MI – myocardial infarction (ICD9=410; ICD10=I21), IS – ischemic stroke (ICD9=433, 434; ICD10=I63).

Notes:

[a]Estimates of annual medical expenditures are from O'Sullivan et al. (2011).

[b]Original values from O'Sullivan et al. (2011) were inflated to $2022 using the medical care Consumer Price Index (USBLS, 2022).

[c]Post-acute MI mortality data for those aged 40-64 years is from Thom et al. (2001); probabilities to survive 1 year, 2 years, and 3 years after the initial event are 0.93, 0.92, and 0.90, respectively. The EPA applies these mortality values to derive the IS value in this age group. Post-acute MI mortality data and post-acute IS mortality data for persons aged 65 years and older are from Li et al. (2019). For MI, probabilities to survive 1 year, 2 years, and 3 years after the initial event are 0.68, 0.57, and 0.49, respectively. For IS, probabilities to survive 1 year, 2 years, and 3 years after the initial event are 0.67, 0.57, and 0.48, respectively.

Tables 53 to 56 provide the health effects avoided and valuation associated with CVD. The EPA estimated that, over the evaluation period, the final rule will result in annualized benefits from avoided CVD cases and deaths of $606 million.

Table 53: National CVD Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal MI Cases Avoided	1,407.7	6,333.1	11,189.0
Number of Non-Fatal IS Cases Avoided	2,074.8	9,247.6	16,279.0
Number of CVD Deaths Avoided	845.5	3,715.8	6,555.6
Total Annualized CVD Benefits (Million $2022) [2]	$140.66	$606.09	$1,069.40

Notes:

Detail may not add exactly to total due to independent rounding. Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 54: National CVD Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L)

(Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal MI Cases Avoided	1,400.8	6,296.0	11,115.0
Number of Non-Fatal IS Cases Avoided	2,065.0	9,194.8	16,203.0
Number of CVD Deaths Avoided	839.9	3,695.1	6,484.4
Total Annualized CVD Benefits (Million $2022) [2]	$140.12	$602.72	$1,059.60

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 55: National CVD Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L)

(Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal MI Cases Avoided	1,209.2	5,352.0	9,417.5
Number of Non-Fatal IS Cases Avoided	1,778.3	7,826.9	13,778.0
Number of CVD Deaths Avoided	733.1	3,146.8	5,518.0
Total Annualized CVD Benefits (Million $2022) [2]	$119.18	$513.27	$900.13

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 56: National CVD Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L)

(Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal MI Cases Avoided	673.7	2,776.5	4,872.8
Number of Non-Fatal IS Cases Avoided	987.0	4,079.2	7,145.6
Number of CVD Deaths Avoided	411.6	1,640.9	2,878.1
Total Annualized CVD Benefits (Million $2022) [2]	$66.97	$267.56	$469.05

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

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3. Quantified Kidney Cancer Effects

Data on the association between PFOA exposure and kidney cancer (*i.e.,* RCC), particularly from epidemiological studies, indicate a positive association between exposure and increased risk of RCC. Epidemiology studies indicated that exposure to PFOA was associated with an increased risk of RCC (CalEPA, 2021; ATSDR, 2021; USEPA, 2016c; USEPA, 2024c, USEPA, 2024j). In the PFOA HESD (USEPA, 2016c), the EPA determined that PFOA is likely to be carcinogenic to humans (USEPA, 2005a) based in part on evidence of associations between PFOA exposure and kidney cancer in humans. A recent study of the relationship between PFOA and RCC in U.S. general populations found strong evidence of a positive association between exposure to PFOA and RCC in humans (Shearer et al., 2021). A meta-analysis of epidemiological literature also concluded that there was an increased risk of kidney cancer associated with increased PFOA serum concentrations (Bartell and Vieira, 2021). As such, the EPA selected RCC as a key outcome when assessing the health impacts of reduced PFOA exposures.

The EPA quantified and valued the changes in RCC risk associated with reductions in serum PFOA levels that are in turn associated with reductions in drinking water PFOA concentrations under the regulatory alternatives. PWS EP-specific time series of the differences between serum PFOA concentrations under baseline and regulatory alternatives are inputs into this analysis. For each PWS EP, evaluation of the changes in RCC impacts involves the following key steps:

1. Estimating the changes in RCC risk based on modeled changes in serum PFOA levels and the exposure-response function for the effect of serum PFOA on RCC;

2. Estimating the annual incidence of RCC cases and excess mortality among those with RCC in all populations corresponding to baseline and regulatory alternative RCC risk levels, as well as estimating the regulatory alternative-specific reduction in cases relative to the baseline, and

3. Estimating the economic value of reducing RCC mortality from baseline to regulatory alternative levels, using the Value of a Statistical Life and cost of illness measures, respectively.

To identify an exposure-response function, the EPA reviewed studies highlighted in the HESD for PFOA (USEPA, 2016c) and a recent study discussed in both the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) *PFOA Public Health Goals* report (CalEPA, 2021) and the EPA's *Final Human Health Toxicity Assessment for PFOA* (USEPA, 2024c; USEPA, 2024j). Steenland et al. (2015) observed an increase in kidney cancer deaths among workers with high exposures to PFOA. Vieira et al. (2013) found that kidney cancer was positively associated with ''high'' and ''very high'' PFOA exposures. Barry et al. (2013) found a slight trend in cumulative PFOA serum exposures and kidney cancer among the C8 Health Project population. In a large case-control general population study of the relationship between PFOA and kidney cancer in 10 locations across the U.S., Shearer et al. (2021) found evidence that exposure to PFOA is associated with RCC, the most common form of kidney cancer, in humans.

To evaluate changes between baseline and regulatory alternative RCC risk resulting from reduced exposure to PFOA, the EPA relied on the estimated time series of changes in serum PFOA concentrations (section 6.3) and the

serum-RCC exposure-response function provided by Shearer et al. (2021): 0.00178 $(ng/mL)^{-1}$. The analysis reported in Shearer et al. (2021) was designed as a case-control study with population controls based on 10 sites within the U.S. population. Shearer et al. (2021) accounted for age, sex, race, ethnicity, study center, year of blood draw, smoking, and hypertension in modeling the association between PFOA and RCC. Results showed a strong and statistically significant association between PFOA and RCC. The EPA selected the exposure-response relationship from Shearer et al. (2021) because it included exposure levels typical in the general population and the study was found to have a low risk of bias when assessed in the EPA's *Final Human Health Toxicity Assessment for PFOA* (USEPA, 2024c; USEPA, 2024j).

The linear slope factor developed by the agency (see section 4.2 of USEPA, 2024c) based on Shearer et al. (2021) enables estimation of the changes in the lifetime RCC risk associated with reduced lifetime serum PFOA levels. Because baseline RCC incidence statistics are not readily available from the National Cancer Institute (NCI) public use data, the EPA used kidney cancer statistics in conjunction with an assumption that RCC comprises 90 percent of all kidney cancer cases to estimate baseline lifetime probability of RCC (USEPA, 2024c; American Cancer Society, 2020). The EPA estimated the baseline lifetime RCC incidence for males at 1.89 percent and the baseline lifetime RCC incidence for females at 1.05 percent. Details of these calculations are provided in appendix H of USEPA (2024e).

Similar to the EPA's approach for estimating CVD risk reductions, the EPA relies on the life table approach to estimate RCC risk reductions. The outputs of the life table calculations are the PWS EP-specific estimates of the annual change in the number of RCC cases and the annual change in excess RCC population mortality. For more detail on the EPA's application of the life table to cancer benefits analyses, please see appendix H of USEPA (2024e).

Although the change in PFOA exposure likely affects the risk of developing RCC beyond the end of the analysis period (the majority of RCC cases manifest during the latter half of the average individual lifespan; see appendix H of USEPA (2024e), the EPA does not capture effects after the end of the period of analysis, 2105. Individuals alive after the end of the period of analysis likely benefit from lower lifetime exposure to PFOA. Lifetime health risk model data sources include the EPA SDWIS, age-, sex-, and race/ethnicity-specific population estimates from the U.S. Census Bureau (2020), the Surveillance, Epidemiology, and End Results (SEER) program database (Surveillance Research Program—National Cancer Institute, 2020a; National Cancer Institute, 2020b), and the CDC NCHS. Appendix H of USEPA (2024e) provides additional detail on the data sources and information used in this analysis as well as baseline kidney cancer statistics. Appendix B of USEPA (2024e) describes estimation of the affected population.

The EPA uses the Value of a Statistical Life to estimate the benefits of reducing mortality associated with RCC in the population exposed to PFOA in drinking water. The EPA uses the cost of illness-based valuation to estimate the benefits of reducing morbidity associated with RCC.

The EPA used the medical cost information from a recent RCC cost-effectiveness study by Ambavane et al. (2020) to develop cost of illness estimates for RCC morbidity. Ambavane et al. (2020) used a discrete event simulation model to estimate the lifetime treatment costs of several RCC treatment sequences, which included first and second line treatment medication costs, medication administration costs, adverse effect management costs, and disease management costs on- and off-treatment. To this end, the authors combined RCC cohort data from CheckMate 214 clinical trial and recent US-based healthcare cost information assembled from multiple sources (see supplementary information from Ambavane et al. (2020)).

The EPA received public comments on the EA for the proposed rule related to the EPA's use of cost of illness information for morbidity valuation. Specifically, some commenters recommended that the EPA use willingness to pay information (instead of cost of illness information) when valuing the costs associated with non-fatal illnesses, stating that willingness to pay information better accounts for lost opportunity costs (*e.g.,* lost productivity and pain and suffering) associated with non-fatal illnesses (USEPA, 2024k). To better account for these opportunity costs, the EPA used recently available willingness to pay values in a sensitivity analysis for morbidity associated with RCC. The sensitivity analysis results show that when willingness to pay values are used in RCC benefits analysis, morbidity benefits are increased by approximately 2 percent. See appendix O of the EA for full details and results on the willingness to pay sensitivity analyses.

Table 57 summarizes RCC morbidity cost of illness estimates derived by the EPA using Ambavane et al. (2020)-reported disease management costs on- and off-treatment along with medication, administration, and adverse effect management costs for the first line treatment that initiated the most cost-effective treatment sequences as identified by Ambavane et al. (2020), *i.e.,* the nivolumab and ipilimumab drug combination. This is a forward-looking valuation approach in that it assumes that the clinical practice would follow the treatment recommendations in Ambavane et al. (2020) and other recent studies cited therein. The EPA notes that the second line treatment costs are not reflected in the EPA's cost of illness estimates, because Ambavane et al. (2020) did not report information on the expected durations of the treatment-free interval (between the first line treatment discontinuation and the second line treatment initiation) and the second line treatment phase, conditional on survival beyond discontinuation of the second line treatment. As such, the EPA valued RCC morbidity at $261,175 ($2022) during year 1 of the diagnosis, $198,705 ($2022) during year 2 of the diagnosis, and $1,661 ($2022) starting from year 3 of the diagnosis. Additionally, the EPA assumed that for individuals with RCC who die during the specific year, the entire year-specific cancer treatment regimen is applied prior to the death event. This may overestimate benefits if a person does not survive the entire year.

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Table 57: RCC Morbidity Valuation

Time Interval	First Line Medication ($2018)[a]	First Line Administration ($2018)[a]	First Line Adverse Effect Management	Disease Management ($2018)[a]	Total ($2018)	Total ($2022)[d]
Monthly cost, month 1-3 from diagnosis[a,e]	32,485	516	78	73	33,152	37,382
Monthly cost, month 4-24 from diagnosis[b,f]	13,887	647	78	73	14,685	16,559
Monthly cost, month 25+ from diagnosis[g]	-	-	-	123	123	139
Annual cost, year 1 from diagnosis	222,438	7,371	934	878	231,621	261,175
Annual cost, year 2 from diagnosis	166,644	7,764	934	878	176,220	198,705
Annual cost, year 3+ from diagnosis	-	-	-	1,473	1,473	1,661

Notes:

[a] Ambavane et al. (2020) Table 1.

[b] Ambavane et al. (2020) p. 41, a maximum treatment duration assumption of 2 years.

[c] The adverse effect management costs of $1,868 in Ambavane et al. (2020) Table 1 were reported for the treatment duration. The EPA used the treatment duration of 24 months (i.e., 2 years) to derive monthly costs of $77.83.

[d] To adjust for inflation, the EPA used U.S. Bureau of Labor Statistics Consumer Price Index for All Urban Consumers: Medical Care Services in U.S. (City Average).

[e] First line treatment induction.

[f] First line treatment maintenance.

[g] Treatment-free interval.

Tables 58 to 61 provide the health effects avoided and valuation associated with RCC. The EPA estimated that, over the evaluation period, the final rule will result in annualized benefits from avoided RCC cases and deaths of $354 million.

Table 58: National RCC Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1)

(Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal RCC Cases Avoided	1,091.5	6,964.2	17,937.0
Number of RCC-Related Deaths Avoided	320.4	2,028.8	5,206.5
Total Annualized RCC Benefits (Million $2022) [2, 3]	$61.33	$353.90	$883.55

Notes:

Detail may not add exactly to total due to independent rounding. Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

[3] When using willingness-to-pay metrics to monetize morbidity benefits, total annualized RCC benefits are increased by $7.1 million.

Table 59: National RCC Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L)

(Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal RCC Cases Avoided	1,082.0	6,922.4	17,870.0
Number of RCC-Related Deaths Avoided	319.1	2,016.7	5,190.9
Total Annualized RCC Benefits (Million $2022) [2]	$60.90	$351.79	$877.47

Notes: Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 60: National RCC Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L)

(Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal RCC Cases Avoided	851.9	5,696.1	14,906.0
Number of RCC-Related Deaths Avoided	251.6	1,663.8	4,328.4
Total Annualized RCC Benefits (Million $2022) [2]	$48.41	$290.72	$730.99

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 61: National RCC Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L)

(Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal RCC Cases Avoided	372.1	2,648.1	6,967.4
Number of RCC-Related Deaths Avoided	111.5	782.8	2,057.3
Total Annualized RCC Benefits (Million $2022) [2]	$21.20	$137.30	$352.07

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

4. Key Limitations and Uncertainties in the Benefits Analysis

The following section discusses the uncertainty information incorporated in the quantitative benefits analysis. There are additional sources of uncertainty and limitations that could not be modeled quantitatively as part of the national benefits analysis. These sources of uncertainty are characterized in detail in section 6.8 of USEPA (2024g). This summary includes uncertainties that are specific to application of PK models for blood serum PFAS concentration estimation, developmental effects (*i.e.,* infant birth weight) modeling, CVD impacts modeling, RCC impacts modeling, and modeling of bladder cancer impacts from GAC treatment-related reductions in the sum of four trihalomethanes (THM4). Table 62 presents the key limitations and uncertainties that apply to the benefits analysis for the final rule. The EPA notes that in most cases it is not possible to judge the extent to which a particular limitation or uncertainty could affect the magnitude of the estimated benefits. Therefore, in each of the following tables, the EPA notes the potential direction of the impact on the quantified benefits (*e.g.,* a source of uncertainty that tends to underestimate quantified benefits indicates expectation for larger quantified benefits) but does not prioritize the entries with respect to the impact magnitude.

Table 62: Key Limitations and Uncertainties that Apply to Benefits Analyses Considered for the Final PFAS Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
The EPA has quantified benefits for three health endpoints for PFOA (birth weight, CVD, and RCC) and two health endpoints for PFOS (birth weight and CVD)	Underestimate	For various reasons, the EPA has not quantified the benefit of removing PFOA and PFOS from drinking water for most of the health endpoints PFOA and PFOS are expected to impact. See discussion in section F for more information about these nonquantifiable benefits.
The EPA has only quantified benefits for one co-removed contaminant group (THM4)	Underestimate	Treatment technologies that remove PFAS can also remove numerous other contaminants, including some other PFAS compounds, additional regulated and unregulated DBPs, heavy metals, organic contaminants, pesticides, among others. These co-removal benefits may be significant, depending on co-occurrence, how many facilities install treatment and which treatment option they select.
The EPA has not quantified national benefits for any health endpoint for the PFAS that make up the Hazard Index (PFHxS, PFNA, HFPO-DA, and PFBS)	Underestimate	PFHxS, PFNA, HFPO-DA, and PFBS each have substantial health impacts on multiple health endpoints. However, the effects of PFNA on birth weight are evaluated as part of a sensitivity analysis in appendix K. See discussion in section D for more information about these nonquantifiable benefits.
The analysis considers PFOA/PFOS concentrations from NTNCWSs	Overestimate	SDWIS population served estimates for NTNCWSs represent both the population that has regular exposure to the NTNCWS' drinking water (e.g., the employees at a location) and the peak day transient population (e.g., customers) who have infrequent exposure to the NTNCWS' drinking water. Estimating the demographic distribution and the share of daily drinking water consumption for these two types of NTNCWS populations would be difficult across many of the industries which operate NTNCWSs. The inclusion of NTNCWS results is an overestimate of benefits because daily drinking water consumption for these populations is also modeled at their residential CWS.
The EPA assumes that the effects of PFOA and	Uncertain	The exposure-response functions used in benefits analyses assume that the effects of serum PFOA/PFOS on the health outcomes considered

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
PFOS exposures are independent.		are independent and therefore additive. This assumption is consistent with the *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (*USEPA, 2024a*).* Due to limited evidence, the EPA does not consider synergies or antagonisms in PFOA/PFOS exposure-response.
The derivation of PFOA/PFOS exposure-response functions for the relationship between PFOA/PFOS serum and associated health outcomes assumes that there are no threshold serum concentrations below which effects do not occur.	Overestimate	The new data and the EPA's Final Human Health Toxicity Assessments indicate that the levels at which adverse health effects could occur are much lower than previously understood when the EPA issued the 2016 health advisories for PFOA and PFOS (70 ng/L) – including near zero for certain health effects. Therefore, the exposure-response functions used in benefits analyses assume that there are no threshold serum concentrations below which effects do not occur. This could result in a slight overestimate of benefits for noncancer health endpoints.
Causality is assumed for all health effects for which exposure-response functions are used to estimate risk.	Overestimate	Analyses evaluating the evidence on the associations between PFAS exposure and health outcomes are ongoing and the EPA has not conclusively determined causality. As described in section 6.2 of the EA, the EPA modeled health risks from PFOA/PFOS exposure for endpoints for which the evidence of association was found to be likely. These endpoints include birth weight, TC, and RCC. While the evidence supporting causality between DBP exposure and bladder cancer has increased since the EPA's Stage 2 DBP Rule (NTP, 2021; Weisman et al., 2022), causality has not yet been conclusively determined (Regli et al., 2015).
The analysis assumes that quantified benefits categories are additive.	Uncertain	The EPA did not model birth weight, CVD, RCC, and bladder cancer benefits jointly, in a competing risk framework. Therefore, reductions in health risk in a specific benefits category do not influence health risk reductions in another benefits category. For example, lower risk of CVD and associated mortality implies a larger population that could benefit from cancer risk reductions, because cancer incidence grows considerably later in life (see

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
		Tables G-3 through G-6 in appendix G of the EA; USEPA, 2024e).
The analysis does not take into account population growth and other changes in long-term trends.	Underestimate	The benefits analysis does not reflect the effects of growing population that may benefit from reduction in PFOA/PFOS exposure, which is expected to result in underestimated benefits. The EPA uses present-day information on life expectancy, disease, environmental exposure, and other factors, which are likely to change in the future.
For PWSs with multiple EP, the analysis assumes a uniform population distribution across the EP.	Uncertain	Data on the populations served by each EP are not available, and the EPA therefore uniformly distributes system population across EP. Effects of the regulatory alternative may be greater or smaller than estimated, depending on actual populations served by affected EP. For one large system serving more than one million customers the EPA has sufficient data on EP flow to proportionally assign effected populations.
The EPA does not characterize uncertainty associated with the Value of Statistical Life reference value or Value of Statistical Life elasticity	Uncertain	The EPA did not quantitatively characterize the uncertainty for the Value of Statistical Life reference value and income elasticity. Because the economic value of avoided premature mortality comprises most of the overall benefits estimate, not considering uncertainty surrounding the Value of Statistical Life is a limitation.
Process wastes not classified as hazardous	Underestimate	The national EA reflects the assumption that PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes. The EPA acknowledges that if Federal authorities later determine that PFAS-contaminated wastes require handling as hazardous wastes, there will be additional benefits to public health and the environment from reduced exposures to PFAS that have not been quantified as part of this analysis.

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G. Nonquantifiable Benefits of PFOA and PFOS Exposure Reduction

In this section, the EPA qualitatively discusses the potential health benefits resulting from reduced exposure to PFOA and PFOS in drinking water. These nonquantifiable benefits are expected to be realized as avoided adverse health effects as a result of the final NPDWR, in addition to the benefits that the EPA has quantified, because of their known toxicity and additive health concerns as well as occurrence and likely co-occurrence in drinking water. The EPA anticipates additional benefits associated with developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects beyond those benefits that the EPA has quantified. The evidence for these adverse health effects is briefly summarized here.

The EPA identified a wide range of potential health effects associated with exposure to PFOA and PFOS using five comprehensive Federal Government health effects assessments that summarize the recent literature on PFAS (mainly PFOA and PFOS, although many of the same health effects have been observed for the other PFAS in this rule) exposure and its health impacts: the EPA's HESDs for PFOA and PFOS, hereafter referred to as the EPA HESDs (USEPA, 2016c; USEPA, 2016d); the EPA's Final Human Health Toxicity Assessments for PFOA and

PFOS (USEPA, 2024c; USEPA, 2024d); and the U.S. Department of Health and Human Services (HHS) ATSDR *Toxicological Profile for Perfluoroalkyls* (ATSDR, 2021). Each source presents comprehensive literature reviews on adverse health effects associated with PFOA and PFOS. The EPA notes that NASEM also published a report which includes a review of the adverse health effects for numerous PFAS (NASEM, 2022). That document is included in the docket for this final rule.

The most recent literature reviews on PFAS exposures and health impacts, which are included in the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS* (USEPA, 2024c; USEPA, 2024d), describe the weight of evidence supporting PFOA and PFOS associations with health outcomes as either demonstrative, indicative (likely), suggestive, inadequate, or strong evidence supportive of no effect according to the evidence integration judgments outlined in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f; USEPA, 2024c; USEPA, 2024d). For the purposes of the reviews conducted to develop the *Final Human Health Toxicity Assessments for PFOA and PFOS,* an association is deemed demonstrative when there is a strong evidence base demonstrating that the chemical exposure causes a health effect in humans. The association is deemed indicative (likely) when the evidence base indicates that the chemical exposure likely causes a health effect in humans, although there might be outstanding questions or limitations that remain, and the evidence is insufficient for the higher conclusion level. The association is suggestive if the evidence base suggests that the chemical exposure might cause a health effect in humans, but there are very few studies that contributed to the evaluation, the evidence is very weak or conflicting, or the methodological conduct of the studies is poor. The association is inadequate if there is a lack of information or an inability to interpret the available evidence (*e.g.,* findings across studies). The association supports no effect when extensive evidence across a range of populations and exposure levels has identified no effects/associations. Note that the EPA considered information available as of September 2023 for the analyses presented herein.

Developmental effects: Exposure to PFOA and PFOS is linked to developmental effects including but not limited to the infant birth weight effects that the EPA quantified. Other developmental effects include small for gestational age (SGA), birth length, head circumference at birth, and other effects (Verner et al., 2015; Negri et al., 2017; ATSDR, 2021; Waterfield et al., 2020; USEPA, 2016c; USEPA, 2016d; USEPA, 2024c; USEPA, 2024d). SGA is a developmental health outcome of interest when studying potential effects of PFOA/PFOS exposure because SGA infants have increased health risks during pregnancy and delivery as well as post-delivery (Osuchukwu and Reed, 2022). The majority of epidemiology studies indicated increased risk of SGA with PFOA/PFOS exposure, although some studies reported null results (USEPA, 2024c; USEPA, 2024d). For instance, some studies suggested a potentially positive association between PFOA exposure and SGA (Govarts et al., 2018; Lauritzen et al., 2017; Wang et al., 2016; Souza et al., 2020; Wikström et al., 2020; Chang et al., 2022; USEPA, 2024c). In addition to decreases in offspring weight, toxicology studies on PFOA and PFOS exposures in rodents demonstrated relationships with multiple other developmental toxicity endpoints, including increased offspring mortality, decreased maternal body weight and body weight change, skeletal and soft tissue effects, and delayed eye-opening (USEPA, 2024c; USEPA, 2024d). For additional details on developmental studies and their individual outcomes, see chapter 3.4.4 (*Developmental*) in USEPA (2024c) and USEPA (2024d).

Cardiovascular effects: In addition to the CVD effects that the EPA quantified associated with changes in TC and blood pressure from exposure to PFOA and PFOS (see section 6.2 of USEPA (2024g)), available evidence suggests an association between exposure to PFOA and PFOS and increased low-density lipoprotein cholesterol (LDLC) (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). High levels of LDLC are known as the 'bad' cholesterol because it can lead to the buildup of cholesterol in the arteries, which can raise the risk of heart disease and stroke. Epidemiology studies showed a positive association between PFOA or PFOS exposure and LDLC levels in adults and children (USEPA, 2024c; USEPA, 2024d). In particular, the evidence suggested positive associations between serum PFOA and PFOS levels and LDLC levels in adolescents ages 12–18, while positive associations between serum levels and LDLC levels in younger children were observed only for PFOA (ATSDR, 2021). Additionally, available evidence supports a relatively consistent positive association between PFOA or PFOS and low-density lipoprotein (LDL) in adults, especially those who are obese or prediabetic. Associations with other lipoprotein cholesterol known to increase cardiovascular risks were also positive, which increased confidence in the findings for LDLC. Available evidence regarding the impact of PFOA and PFOS exposure on pregnant women was too limited for the EPA to determine an association (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). Toxicology studies generally reported alterations in serum lipid levels in mice and rats following oral exposure to PFOA (USEPA, 2024d) or PFOS (USEPA, 2024c), indicating a disruption in lipid metabolism, which is coherent with effects observed in humans. For additional details on LDLC studies and their individual outcomes, see chapter 3.4.3 (*Cardiovascular*) in USEPA (2024c) and USEPA (2024d).

Liver effects: Several biomarkers can be used clinically to diagnose liver diseases, including alanine aminotransferase (ALT). Serum ALT measures are considered a reliable indicator of impaired liver function because increased serum ALT is indicative of leakage of ALT from damaged hepatocytes (Boone et al., 2005; Z. Liu et al., 2014; USEPA, 2002d). Additionally, evidence from both human epidemiological and animal toxicological studies indicates that increased serum ALT is associated with liver disease (Ioannou et al., 2006a; Ioannou et al., 2006b; Kwo et al., 2017; Roth et al., 2021). Human epidemiological studies have demonstrated that even low magnitude increases in serum ALT can be clinically significant (Mathiesen et al., 1999; Park et al., 2019). Additionally, numerous studies have demonstrated an association between elevated ALT and liver-related mortality (reviewed by Kwo et al., 2017). Furthermore, the American Association for the Study of Liver Diseases (AASLD) recognizes serum ALT as an indicator of overall human health and mortality (Kim et al., 2008). Epidemiology data provides consistent evidence of a positive association between PFOS/PFOA exposure and ALT levels in adults (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). Studies of adults showed consistent evidence of a positive association between PFOA exposure and elevated ALT levels at both high exposure levels and exposure levels typical of the general population (USEPA, 2024c). There is also consistent epidemiology evidence of associations between PFOS and elevated ALT levels. A limited number of studies reported

inconsistent evidence on whether PFOA/PFOS exposure is associated with increased risk of liver disease (USEPA, 2024d). It is also important to note that while evaluation of direct liver damage is possible in animal studies, it is difficult to obtain biopsy-confirmed histological data in humans. Therefore, liver injury is typically assessed using serum biomarkers of hepatotoxicity (Costello et al., 2022). Associations between PFOA/PFOS exposure and ALT levels in children were less consistent than in adults (USEPA, 2024c; USEPA, 2024d).

PFOA toxicology studies showed increases in ALT and other serum liver enzymes across multiple species, sexes, and exposure paradigms (USEPA, 2024c). Toxicology studies on the impact of PFOS exposure on ALT also reported increases in ALT and other serum liver enzyme levels in rodents, though these increases were modest (USEPA, 2024d). Several studies in animals also reported increases in the incidence of liver lesions or cellular alterations, such as hepatocellular cell death (USEPA, 2024c; USEPA, 2024d). For additional details on the ALT studies and their individual outcomes, see section 3.4.1 (Hepatic) in USEPA (2024c) and USEPA (2024d).

Immune effects: Proper antibody response helps maintain the immune system by recognizing and responding to antigens. The available evidence indicates a relationship between PFOA exposure and immunosuppression; epidemiology studies showed suppression of at least one measure of the antibody response for tetanus and diphtheria among people with higher prenatal and childhood serum concentrations of PFOA (ATSDR, 2021; USEPA, 2024c). Data reporting on associations between PFOA exposure and antibody response to vaccinations other than tetanus and diphtheria (*i.e.,* rubella and hand, foot, and mouth disease) are limited but supportive of associations between PFOA and decreased immune response in children (USEPA, 2024c). Available studies supported an association between PFOS exposure and immunosuppression in children, where increased PFOS serum levels were associated with decreased antibody production in response to tetanus, diphtheria, and rubella vaccinations (USEPA, 2024d). Studies reporting associations between PFOA or PFOS exposure and immunosuppression in adults are less consistent, though this may be due to a lack of high confidence data (USEPA, 2024c; USEPA, 2024d). Toxicology evidence suggested that PFOA and PFOS exposure results in effects similarly indicating immune suppression, such as reduced response of immune cells to challenges (*e.g.,* reduced natural killer cell activity and immunoglobulin production) (USEPA, 2024c; USEPA, 2024d). For additional details on immune studies and their individual outcomes, see section 3.4.2 (*Immune*) in USEPA (2024c) and USEPA (2024d).

Endocrine effects: Elevated circulating thyroid hormone levels can accelerate metabolism and cause irregular heartbeat; low levels of thyroid hormones can cause neurodevelopmental effects, tiredness, weight gain, and increased susceptibility to the common cold. There is suggestive evidence of a positive association between PFOA/PFOS exposure and thyroid hormone disruption (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). Epidemiology studies reported inconsistent evidence regarding associations between PFOA and PFOS exposure and general endocrine outcomes, such as thyroid disease, hypothyroidism, and hypothyroxinemia (USEPA, 2024c; USEPA, 2024d). However, for PFOA, epidemiological studies reported suggestive evidence of positive associations for serum levels of thyroid stimulating hormone (TSH) and the thyroid hormone triiodothyronine (T3) in adults, and the thyroid hormone thyroxine (T4) in children (USEPA, 2024c; USEPA, 2024d). For PFOS, epidemiological studies reported suggestive evidence of positive associations for TSH in adults, positive associations for T3 in children, and inverse associations for T4 in children (USEPA, 2024d). Toxicology studies indicated that PFOA and PFOS exposure leads to decreases in serum thyroid hormone levels [26] and adverse effects to the endocrine system (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d; USEPA, 2024h). Overall, changes in serum thyroid hormone levels in animals indicate PFOS and PFOA toxicity potentially relevant to humans (USEPA, 2024c; USEPA, 2024d). For additional details on endocrine effects studies and their individual outcomes, see appendix C.2 (*Endocrine*) in USEPA (2024h) and USEPA (2024i).

Metabolic effects: Leptin is a hormone that, along with adiponectin, can be a marker of adipose tissue dysfunction. Chronic high levels of leptin lead to leptin resistance that mirrors many of the characteristics associated with diet-induced obesity, including reduced leptin receptors and diminished signaling. Therefore, high leptin levels are associated with higher body fat mass, a larger size of individual fat cells, overeating, and inflammation (*e.g.,* of adipose tissue, the hypothalamus, blood vessels, and other areas). Evidence suggests an association between PFOA exposure and leptin levels in the general adult population (ATSDR, 2021; USEPA, 2024c). Based on a review of human epidemiology studies, evidence of associations between PFOS and metabolic outcomes appears inconsistent, but in some studies, positive associations were observed between PFOS exposure and leptin levels (USEPA, 2024d). Studies examining newborn leptin levels did not find associations with maternal PFOA levels (ATSDR, 2021). Maternal PFOS levels were also not associated with alterations in leptin levels (ATSDR, 2021). For additional details on metabolic effect studies and their individual outcomes, see appendix C.3 (*Metabolic/Systemic*) in USEPA (2024h) and USEPA (2024i).

Reproductive effects: Studies of the reproductive effects from PFOA/PFOS exposure have focused on associations between exposure to these contaminants and increased risk of gestational hypertension and preeclampsia in pregnant women (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). Gestational hypertension (high blood pressure during pregnancy) can lead to fetal problems such as poor growth and stillbirth. Preeclampsia—instances of gestational hypertension where the mother also has increased levels of protein in her urine—can similarly pose significant risks to both the fetus and mother. Risks to the fetus include impaired fetal growth due to the lack of oxygen and nutrients, stillbirth, preterm birth, and infant death (NIH, 2017). Even if born full term, the infant may be at risk for later problems such as diabetes, high blood pressure, and congestive heart failure. Effects of preeclampsia on the mother may include kidney and liver damage, blood clotting problems, brain injury, fluid on the lungs, seizures, and mortality (NIH, 2018). The epidemiology evidence yields mixed (positive and null) associations, with some suggestive evidence supporting positive associations between PFOA/PFOS exposure and both preeclampsia and gestational hypertension (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). For additional details on reproductive effects studies and their individual

[26] Decreased thyroid hormone levels are associated with effects such as changes in thyroid and adrenal gland weight, hormone fluctuations, and organ histopathology, as well as adverse neurodevelopmental outcomes (ATSDR, 2021; USEPA, 2024c).

outcomes, see appendix C.1 (*Reproductive*) in USEPA (2024h) and USEPA (2024i).

Musculoskeletal effects: Adverse musculoskeletal effects such as osteoarthritis and decreased bone mineral density impact bone integrity and cause bones to become brittle and more prone to fracture. The available epidemiology evidence suggests that PFOA exposure may be linked to decreased bone mineral density, bone mineral density relative to bone area, height in adolescence, osteoporosis, and osteoarthritis (ATSDR, 2021; USEPA, 2024c). Some studies found that PFOA/PFOS exposure was linked to osteoarthritis, in particular among women under 50 years of age (ATSDR, 2021). There is limited evidence from studies pointing to effects of PFOS on skeletal size (height), lean body mass, and osteoarthritis (USEPA, 2024d). Evidence from some studies suggests that PFOS exposure has a harmful effect on bone health, particularly measures of bone mineral density, with greater statistically significance of effects occurring among females (USEPA, 2024d). However, other reviews reported mixed findings on the effects of PFOS exposure including decreased risk of osteoarthritis, increased risk for some demographic subgroups, or no association (ATSDR, 2021). For additional details on musculoskeletal effects studies and their individual outcomes, see appendix C.8 (*Musculoskeletal*) in USEPA (2024h) and USEPA (2024i).

Cancer Effects: In the EPA's *Final Human Health Toxicity Assessment for PFOA,* the agency evaluates the evidence for carcinogenicity of PFOA that has been documented in both epidemiological and animal toxicity studies (USEPA, 2024c; USEPA, 2024j). The evidence in epidemiological studies is primarily based on the incidence of kidney and testicular cancer, as well as potential incidence of breast cancer in genetically susceptible subpopulations or for particular breast cancer types. Other cancer types have been observed in humans, although the evidence for these is generally limited to low confidence studies. The evidence of carcinogenicity in animal models is provided in three chronic oral animal bioassays in Sprague-Dawley rats which identified neoplastic lesions of the liver, pancreas, and testes (USEPA, 2024c; USEPA, 2024j). The EPA determined that PFOA is *Likely to Be Carcinogenic to Humans,* as ''the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans.'' This determination is based on the evidence of kidney and testicular cancer in humans and LCTs, PACTs, and hepatocellular adenomas in rats (USEPA, 2024c; USEPA, 2024j). The EPA's benefits analysis for avoided RCC cases from reduced PFOA exposure is discussed in section XII.E of this preamble and in section 6.6 of USEPA (2024g).

In the EPA's *Final Human Health Toxicity Assessment for PFOS,* the agency evaluates the evidence for carcinogenicity of PFOS and found that several epidemiological studies and a chronic cancer bioassay comprise the evidence database for the carcinogenicity of PFOS (USEPA, 2024d; USEPA 2024j). The available epidemiology studies report elevated risk of liver cancer, consistent with increased incidence of liver tumors reported in male and female rats. There is also mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans. The animal chronic cancer bioassay study also provides evidence of increased incidence of pancreatic islet cell tumors in male rats. The EPA reviewed the weight of the evidence and determined that PFOS is *Likely to Be Carcinogenic to Humans,* as ''the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans.'' The EPA's national-level benefits sensitivity analysis for avoided liver cancer cases from reduced PFOS exposure is detailed in appendix O of the EA.

The EPA anticipates there are additional nonquantifiable benefits related to potential testicular, bladder, prostate, and breast cancer effects summarized above. Benefits associated with avoiding cancer cases not quantified in the EPA's analysis could be substantial. For example, a study by Obsekov et al. (2023) reports the number of breast cancer cases attributable to PFAS exposure ranges from 421 to 3,095 annually, with an estimated direct cost of 6-month treatment ranging from $27.1 to $198.4 million per year ($2022). This study also finds that approximately 5 (0.076 percent) annual testicular cases are attributable to PFOA exposure with an estimated direct cost of treatment of $173,450 per year ($2022). Although the methods used by Obsekov et al. (2023) differ from those used to support the national quantified benefits of the rule, the information provided in the study is helpful in portraying the costs of cancers that are associated with PFAS exposures. For additional details on cancer studies and their individual outcomes, see chapter 3.5 (*Cancer*) in USEPA (2024c) and USEPA (2024d).

After assessing available health and economic information, the EPA was unable to quantify the benefits of avoided health effects discussed above. The agency prioritized health endpoints with the strongest weight of evidence conclusions and readily available data for monetization, namely cardiovascular effects, developmental effects, and carcinogenic effects. Several other health endpoints that had indicative or suggestive evidence of associations with exposure to PFOA and PFOS have not been selected for the EA:

- While immune effects had indicative evidence of associations with exposure to PFOA and PFOS, the EPA did not identify the necessary information to connect the measured biomarker responses (*i.e.,* decrease in antibodies) to a disease that could be valued in the EA;
- Evidence indicates associations between PFOA and PFOS exposure and hepatic effects, such as increases in ALT. While increased ALT is considered an adverse effect, ALT can be one of several contributors to a variety of diseases, including liver disease, and it is difficult to therefore quantify the relationship between this biomarker and a disease that can be monetized. Similar challenges with the biomarkers representing metabolic effects (*i.e.,* leptin) and musculoskeletal effects (*i.e.,* bone density) prevented economic analysis of these endpoints;
- There is evidence of association between exposure to PFOA and testicular cancer in human and animal studies; however, the available slope factor in rats implied small changes in the risk of this endpoint. Because testicular cancer is rarely fatal and the Value of Statistical Life is the driver of economic benefits evaluated in the EA, the benefit of decreased testicular cancer expected with this rule was smaller in comparison and not quantified;
- There is evidence of association between exposure to PFOS and hepatic carcinogenicity in human and animal studies. The EPA quantified benefits associated with reduced liver cancer cases and deaths as part of a sensitivity analysis for the final rule in response to public comments received on the proposed rule requesting that the EPA quantify additional health benefits (see appendix O of the EA (USEPA, 2024e));
- Finally, other health endpoints, such as SGA and LDLC effects, were not modeled in the EA because they overlap with effects that the EPA did model. More specifically, SGA infants are often born with decreased birth weight or

receive similar care to infants born with decreased birth weight. LDLC is a component of TC and could not be modeled separately as the EPA used TC as an input to the ASCVD model to estimate CVD outcomes.

H. Nonquantifiable Benefits of Removal of PFAS Included in the Final Regulation and Co-Removed PFAS

The EPA also qualitatively summarized the potential health benefits resulting from reduced exposure to PFAS other than PFOA and PFOS in drinking water. The final rule and all regulatory alternatives are expected to result in additional benefits that have not been quantified. The final rule will reduce exposure to PFHxS, HFPO–DA, and PFNA to below their individual MCLs. It will also reduce exposure to PFBS to below the Hazard Index MCLG and MCL of 1 when the mixture contains two or more of PFHxS, PFNA, HFPO–DA, and PFBS. Benefits from avoided cases of the adverse health effects discussed in this section are expected from the final rule due to co-occurrence of these contaminants in source waters containing PFOA and/or PFOS, as described in the *Per- and Polyfluoroalkyl Substances (PFAS) Occurrence & Contaminant Background Support Document* (USEPA, 2024b) and part VI of this preamble. In addition, PFAS, including PFHxS, PFNA, HFPO–DA, and PFBS and their mixtures affect common target organs, tissues, or systems to produce dose-additive effects from their co-exposures with each other, as well as PFOA and PFOS (USEPA, 2024a). The EPA expects that compliance actions taken under the final rule will remove additional unregulated co-occurring PFAS contaminants where present because the best available technologies have been demonstrated to co-remove additional PFAS. Treatment responses implemented to reduce PFOA and PFOS exposure under the final rule and Options 1a–c are likely to remove some amount of additional PFAS contaminants where they co-occur.

Ion exchange (IX) and granulated activated carbon (GAC) are effective at removing PFAS; there is generally a linear relationship between PFAS chain length and removal efficiency, shifted by functional group (McCleaf et al., 2017; Sörengård, 2020). Perfluoroalkyl sulfonates (PFSAs), such as PFOS, are removed with greater efficiency than corresponding perfluoroalkyl carboxylates (PFCAs), such as PFOA, of the same carbon backbone length (Appleman et al., 2014; Du et al., 2014; Eschauzier et al., 2012; Ochoa-Herrera and Sierra-Alvarez, 2008; Zaggia et al., 2016). Generally, for a given water type and concentration, PFSAs are removed approximately as effectively as PFCAs, which have two additional fully perfluorinated carbons in the carbon backbone. For example, PFHxS (*i.e.,* sulfonic acid with a six-carbon backbone) is removed approximately as well as PFOA (*i.e.,* carboxylic acid with an eight-carbon backbone) and PFHxA (*i.e.,* carboxylic acid with a six-carbon backbone) is removed approximately as well as PFBS (*i.e.,* sulfonic acid with a four-carbon backbone). Further, PFAS compounds with longer carbon chains display lower percentage decreases in average removal efficiency over time (McCleaf et al., 2017).

In cases where the six PFAS included in the final rule occur at concentrations above their respective regulatory standards, there is also an increased probability of co-occurrence of additional unregulated PFAS. Further, as the same technologies also remove other long-chain and higher carbon/higher molecular weight PFAS, the EPA expects that treatment will provide additional public health protection and benefits due to co-removal of unregulated PFAS that may have adverse health effects. While the EPA has not quantified these additional benefits, the agency expects that these important co-removal benefits will further enhance public health protection.

The EPA identified a wide range of potential health effects associated with exposure to PFAS other than PFOA and PFOS using documents that summarize the recent literature on exposure and associated health impacts: the ATSDR's *Toxicological Profile for Perfluoroalkyls* (ATSDR, 2021); the EPA's toxicity assessment of HFPO–DA (USEPA, 2021b); publicly available IRIS assessments for PFBA and PFHxA (USEPA, 2022g; USEPA, 2023p); the EPA's toxicity assessment of PFBS (USEPA, 2021a); and the recent National Academies of Sciences, Engineering, and Medicine *Guidance on PFAS Exposure, Testing, and Clinical Follow-up* (NASEM, 2022). Note that the determinations of associations between PFAS and associated health effects are based on information available as of September 2023.

Developmental effects: Toxicology and/or epidemiology studies observed evidence of associations between birth weight and/or other developmental effects and exposure to PFBA, PFDA, PFHxS, PFHxA, PFNA, HFPO–DA, PFUnA, and PFBS. Specifically, data from toxicology studies support this association for PFBS, PFBA, PFHxA, and HFPO–DA, while both toxicology and epidemiology studies support this association for PFHxS, PFDA, PFUnA, and PFNA (ATSDR, 2021; USEPA, 2021b; USEPA, 2022g; USEPA, 2023e; Wright et al., 2023). In general, epidemiological studies did not find associations between exposure and adverse pregnancy outcomes (miscarriage, preterm birth, or gestational age) for PFNA, PFUnA and PFHxS (ATSDR, 2021; NASEM, 2022). Epidemiological studies support an association between PFNA, PFHxS or PFDA exposure and developmental effects such as decreases in infant birth weight and birth length, small for gestational age and increased risk of low birth weight (Valvi et al., 2017; Bach et al., 2016; Louis et al., 2018; Wright et al., 2023; Manzano-Salgado et al., 2017; Starling et al., 2017). Few epidemiologic studies also indicate that PFDA exposure is associated with developmental effects (Wikström et al., 2020; Valvi et al., 2017; Luo et al., 2021; Yao et al., 2021). The EPA has determined that evidence indicates that exposure to PFBA or PFHxA likely causes developmental effects, based on moderate evidence from animal studies and indeterminate evidence from human studies (USEPA, 2022g; USEPA, 2023p).

Cardiovascular effects: Epidemiology and/or toxicology studies observed evidence of associations between PFNA, PFDA, and PFHxS exposures and effects on total cholesterol, LDLC, and HDLC. Epidemiological studies report consistent associations between PFHxS and total cholesterol in adults (Cakmak et al., 2022; Dunder et al., 2022; Canova et al., 2020; Lin et al., 2019; Liu et al., 2020; Fisher et al., 2013).

In an analysis based on studies published before 2018, evidence for associations between PFNA exposure and serum lipid levels in epidemiology studies was mixed; associations have been observed between serum PFNA levels and total cholesterol in general populations of adults but not in pregnant women, and evidence in children is inconsistent (ATSDR, 2021). Most epidemiology studies did not observe associations between PFNA and LDLC or HDLC. Epidemiological studies report consistent associations between PFDA and effects on total cholesterol in adults (Cakmak et al., 2022; Dunder et al, 2022; Liu et al., 2020; Dong et al., 2019). Positive associations between PFDA and other serum lipids, adiposity, cardiovascular disease, and atherosclerosis were observed in some epidemiology studies, but findings were inconsistent (Huang et al., 2018; Mattsson et al., 2015; Christensen et al., 2016). A single animal study observed

decreases in cholesterol and triglyceride levels in rats at PFDA doses above 1.25 mg/kg/d for 28 days (NTP, 2018b). There was no association between PFBA and serum lipids in a single epidemiology study and no animal studies on PFBA evaluated cardiovascular endpoints (USEPA, 2022g).

Other PFAS for which lipid outcomes were examined in toxicology or epidemiology studies showed limited to no evidence of associations. Studies have examined possible associations between various PFAS and blood pressure in humans or heart histopathology in animals. Epidemiological studies report positive associations between PFHxS and hypertension in adolescents and young adults (Averina et al., 2021; Li et al., 2021; Pitter et al., 2020), but not in other adults (Lin et al., 2020; Chen et al., 2019; Christensen et al., 2018; Liu et al., 2018; Bao et al., 2017; Christensen et al., 2016) or children (Papadopoulou et al., 2021; Khalil et al., 2018; Manzano-Salgado et al., 2017). No evidence was observed of associations between PFHxS and cardiovascular diseases (Huang et al., 2018; Mattsson et al., 2015). Overall, studies did not find likely evidence of cardiovascular effects for other PFAS except for PFOA and PFOS (USEPA, 2024c; USEPA, 2024d).

Hepatic effects: Toxicology and/or epidemiology studies have reported associations between exposure to PFAS (PFBA, PFDA, PFUnA, PFDoDA, PFHxA, PFHxS, HFPO–DA, and PFBS) and hepatotoxicity. The results of the animal toxicology studies provide strong evidence that the liver is a sensitive target of PFHxS, PFNA, PFDA, PFUnA, PFBS, PFBA, PFDoDA, HFPO–DA and PFHxA toxicity. Observed effects in rodents include increases in liver weight, hepatocellular hypertrophy, hyperplasia, and necrosis (ATSDR, 2021; USEPA, 2021b; USEPA, 2022g; USEPA, 2023p). Increases in serum enzymes (such as ALT) and decreases in serum bilirubin were observed in several epidemiological studies of PFNA and PFDA (Nian et al., 2019; Jain and Ducatman, 2019; Liu et al., 2022; Cakmak et al., 2022). Associations between exposure to PFHxS and effects on serum hepatic enzymes are less consistent (Cakmak et al., 2022; Liu et al., 2022; Jain and Ducatman, 2019; Salihovic et al., 2018; Gleason et al., 2015). Mixed effects were observed for serum liver enzymes in epidemiological studies for PFNA (ATSDR, 2021).

Immune effects: Epidemiology studies have reported evidence of associations between PFDA or PFHxS exposure and antibody response to tetanus or diphtheria (Grandjean et al., 2012; Grandjean et al., 2017a; Grandjean et al., 2017b; Budtz-Jørgensen and Grandjean, 2018). There is also some limited evidence for decreased antibody response for PFNA, PFUnA, and PFDoDA, although there were notable inconsistencies across studies examining associations for these compounds (ATSDR, 2021). There is limited evidence for associations between PFHxS, PFNA, PFDA, PFBS, and PFDoDA and increased risk of asthma due to the small number of studies evaluating the outcome and/or inconsistent study results (ATSDR, 2021). The small number of studies investigating immunotoxicity in humans following exposure to PFHpA and PFHxA did not find associations (ATSDR, 2021; USEPA, 2023p; NASEM, 2022). Toxicology studies have reported evidence of associations between HFPO–DA exposure and effects on various immune-related endpoints in animals (ATSDR, 2021; USEPA, 2021b). No laboratory animal studies were identified for PFUnA, PFHpA, PFDoDA, or FOSA. A small number of toxicology studies evaluated the immunotoxicity of other perfluoroalkyls and most did not evaluate immune function. No alterations in spleen or thymus organ weights or morphology were observed in studies on PFHxS and PFBA. A study on PFNA found decreases in spleen and thymus weights and alterations in splenic lymphocyte phenotypes (ATSDR, 2021). Changes in spleen and thymus weights were reported in female mice and male/female rats in two 28-day gavage studies of PFDA, although the direction and dose-dependency of these changes in rats was inconsistent across studies (Frawley et al., 2018; NTP, 2018b).

COVID–19: A cross-sectional study in Denmark (Grandjean et al., 2020) showed that PFBA exposure was associated with increasing severity of COVID–19, with an OR of 1.77 (95% CI: 1.09, 2.87) after adjustment for age, sex, sampling site, and interval between blood sampling and diagnosis. A case-control study showed increased risk of COVID–19 infection with high urinary PFAS (including PFOA, PFOS, PFHxA, PFHpA, PFHxS, PFNA, PFBS, PFDA, PFUnA, PFDoA, PFTrDA, PFTeDA) levels (Ji et al., 2021). Adjusted odds ratios were 1.94 (95% CI: 1.39, 2.96) for PFOS, 2.73 (95% CI: 1.71, 4.55) for PFOA, and 2.82 (95% CI: 1.97–3.51) for total PFAS (sum of 12 PFAS), while other PFAS were not significantly associated with COVID–19 susceptibility after adjusting for confounders. In a spatial ecological analysis, Catelan et al. (2021) showed higher mortality risk for COVID–19 in a population heavily exposed to PFAS (including PFOA, PFOS, PFHxS, PFBS, PFBA, PFPeA, PFHxA, and PFHpA) via drinking water. Overall, results suggested a general immunosuppressive effect of PFAS and/or increased COVID–19 respiratory toxicity due to a concentration of PFBA in the lungs. Although these studies provide a suggestion of possible associations, the body of evidence does not permit conclusions about the relationship between COVID–19 infection, severity, or mortality, and exposures to PFAS.

In addition to the adverse health effects listed above, there was little or no evidence that exposure to the various PFAS is associated with the additional health effects summarized in this section.

Endocrine effects: Epidemiology studies have observed associations between serum PFHxS, PFNA, PFDA, and PFUnA and effects on thyroid stimulating hormone (TSH), triiodothyronine (T3), or thyroxine (T4) levels in serum or thyroid disease; however, there are notable inconsistencies across the studies identified in the available reports (ATSDR, 2021; NASEM, 2022). Toxicology studies have reported consistent associations between exposure to PFHxS, PFBA, PFHxA, and PFBS and effects on thyroid hormones, thyroid organ weight, and thyroid histopathology in animals; the endocrine system was a notable target of PFBS and PFHxS toxicity (ATSDR, 2021; USEPA, 2021a; USEPA, 2022g; USEPA, 2023p; NTP, 2018b; Ramhøj et al., 2018; Ramhøj et al., 2020; Butenhoff et al., 2009).

Metabolic effects: Epidemiology and toxicology studies have examined possible associations between various PFAS and metabolic effects, including leptin, body weight, or body fat in humans or animals (ATSDR, 2021). Exposure to PFDA has been associated with an increase in adiposity in adults (Blake et al., 2018; Christensen et al., 2018; Liu et al., 2018). However, evidence of associations was not suggestive or likely for any PFAS in this summary except for PFOA and PFOS (USEPA, 2024c; USEPA, 2024d). Evidence for changes such as maternal body weight gain, pup body weight, or other developmentally focused weight outcomes is strong but is considered under the Developmental effects category (ATSDR, 2021; NASEM, 2022).

Renal effects: A small number of epidemiology studies with inconsistent results evaluated possible associations

between PFHxS, PFNA, PFDA, PFBS, PFDoDA, or PFHxA and renal functions (including estimated glomerular filtration rate and increases in uric acid levels) (ATSDR, 2021; NASEM 2022; USEPA, 2023p). Toxicology studies have not observed impaired renal function or morphological damage following exposure to PFHxS, PFDA, PFUnA, PFBS, PFBA, PFDoDA, or PFHxA (ATSDR, 2021). Associations with kidney weight in animals were observed for PFBS and HFPO–DA and was a notable target for PFBS toxicity (ATSDR, 2021; USEPA, 2021a; USEPA, 2021b; USEPA, 2023p).

Reproductive effects: A small number of epidemiology studies with inconsistent results evaluated possible associations between reproductive hormone levels and PFHxS, PFNA, PFDA, PFUnA, PFDoDA, or PFHxA. Some associations between PFAS (PFHxS, PFHxA, PFNA, PFDA) exposures and sperm parameters have been observed, but often only one sperm parameter was altered. While there is suggestive evidence of an association between PFHxS or PFNA exposure and an increased risk of early menopause, this may be due to reverse causation since an earlier onset of menopause would result in a decrease in the removal of PFAS in menstrual blood. Epidemiological studies provide mixed evidence of impaired fertility (increased risks of longer time to pregnancy and infertility), with some evidence for PFHxS, PFNA, PFHpA, and PFBS but the results are inconsistent across studies or were only based on one study (ATSDR, 2021; Bach et al., 2018; Vélez et al., 2015). Toxicology studies have evaluated the potential histological alterations in reproductive tissues, alterations in reproductive hormones, and impaired reproductive functions. No effect on fertility was observed for PFBS and PFDoDA, and no histological alterations were observed for PFBS and PFBA. One study found alterations in sperm parameters and decreases in fertility in mice exposed to PFNA, and one study for PFDoDA observed ultrastructural alterations in the testes (ATSDR, 2021). Decreased uterine weights, changes in hormone levels, and increased time spent in diestrus were observed in studies of PFDA or PFHxS exposures (NTP, 2018b; Yin et al., 2021).

Musculoskeletal effects: Epidemiology studies observed evidence of associations between PFNA and PFHxS and musculoskeletal effects including osteoarthritis and bone mineral density, but data are limited to two studies (ATSDR, 2021; Khalil et al., 2016; Khalil et al., 2018). Toxicology studies reported no morphological alterations in bone or skeletal muscle in animals exposed to PFBA, PFDA, PFHxA, PFHxS, or PFBS, but evidence is based on a very small number of studies (NTP, 2018b; ATSDR, 2021; USEPA, 2022g; USEPA, 2023p).

Hematological effects: A single uninformative epidemiological study reported on blood counts in pregnant women exposed to PFHxA (USEPA, 2023p). Epidemiological data were not identified for the other PFAS (ATSDR, 2021). A limited number of toxicology studies observed alterations in hematological indices following exposure to relatively high doses of PFHxS, PFDA, PFUnA, PFBS, PFBA, or PFDoDA (ATSDR, 2021; USEPA, 2022g; NTP, 2018b; 3M Company, 2000; Frawley et al., 2018). Toxicology studies observed robust evidence of association between PFHxA or HFPO–DA exposure and hematological effects, including decreases in red blood cell (RBC) number, hemoglobin, and percentage of RBCs in the blood (USEPA, 2021b; USEPA, 2023p). A small number of toxicology studies observed slight evidence of associations between exposure to PFHxS, PFDA, or PFBA and decreases in multiple red blood cell parameters and in prothrombin time; however, effects were not consistent (USEPA, 2022g; Butenhoff et al., 2009).

Other non-cancer effects: A limited number of epidemiology and toxicology studies have examined possible associations between various PFAS and dermal, ocular, and other non-cancer effects. However, the evidence does not support associations for any PFAS in this summary except for PFOA and PFOS (ATSDR, 2021; USEPA, 2021a; USEPA, 2023p).

Cancer effects: A small number of epidemiology studies reported limited associations between multiple PFAS (*i.e.,* PFHxS, PFDA, PFUnA, and FOSA) and cancer effects. No consistent associations were observed for breast cancer risk for PFHxS, PFHxA, PFNA, PFHpA, or PFDoDA; increased breast cancer risks were observed for PFDA and FOSA, but this was based on a single study (Bonefeld-Jørgensen et al., 2014), and one study observed non-significant increased risk for breast cancer risk and PFDA (Tsai et al., 2020). Exposure to PFHxS was associated with increased breast cancer risk in one study and with decreased breast cancer risk in two related studies (Bonefeld-Jørgensen et al., 2014; Ghisari et al., 2017; Tsai et al., 2020). No associations between exposure to PFHxS, PFNA, PFDA, or PFUnA and prostate cancer risk were observed. However, among men with a first-degree relative with prostate cancer, associations were observed for PFHxS, PFDA (Hardell et al., 2014), and PFUnA, but not for PFNA (ATSDR, 2021; USEPA, 2022g; USEPA, 2023p). A decreased risk of thyroid cancer was associated with exposure to PFHxS and PFDA in a single study (Liu et al., 2021). Epidemiological studies examining potential cancer effects were not identified for PFBS or PFBA (ATSDR, 2021; USEPA 2022g). No animal studies examined carcinogenicity of PFHxS or PFBA. Aside from a study that suggested an increased incidence of liver tumors in rats exposed to high doses of HFPO–DA, the limited number of available toxicology studies reported no evidence of associations between exposure to other PFAS (*i.e.,* PFDA and PFHxA) and risk of cancer (ATSDR, 2021; USEPA, 2021b; USEPA, 2023p). At this time, there is inadequate information to assess carcinogenic potential for PFAS other than PFOA, PFOS, and HFPO–DA.

I. Benefits Resulting From Disinfection By-Product Co-Removal

As part of its HRRCA, the EPA is directed by SDWA to evaluate quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL (SDWA 1412(b)(3)(C)(II)). These co-occurring contaminants are expected to include additional PFAS contaminants not directly regulated by the final PFAS NPDWR, co-occurring chemical contaminants such as SOCs, VOCs, and DBP precursors. In this section, the EPA presents a quantified estimate of the reductions in DBP formation potential that are likely to occur as a result of compliance with the final PFAS NPDWR. The methodology detailed here and in section 6.7.1 of USEPA (2024g) to estimate DBP reductions was externally peer reviewed by three experts in GAC treatment for PFAS removal and DBP formation potential (USEPA, 2023m). The external peer reviewers supported the EPA's approach and edits based on their recommendations for clarity and completeness are reflected in the following analysis and discussion.

DBPs are formed when disinfectants react with naturally occurring materials in water. There is a substantial body of literature on DBP precursor occurrence and THM4 formation mechanisms in drinking water treatment. Under the Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBP Rule, USEPA, 2006a), the EPA regulates 11

individual DBPs from three subgroups: THM4, HAA5, and two inorganic compounds (bromate and chlorite). The formation of THM4 in a particular drinking water treatment plant is a function of several factors including disinfectant type, disinfectant dose, bromide concentration, organic material type and concentration, temperature, pH, and system residence times. Epidemiology studies have shown that THM4 exposure, a surrogate for chlorinated drinking water, is associated with an increased risk of bladder cancer, among other diseases (Cantor et al., 1998; Cantor et al., 2010; Costet et al., 2011; Beane Freeman et al., 2017; King and Marrett, 1996; Regli et al., 2015; USEPA, 2019d; Villanueva et al., 2004; Villanueva et al., 2006; Villanueva et al., 2007). These studies considered THM4 as surrogate measures for DBPs formed from the use of chlorination that may co-occur. The relationships between exposure to DBPs, specifically THM4 and other halogenated compounds resulting from water chlorination, and bladder cancer are further discussed in section 6.7 of USEPA (2024g). Reductions in exposure to THM4 is expected to yield public health benefits, including a decrease in bladder cancer incidence (Regli et al., 2015). Among other things, Weisman et al. (2022) found that there is even a stronger weight of evidence linking DBPs and bladder cancer since the promulgation of the 2006 Stage 2 DBP regulations (USEPA, 2006a) and publication of Regli et al. (2015). While not the regulated contaminant for this rulemaking, the expected reduction of DBP precursors and subsequent DBPs that result from this rulemaking are anticipated to reduce cancer risk in the U.S. population.

GAC adsorption has been used to remove SOCs, taste and odor compounds, and natural organic matter (NOM) during drinking water treatment (Chowdhury et al., 2013). Recently, many water utilities have installed or are considering installing GAC and/or other advanced technologies as a protective or mitigation measure to remove various contaminants of emerging concern, such as PFAS (Dickenson and Higgins, 2016). Because NOM often exists in a much higher concentration (in mg/L) than trace organics (in µg/L or ng/L) in water, NOM, often measured as TOC, can interfere with the adsorption of trace organics by outcompeting the contaminants for adsorption sites and by general fouling (blockage of adsorption pores) of the GAC.

NOM and inorganic matter are precursors for the formation of THMs and other DBPs when water is disinfected using chlorine and other disinfectants to control microbial contaminants in finished drinking water. Removal of DBP precursors through adsorption onto GAC has been included as a treatment technology for compliance with the existing DBP Rules and is a BAT for the Stage 2 DBP Rule. Dissolved organic matter (DOM) can be removed by GAC through adsorption and biodegradation (Crittenden et al., 1993; Kim et al., 1997; Yapsakli et al., 2010). GAC is well-established for removal of THM and HAA precursors (Cheng et al., 2005; Dastgheib et al., 2004; Iriarte-Velasco et al., 2008; Summers et al., 2013; Cuthbertson et al., 2019; Wang et al., 2019). In addition to removal of organic DBPs, GAC also exhibits some capacity for removal of inorganic DBPs such as bromate and chlorite (Kirisits et al., 2000; Sorlini et al., 2005) and removal of preformed organic DBPs via adsorption and biodegradation (Jiang et al., 2017; Terry and Summers, 2018). Further, GAC may offer limited removal of dissolved organic nitrogen (Chili et al., 2012).

Based on an extensive review of published literature in sampling studies where both contaminant groups (PFAS and DBPs) were sampled, there is limited information about PFAS removal and co-occurring reductions in DBPs, specifically THMs. To help inform its EA, the EPA relied on the DBP Information Collection Rule Treatment Study Database and DBP formation studies to estimate reductions in THM4 (ΔTHM4) that may occur when GAC is used to remove PFAS. Subsequently, these results were compared to THM4 data from PWSs that have detected PFAS and have indicated use of GAC.

The objective of the EPA's co-removal benefits analysis is to determine the reduction in bladder cancer cases associated with the decrease of regulated THM4 in treatment plants due to the installation of GAC for PFAS removal. Evaluation of the expected reductions in bladder cancer risk resulting from treatment of PFAS in drinking water involves five steps:

1. Estimating the number of systems expected to install GAC treatment in compliance with the final PFAS NPDWR and affected population size;

2. Estimating changes in THM4 levels that may occur when GAC is installed for PFAS removal based on influent TOC levels;

3. Estimating changes in the cumulative risk of bladder cancer using an exposure-response function linking lifetime risk of bladder cancer to THM4 concentrations in residential water supply (Regli et al., 2015);

4. Estimating annual changes in the number of bladder cancer cases and excess mortality in the bladder cancer population corresponding to changes in THM4 levels under the regulatory alternative in all populations alive during or born after the start of the evaluation period; and

5. Estimating the economic value of reducing bladder cancer morbidity and mortality from baseline to regulatory alternative levels, using COI measures and the Value of a Statistical Life, respectively.

The EPA expects PWSs that exceed the PFAS MCLs to consider both treatment and nontreatment options to achieve compliance with the drinking water standard. The EPA assumes that the populations served by systems with EP expected to install GAC based on the compliance forecast detailed in section 5.3 of USEPA (2024g) will receive the DBP exposure reduction benefits. The EPA notes that other compliance actions included in the compliance forecast could result in DBP exposure reductions, including installation of RO. However, these compliance actions are not included in the DBP benefits analysis because this DBP exposure reduction function is specific to GAC. Switching water sources may or may not result in DBP exposure reductions, therefore the EPA assumed no additional DBP benefits for an estimated percentage of systems that elect this compliance option. Lastly, the EPA assumed no change in DBP exposure at water systems that install IX, as that treatment technology is not expected to remove a substantial amount of DBP precursors. The EPA also assumed that the PWSs included in this analysis use chlorine only for disinfection and have conventional treatment in place prior to GAC installation.

The EPA used the relationship between median raw water TOC levels and changes in THM4 levels estimated in the 1998 DBP Information Collection Rule to estimate changes in THM4 concentrations in the finished water of PWSs fitted with GAC treatment. For more detail on the approach the EPA used to apply changes in THM4 levels to PWSs treating for PFAS under the final rule, please see section 6.7 of USEPA (2024g).

The EPA models a scenario where reduced exposures to THM4 begin in 2029. Therefore, the EPA assumed that the population affected by reduced THM4 levels resulting from implementation of GAC treatment is exposed to baseline THM4 levels prior to actions to comply with the rule (*i.e.,*

prior to 2029) and to reduced THM4 levels from 2029 through 2105. Rather than modeling individual locations (*e.g.,* PWS), the EPA evaluates changes in bladder cancer cases among the aggregate population per treatment scenario and source water type that is expected to install GAC treatment to reduce PFAS levels. Because of this aggregate modeling approach, the EPA used national-level population estimates to distribute the SDWIS populations based on single-year age and sex and to extrapolate the age- and sex-specific populations to future years. Appendix B of USEPA (2024g) provides additional details on estimation of the affected population.

Regli et al. (2015) analyzed the potential lifetime bladder cancer risks associated with increased bromide levels in surface source water resulting in increased THM4 levels in finished water. To account for variable levels of uncertainty across the range of THM4 exposures from the pooled analysis of Villanueva et al. (2004), they derived a weighted mean slope factor from the odds ratios reported in Villanueva et al. (2004). They showed that, while the original analysis deviated from linearity, particularly at low concentrations, the overall pooled exposure-response relationship for THM4 could be well-approximated by a linear slope factor that predicted an incremental lifetime cancer risk of 1 in 10,000 exposed individuals (10^{-4}) per 1 µg/L increase in THM4. The linear slope factor developed by Regli et al. (2015) enables estimation of the changes in the lifetime bladder cancer risk associated with lifetime exposures to reduced THM4 levels. Weisman et al. (2022) applied the dose-response information from Regli et al. (2015) and developed a robust, national-level risk assessment of DBP impacts, where the authors estimated that approximately 8,000 of 79,000 annual U.S. bladder cancer cases are attributable to chlorination DBPs, specifically associated with THM4 concentrations.

The EPA estimated changes in annual bladder cancer cases and annual excess mortality in the bladder cancer population due to estimated reductions in lifetime THM4 exposure using a life table-based approach. This approach was used because (1) annual risk of new bladder cancer should be quantified only among those not already experiencing this chronic condition, and (2) bladder cancer has elevated mortality implications.

The EPA used recurrent life table calculations to estimate a water source type-specific time series of bladder cancer incidence for a population cohort characterized by sex, birth year, and age at the beginning of the PFOA/PFOS evaluation period under the baseline scenario and the GAC regulatory alternative. The estimated risk reduction from lower exposure to DBPs in drinking water was calculated based on changes in THM4 levels used as inputs to the Regli et al. (2015)-based health impact function, described in more detail in section 6.7 of USEPA (2024g). The life table analysis accounts for the gradual changes in lifetime exposures to THM4 following implementation of GAC treatment under the regulatory alternative compared to the baseline. The outputs of the life table calculations are the water source type-specific estimates of the annual change in the number of bladder cancer cases and the annual change in excess bladder cancer population mortality.

The EPA used the Value of a Statistical Life to estimate the benefits of reducing mortality associated with bladder cancer in the affected population. The EPA used the cost of illness-based valuation to estimate the benefits of reducing morbidity associated with bladder cancer. Specifically, the EPA used bladder cancer treatment-related medical care and opportunity cost estimates from Greco et al. (2019). Table 63 shows the original cost of illness estimates from Greco et al. (2019), along with the values updated to $2022 used in this analysis.

The EPA received public comments on the EA for the proposed rule related to the EPA's use of cost of illness information for morbidity valuation. Specifically, a couple of commenters recommended that the EPA use willingness to pay information (instead of cost of illness information) when valuing the costs associated with non-fatal illnesses, stating that willingness to pay information better accounts for lost opportunity costs (*e.g.,* lost productivity and pain and suffering) associated with non-fatal illnesses (USEPA, 2024k). To better account for these opportunity costs, the EPA used recently available willingness to pay values in a sensitivity analysis for morbidity associated with bladder cancer. The sensitivity analysis results show that when willingness to pay values are used in bladder cancer benefits analysis, morbidity benefits are increased by approximately 19.9 percent. See appendix O of the EA for full details and results on the willingness to pay sensitivity analyses.

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Table 63: Bladder Cancer Morbidity Valuation

Bladder Cancer Subtype[a]	Type of Cost	Cost in First Year ($2010)[b]	Cost in Subsequent Years ($2010)[b]	Cost in First Year ($2022)[c]	Cost in Subsequent Years ($2022)[c]
Non-invasive	Medical care	9,133	916	$12,851	$1,289
	Opportunity cost	4,572	24	$6,212	$33
	Total cost	13,705	941	$19,062	$1,321
Invasive	Medical care	26,951	2,455	$37,922	$3,454
	Opportunity cost	10,513	77	$14,283	$105
	Total cost	37,463	2,532	$52,205	$3,559

Notes:

[a]The estimates for non-invasive bladder cancer subtype were used to value local, regional, and unstaged bladder cancer morbidity reductions, while the estimates for the invasive bladder cancer subtype were used to value distant bladder cancer morbidity reductions.

[b]The estimates come from Greco et al. (2019).

[c]To adjust for inflation, the EPA used U.S. Bureau of Labor Statistics Consumer Price Index for All Urban Consumers: Medical Care Services in U.S. (City Average).

Tables 64 to 67 presents the estimated changes in non-fatal bladder cancer cases and bladder cancer-related deaths from exposure to THM4 due to implementation of GAC treatment by option. The EPA estimated that, over the evaluation period, the final rule will result in annualized benefits from avoided bladder cancer cases and deaths of $380 million.

Table 64: National Bladder Cancer Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L, each and Hazard Index of 1) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal Bladder Cancer Cases Avoided	5,781.0	7,313.0	8,912.7
Number of Bladder Cancer-Related Deaths Avoided	2,029.6	2,567.8	3,129.9
Total Annualized Bladder Cancer Benefits (Million $2022) [2, 3]	$300.64	$380.41	$463.74

Notes: Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized annualized benefits in this table.

[3] When using willingness-to-pay metrics to monetize morbidity benefits, total annualized bladder cancer benefits are increased by $75.87 million.

Table 65: National Bladder Cancer Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile[1]**
Number of Non-Fatal Bladder Cancer Cases Avoided	5,789.3	7,312.9	8,896.0
Number of Bladder Cancer-Related Deaths Avoided	2,032.5	2,567.8	3,123.2
Total Annualized Bladder Cancer Benefits (Million $2022)[2]	$301.06	$380.41	$462.73

Notes:

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized annualized benefits in this table.

Table 66: National Bladder Cancer Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L) (Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile[1]**
Number of Non-Fatal Bladder Cancer Cases Avoided	4,739.4	6,034.0	7,367.1
Number of Bladder Cancer-Related Deaths Avoided	1,664.0	2,118.7	2,587.1
Total Annualized Bladder Cancer Benefits (Million $2022) [2]	$246.48	$313.88	$383.32

Notes:

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized annualized benefits in this table.

Table 67: National Bladder Cancer Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal Bladder Cancer Cases Avoided	2,326.9	3,087.9	3,885.3
Number of Bladder Cancer-Related Deaths Avoided	816.8	1,084.3	1,364.3
Total Annualized Bladder Cancer Benefits (Million $2022) [2]	$120.97	$160.62	$202.14

Notes:

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized annualized benefits in this table.

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J. Comparison of Costs and Benefits

This section provides a comparison of the incremental costs and benefits of the final rule, as described in chapter 7 of the EA. Included here are estimates of total quantified annualized costs and benefits for the final rule and regulatory alternative MCLs under options 1a-1c, as well as considerations for the nonquantifiable costs and benefits. The EPA's determinations as to whether the costs are justified by the benefits must be based on an analysis of both the quantified costs and benefits as well as the nonquantifiable benefits and nonquantifiable costs, per SDWA 1412(b)(3)(C)(I)–(III).

The incremental cost is the difference between quantified costs that will be incurred if the final rule is enacted over current baseline conditions. Incremental benefits reflect the avoided future adverse health outcomes attributable to PFAS reductions and co-removal of additional contaminants due to actions undertaken to comply with the final rule.

Table 68 provides the incremental quantified costs and benefits of the final rule at a 2 percent discount rate in 2022 dollars. The top row shows total monetized annualized costs including total PWS costs and primacy agency costs. The second row shows total monetized annualized benefits including all endpoints that could be quantified and valued. For both, the estimates are the expected (mean) values and the 5th percentile and 95th percentile quantified estimates from the uncertainty distribution. These percentile estimates come from the distributions of annualized costs and annualized benefits generated by the 4,000 iterations of SafeWater MCBC. Therefore, these distributions reflect the joint effect of the multiple sources of variability and uncertainty for quantified costs, quantified benefits, and the baseline uncertainties such as PFAS occurrence, as detailed in sections 5.1.2, 6.1.2, and chapter 4 of the EA, respectively (USEPA, 2024g). For further discussion of the quantified uncertainties in the EA, see section XII.K of this preamble.

The third row shows net quantified benefits (benefits minus costs). The net annual quantified incremental benefits are $760,000. Because of the variation associated with the use of statistical models such as SafeWater MCBC, the modeled quantified net benefits are nearly at parity. The uncertainty range for net benefits is a negative $622 million to $725 million. Additional uncertainties are presented in Table 72.

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Table 68: Annualized Quantified National Costs and Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Total Annualized Rule Costs [2,3,4]	$1,435.70	$1,548.64	$1,672.10
Total Annualized Rule Benefits [4]	$920.91	$1,549.40	$2,293.80
Total Net Benefits	-$621.99	$0.76	$725.07

Notes:

Detail may not add exactly to total due to independent rounding. Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.K of this preamble and Tables 74 and 75. This range does not include the uncertainty described in Table 43 for costs and Table 62 for benefits.

[2] The national level cost estimates for PFHxS are reflective of both the total national cost for PFHxS individual MCL exceedances, and Hazard Index MCL exceedances where PFHxS is present above its HBWC while one or more other Hazard Index PFAS is also present in that same mixture. Total quantified national cost values do not include the incremental treatment costs associated with the co-occurrence of PFNA, HFPO-DA, and PFBS. The EPA has considered the additional national costs of the Hazard Index and individual MCLs associated with HFPO-DA, PFBS, and PFNA occurrence in a quantified sensitivity analysis; see appendix N, section 3 of the EA (USEPA, 2024e) for the analysis and more information.

[3] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N, section 2 of the EA (USEPA, 2024e) for additional detail.

[4] See Table 72 for a list of the nonquantifiable benefits and costs, and the potential direction of impact these benefits and costs would have on the estimated monetized total annualized benefits and costs in this table.

Tables 69 to 71 summarize the total annual costs and benefits for options 1a, 1b, and 1c, respectively.

Table 69: Annualized Quantified National Costs and Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Total Annualized Rule Costs [2,3]	$1,423.60	$1,537.07	$1,660.30
Total Annualized Rule Benefits [3]	$913.05	$1,542.74	$2,280.10
Total Net Benefits	-$613.79	$5.67	$722.09

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.K of this preamble and Tables 74 and 75. This range does not include the uncertainty described in Table 43 for costs and Table 62 for benefits.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N, section 2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 for a list of the nonquantifiable benefits and costs, and the potential direction of impact these benefits and costs would have on the estimated monetized total annualized benefits and costs in this table.

Table 70: Annualized Quantified National Costs and Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Total Annualized Rule Costs [2,3]	$1,102.60	$1,192.13	$1,291.40
Total Annualized Rule Benefits [3]	$768.55	$1,296.84	$1,919.30
Total Net Benefits	-$414.34	$104.71	$710.38

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.K of this preamble and Tables 74 and 75. This range does not include the uncertainty described in Table 43 for costs and Table 62 for benefits.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N, section 2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 for a list of the nonquantifiable benefits and costs, and the potential direction of impact these benefits and costs would have on the estimated monetized total annualized benefits and costs in this table.

Table 71: Annualized Quantified National Costs and Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Total Annualized Rule Costs [2,3]	$462.87	$499.29	$540.68
Total Annualized Rule Benefits [3]	$397.28	$664.45	$970.70
Total Net Benefits	-$96.42	$165.16	$468.54

Notes:

Detail may not add exactly to total due to independent rounding.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.K of this preamble and Tables 74 and 75. This range does not include the uncertainty described in Table 43 for costs and Table 62 for benefits.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N, section 2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 for a list of the nonquantifiable benefits and costs, and the potential direction of impact these benefits and costs would have on the estimated monetized total annualized benefits and costs in this table

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The benefit-cost analysis reported dollar figures presented above reflect benefits and costs that could be quantified for each regulatory alternative MCL given the best available scientific data. The EPA notes that these quantified benefits are estimated using a cost-of-illness approach. In the sensitivity analysis, the EPA also calculated quantified benefits using a willingness-to-pay approach instead of cost of illness information, for non-fatal RCC and bladder cancer illnesses. In this case, the estimated expected quantified annualized costs are approximately $1,549 million and the estimated expected quantified annualized benefits increase to approximately $1,632 million, resulting in approximately $84 million in expected annualized net benefits. See appendix O of the EA for further discussion.

The quantified benefit-cost results above are not representative of all benefits and costs anticipated under the final NPDWR. Due to occurrence, health, and economic data limitations, there are several adverse health effects associated with PFAS exposure and costs associated with treatment that the EPA could not estimate quantitatively.

PFAS exposure is associated with a wide range of adverse health effects, including reproductive effects such as decreased fertility; increased high blood pressure in pregnant women; developmental effects or delays in children, including low birth weight, accelerated puberty, bone variations, or behavioral changes; increased risk of some cancers, including prostate, kidney, and testicular cancers; reduced ability of the body's immune system to fight infections, including reduced vaccine response; interference with the body's natural hormones; and increased cholesterol levels and/or risk of obesity. Based on the available data at rule proposal and submitted by public commenters, the EPA is only able to quantify three PFOA- and PFOS-related health endpoints (*i.e.,* changes in birth weight, CVD, and RCC) in the national analysis.

The EPA also evaluated the impacts of PFNA on birth weight and PFOS on liver cancer in quantitative sensitivity analyses (See appendices K and O of USEPA, 2024e, respectively). Those analyses demonstrate that there are potentially significant other quantified benefits not included in the national quantified benefits above: for example, the EPA's quantitative sensitivity analysis for PFNA (found in appendix K of USEPA, 2024e) found that the inclusion of a 1 ng/L PFNA reduction could increase annualized birth weight benefits by a factor of 5.6–7.8 in a model system serving 100,000 people, relative to a scenario that quantified a 1 ng/L reduction in PFOA and a 1 ng/L reduction in PFOS only. In the case of PFOS impacts on liver cancer, the EPA has estimated an expected value of $4.79 million in benefits via the reduction in liver cancer cases anticipated to be realized by the final rule. All regulatory alternatives are

expected to produce substantial additional benefits from all the other adverse health effects avoided, but that cannot be quantified at this time. Treatment responses implemented to remove PFOA and PFOS under regulatory alternative MCLs under options 1a-1c are likely to remove some amount of additional PFAS contaminants where they co-occur. Co-occurrence among PFAS compounds has been observed frequently as discussed in the *PFAS Occurrence & Contaminant Background Support Document* (USEPA, 2024b). The final rule is expected to produce the greatest reduction in exposure to PFAS compounds as compared to the three regulatory alternative MCLs because it includes PFHxS, PFNA, HFPO–DA, and PFBS in the regulation. Inclusion of the Hazard Index will trigger more systems to treat (as shown in section 4.4.4 of the EA) and provides enhanced public health protection by ensuring reductions of these additional compounds when present above the Hazard Index of 1. Specifically, as Hazard Index PFAS are reduced, the EPA anticipates additional public health benefits from avoided cardiovascular, developmental, and immune effects. For further discussion of the quantitative and qualitative benefits associated with the final rule, see section 6.2 of the EA.

The EPA also expects that the final rule will result in additional nonquantifiable costs. As noted above, the Hazard Index and individual MCLs are expected to trigger more systems into more frequent monitoring and treatment. In the national cost analysis, the EPA quantified the national treatment and monitoring costs associated with the PFHxS individual MCL and the Hazard Index associated costs based on PFHxS occurrence only. Due to occurrence data limitations, cost estimates for PFNA, PFBS, and HFPO–DA are less precise relative to those for PFOA, PFOS, and PFHxS compounds, and as such, the EPA performed a quantitative sensitivity analysis of the national cost impacts associated with Hazard Index exceedances resulting from PFNA, PFBS, and HFPO–DA and the PNFA and HFPO–DA individual MCLs to understand and consider the potential magnitude of costs associated with treating these three PFAS. The EPA found that in addition to the costs associated with PFHxS exceedances, which are included in the national cost estimate, the Hazard Index and individual MCLs for PFNA and HFPO–DA could cost an additional $82.4 million per year. In cases where these compounds co-occur at locations where PFAS treatment is implemented because of nationally modeled PFOA, PFOS, and PFHxS occurrence, treatment costs are likely to be marginally higher as treatment media estimated bed-life is shortened. In instances where concentrations of PFNA, HFPO–DA, and PFBS are high enough to cause or contribute to a Hazard Index exceedance when the concentrations of PFOA, PFOS, and PFHxS would not have already otherwise triggered treatment, the national modeled costs may be underestimated. If these PFAS occur in isolation at levels that affect treatment decisions, or if these PFAS occur in combination with PFHxS when PFHxS concentrations were otherwise below its respective HBWC in isolation (*i.e.,* less than 10 ng/L) then the quantified costs underestimate the impacts of the final rule. See appendix N.3 of the EA for a sensitivity analysis of additional treatment costs at systems with Hazard Index exceedances (USEPA, 2024e). See appendix N.4 for a sensitivity analysis of the marginal costs of HFPO–DA and PFNA MCLs. For further discussion of how the EPA considered the costs of the five individual MCLs and the HI MCL, see section XII.A.4 of this preamble.

Commenters suggested that another potential source of non-quantified cost comes from the fact that the EPA has proposed designating PFOA and PFOS as CERCLA hazardous substances (USEPA, 2022l). Stakeholders have expressed concern to the EPA that a hazardous substance designation for certain PFAS may limit their disposal options for drinking water treatment residuals (*e.g.,* spent media, concentrated waste streams) and/or potentially increase costs. The designation of PFOA and PFOS as CERCLA hazardous substances would not require waste (*e.g.,* biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any specific particular type of landfill. The designation also would not restrict, change, or recommend any specific activity or type of waste at landfills. In its estimated national costs, the EPA has maintained the assumption that disposal does not have to occur in accordance with hazardous waste standards thus national costs may be underestimated. The EPA has conducted a sensitivity analysis that assumes hazardous waste disposal at all systems treating for PFAS to assess the potential increase in costs (see appendix N of USEPA, 2024e).

Table 72 provides a summary of the likely impact of nonquantifiable benefit-cost categories. In each case, the EPA notes the potential direction of the impact on costs and/or benefits. For example, benefits are underestimated if the PFOA and PFOS reductions result in avoided adverse health outcomes that cannot be quantified and valued. Sections 5.7 and 6.8 of the EA identify the key methodological limitations and the potential effect on the cost or benefit estimates, respectively. Additionally, Table 73 summarizes benefits and costs that are quantified and nonquantifiable under the final rule.

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Table 72: Potential Impact of Nonquantifiable Benefits (B) and Costs (C)

Source	(Final Rule)	Option 1a	Option 1b	Option 1c
Nonquantifiable PFOA and PFOS health endpoints	B: underestimate	B: underestimate	B: underestimate	B: underestimate
Limitations with available occurrence data for PFNA, HFPO-DA, and PFBS	B+C: underestimate	n/a	n/a	n/a
Nonquantifiable HI (PFHxS, PFNA, HFPO-DA, and PFBS) health endpoints	B: underestimate	n/a	n/a	n/a
Limitations with available occurrence data for additional PFAS compounds	B+C: underestimate	B+C: underestimate	B+C: underestimate	B+C: underestimate
Removal of co-occurring non-PFAS contaminants	B+C: underestimate	B+C: underestimate	B+C: underestimate	B+C: underestimate
POU not in compliance forecast	C: overestimate	C: overestimate	C: overestimate	C: overestimate
Unknown future hazardous waste management requirements for PFAS (including HI)	B+C: underestimate	B+C: underestimate	B+C: underestimate	B+C: underestimate

Table 73: Summary of Quantified and Nonquantifiable Benefits and Costs in the National Analysis

Category	Quantified	Non-quantified	Methods (EA Report Section where Analysis is Detailed)
Costs			
PWS treatment costs [1]	X		Section 5.3.1
PWS sampling costs	X		Section 5.3.2.2
PWS implementation and administration costs	X		Section 5.3.2.1
Primacy agency rule implementation and administration costs	X		Section 5.3.2
Hazardous waste disposal for treatment media		X	Section 5.6
POU not in compliance forecast		X	Section 5.6
Benefits			
PFOA and PFOS birth weight effects	X		Section 6.4
PFOA and PFOS cardiovascular effects	X		Section 6.5
PFOA and PFOS RCC	X		Section 6.6
Health effects associated with DBPs, specifically bladder cancer	X		Section 6.7
Other PFOA and PFOS health effects		X	Section 6.2.2.2
Health effects associated with HI compounds (PFHxS, PFNA, HFPO-DA, PFBS)		X	Section 6.2
Health effects associated with other PFAS		X	Section 6.2

Notes:

1 The national level cost estimates for PFHxS are reflective of both the total national cost for PFHxS individual MCL exceedances, and HI MCL exceedances where PFHxS is present above its HBWC while one or more other HI PFAS is also present in that same mixture. Total quantified national cost values do not include the incremental treatment costs associated with the cooccurrence of HFPO-DA, PFBS, and PFNA. EPA has considered the additional national costs of the HI and individual MCLs associated with HFPO-DA, PFNA, and PFBS occurrence in a quantified sensitivity analysis; see appendix N, section N.3 for the analysis and more information. See appendix N, section N.3 for a sensitivity analysis of additional treatment costs from systems with HI and PFNA and HFPO-DA MCL exceedances. For further discussion of how the EPA considered the costs of the five individual MCLs and the HI MCL, see section XII.A.4 of this preamble.

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Sections XII.B to XII.K of this preamble summarize the results of this final rule analysis. The EPA discounted the estimated monetized cost and benefit values using a 2 percent discount rate, consistent with OMB Circular A–4 (OMB, 2003; OMB, 2023) guidance. The U.S. White House and Office of Management and Budget recently finalized and re-issued the A–4 and A–94 benefit-cost analysis guidance (see OMB Circular A–4, 2023), and the update includes new guidance to use a social discount rate of 2 percent. The updated OMB Circular A–4 states that the discount rate should equal the real (inflation-adjusted) rate of return on long-term U.S. government debt, which provides an approximation of the social rate of time preference. This rate for the past 30 years has averaged around 2.0 percent per year in real terms on a pre-tax basis. OMB arrived at the 2 percent discount rate figure by considering the 30-year average of the yield on 10-year Treasury marketable securities, and the approach taken by OMB produces a real rate of 1.7 percent per year, to which OMB added a 0.3 percent per-year rate to reflect inflation as measured by the personal consumption expenditure (PCE) inflation index. The OMB guidance states that Agencies must begin using the 2 percent discount rate for draft final rules that are formally submitted to OIRA after December 31, 2024. The updated OMB Circular A–4 guidance further states that ''to the extent feasible and appropriate, as determined in consultation with OMB, agencies should follow this Circular's guidance earlier than these effective dates.'' Given the updated default social discount rate prescribed in the OMB Circular A–4 and also public input received on the discount rates considered by the EPA in the proposed NPDWR, for this final rule, the EPA estimated national benefits and costs at the 2 percent discount rate for the final rule and incorporated those results into the final economic analysis. Since the EPA proposed this NPDWR with the 3 and 7 percent discount rates based on guidance in the previous version of OMB Circular A–4, the EPA has kept the presentation of results using these discount rates in appendix P. The Administrator reaffirms his determination that the benefits of the rule justify the costs. The EPA's determination is based on its analysis under in SDWA section 1412(b)(3)(C) of the quantifiable benefits and costs at the 2 percent discount rate, in addition to at the 3 and 7 percent discount rate, as well as the nonquantifiable benefits and costs. The EPA found that significant nonquantifiable benefits are likely to occur from the final PFAS NPDWR.

The quantified analysis is limited in its characterization of uncertainty. In section XII.I, Table 68 of this preamble, the EPA provides 5th and 95th percentile values associated with the 2 percent discounted expected values for net benefits. These values represent the quantified, or modeled, potential range in the expected net benefit values associated with the uncertainty resulting from the following variables; the baseline PFAS occurrence; the affected population size; the compliance technology unit cost curves, which are selected as a function of baseline PFAS concentrations and population size, the distribution of feasible treatment technologies, and the three alternative levels of treatment capital costs; the concentration of TOC in a system's source water (which impacts GAC O&M costs); the demographic composition of the system's population; the magnitude of PFAS concentration reductions; the health effect-serum PFOA and PFOS slope factors that quantify the relationship between changes in PFAS serum level and health outcomes for birth weight, CVD, and RCC; and the cap placed on the cumulative RCC risk reductions due to reductions in serum PFOA. These modeled sources of uncertainty are discussed in more detail in section XII.K of this preamble. While the agency reports only the 5th and 95th percentile values, the EPA notes that additional information can be obtained from looking at the whole uncertainty distribution of annualized net benefits (*i.e.,* the distribution of annualized differences between total monetize benefits and total monetized costs).

The quantified 5th and 95th percentile values do not include a number of factors that impact both costs and benefits but for which the agency did not have sufficient data to include in the quantification of uncertainty. The factors influencing the final rule cost estimates that are not quantified in the uncertainty analysis are detailed in Table 43 of this preamble. These uncertainty sources include: the specific design and operating assumptions used in developing treatment unit cost; the use of national average costs that may differ from the geographic distribution of affected systems; the possible future deviation from the compliance technology forecast; and the degree to which actual TOC source water values differ from the EPA's estimated distribution. The EPA has no information to indicate a directional influence of the estimated costs with regard to these uncertainty sources. To the degree that uncertainty exists across the remaining factors it would most likely influence the estimated 5th and 95th percentile range and not significantly impact the expected value estimate of costs.

Table 62 of this preamble discusses the sources of uncertainty affecting the estimated benefits not captured in the estimated 5th and 95th reported values. The modeled values do not capture the uncertainty in: the exposure that results from daily population changes at NTNCWSs or routine population shifting between PWSs, for example spending working hours at a NTNCWS or CWS and home hours at a different CWS; the exposure-response functions used in the benefits analyses assume that the effects of serum PFOA/PFOS on the health outcomes considered are independent, additive, and that there are no threshold serum concentrations below which effects (cardiovascular, developmental, and renal cell carcinoma) do not occur; the distribution of population by size and demographics across EP within modeled systems and future population size and demographic changes; and the Value of Statistical Life reference value or income elasticity used to update the Value of Statistical Life. Given information available to the agency, four of the listed uncertainty sources would not affect the benefits expected value but the dispersion around that estimate. They are the unmodeled movements of populations between PWSs with potentially differing PFAS concentrations; the independence and additivity assumptions with regard to the effects of serum PFOA/PFOS on the health outcomes; the uncertainty in the population and demographic distributions among EP within individual systems; and the Value of Statistical Life value and the income elasticity measures. Two of the areas of uncertainty not captured in the analysis would tend to indicate that the quantified benefits numbers are overestimates. First, the data available to the EPA with regard to population size at NTNCWSs, while likely capturing peaks in populations utilizing the systems, does not account for the variation in use and population and would tend to overestimate the exposed population. The second source of uncertainty, which definitionally would indicate overestimates in the quantified benefits values, is the assumption that there are no threshold serum concentrations below which health effects (cardiovascular, developmental, and renal cell carcinoma) do not occur. One source of possible underestimation of benefits not accounted for in the

quantified analysis is the impact of general population growth over the extended period of analysis.

In addition to the quantified cost and benefit expected values, the modeled uncertainty associated within the 5th and 95th percentile values, and the un-modeled uncertainty associated with a number of factors listed above, there are also significant nonquantifiable costs and benefits which are important to the overall weighing of costs and benefits. Table 72 provides a summary of these nonquantifiable cost and benefit categories along with an indication of the directional impact each category would have on total costs and benefits. Tables 43 and 62 also provide additional information on a number of these nonquantifiable categories.

For the nonquantifiable costs, the EPA had insufficient nationally representative data to precisely characterize occurrence of HFPO–DA, PFNA, and PFBS at the national level and therefore could not include complete treatment costs associated with: the co-occurrence of these PFAS at systems already required to treat as a result of estimated PFOA, PFOS, or PFHxS levels, which would shorten the filtration media life and therefore increase operation costs; and the occurrence of HFPO–DA, PFNA, and/or PFBS at levels high enough to cause systems to exceed the individual MCLs for PFNA and HFPO–DA or the Hazard Index and have to install PFAS treatment. The EPA expects that the quantified national costs, which do not include HFPO–DA, PFNA, and PFBS treatment costs are marginally underestimated (on the order of 5%) as a result of this lack of sufficient nationally representative occurrence data. In an effort to better understand and consider the costs associated with treatment of the PFNA and HFPO–DA MCLs and potentially co-occurring HFPO–DA, PFNA, and PFBS at systems both with and without PFOA, PFOS and PFHxS occurrence in exceedance of the MCLs the EPA performed a quantitative sensitivity analysis of the national cost impacts associated with Hazard Index MCL exceedances resulting from HFPO–DA, PFNA, and PFBS and/or individual MCL exceedances of PFNA and HFPO–DA. The analysis is discussed in section 5.3.1.4 and appendix N.3 of the EA (USEPA, 2024l; USEPA, 2024e). Two additional nonquantifiable cost impacts stemming from insufficient co-occurrence data could also potentially shorten filtration media life and increase operation costs. The co-occurrence of other PFAS and other non-PFAS contaminants not regulated in the final rule could both increase costs to the extent that they reduce media life. The EPA did not include POU treatment in the compliance technology forecast because current POU units are not certified to remove PFAS to the standards required in the final rule. Once certified, this technology may be a low-cost treatment alternative for some subset of small systems. Not including POU treatment in this analysis has resulted in a likely overestimate of costs. Additionally, appendix N.2 of the EA (USEPA, 2024e) contains a sensitivity analysis that estimates possible additional national annualized costs of $99 million, which would accrue to systems if the waste filtration media from GAC and IX were handled as RCRA regulatory or characteristic hazardous waste. This sensitivity analysis includes only disposal costs and does not consider other potential environmental benefits and costs associated with the disposal of the waste filtration media.

There are significant nonquantifiable sources of benefits that were not captured in the quantified benefits estimated for the proposed rule. While the EPA was able to monetize some of the PFOA and PFOS benefits related to CVD, infant birth weight, and RCC effects, the agency was unable to quantify additional reductions in negative health impacts in the national quantitative analysis. In addition to the national analysis for the final rule, the agency developed a sensitivity analysis assessing liver cancer impacts, which is detailed in appendix O of the EA (USEPA, 2024e). The EPA did not quantify PFOA and PFOS benefits related to health endpoints including developmental, cardiovascular, hepatic, immune, endocrine, metabolic, reproductive, musculoskeletal, and other types of carcinogenic effects. See section XII.F of this preamble for additional information on the nonquantifiable impacts of PFOA and PFOS. Further, the agency did not quantify any health benefits associated with the potential reductions in Hazard Index PFAS, which include PFHxS, HFPO–DA, PFNA, and PFBS, or other co-occurring non-regulated PFAS which would be removed due to the installation of required filtration technology at those systems that exceed the final MCLs. The nonquantifiable benefits categories associated with exposure to PFHxS, HFPO–DA, PFNA, and PFBS include developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects. In addition, the EPA did not quantify the potential developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, or carcinogenic impacts related to the removal of other co-occurring non-regulated PFAS. See section XII.G of this preamble for additional information on the nonquantifiable impacts of PFHxS, HFPO–DA, PFNA, and PFBS and other non-regulated co-occurring PFAS.

The treatment technologies installed to remove PFAS can also remove numerous other non-PFAS drinking water contaminants which have negative health impacts including additional regulated and unregulated DBPs (the quantified benefits assessment does estimate benefits associated with THM4), heavy metals, organic contaminants, and pesticides, among others. The removal of these co-occurring non-PFAS contaminants could have additional positive health benefits. In total these nonquantifiable benefits are anticipated to be significant and are discussed qualitatively in section 6.2 of the EA (USEPA, 2024g).

To fully weigh the costs and benefits of the action, the agency considered the totality of the monetized values, the potential impacts of the nonquantifiable uncertainties described above, the nonquantifiable costs and benefits, and public comments received by the agency related to the quantified and qualitative assessment of the costs and benefits. For the final rule, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the rule justify its quantified and nonquantifiable costs (88 FR 18638; USEPA, 2023f).

K. Quantified Uncertainties in the Economic Analysis

The EPA characterized sources of uncertainty in its estimates of costs expected to result from the final rule. The EPA conducted Monte-Carlo based uncertainty analysis as part of SafeWater MCBC. With respect to the cost analysis, the EPA modeled the sources of uncertainty in Table 74.

Table 74: Quantified Sources of Uncertainty in Cost Estimates

Source	Description of Uncertainty
EP concentration of PFAS compounds	The concentration and co-occurrence at each PWS EP of each modeled compound is unknown. The cost analysis uses EP concentrations simulated with system level distributions produced by the Bayesian hierarchical Markov chain Monte Carlo (MCMC) occurrence model (see section 4.4 in EA). The iterative MCMC approach (4,000 iterations) probabilistically estimates parameters for system-level distributions to capture uncertainty. The simulated EP concentrations then reflect the system-level distribution from which they are drawn across 4,000 iterations. Further details on the MCMC model are available in Cadwallader et al. (2022). For more information on the application of the model in this analysis, see chapter 4.4 and appendix A. For more information on the data and analyses that the EPA used to develop national estimates of PFAS occurrence in public drinking water systems see USEPA (2024b).
TOC concentration	The TOC value assigned to each system is from a distribution derived from the SYR4 ICR database (see section 5.3.1.1 in EA)
Compliance technology unit cost curve selection	Cost curve selection varies with baseline PFAS concentrations and includes a random selection from a distribution across feasible technologies (see section 5.3.1.2 in EA), and random selection from a triangular distribution of low-, mid-, and high-cost equipment (25 percent, 50 percent, and 25 percent, respectively).

For each iteration, SafeWater MCBC assigned new values to the three sources of modeled uncertainty as described in Table 74, and then calculated costs for each of the model PWSs. This was repeated 4,000 times to reach an effective sample size for each parameter. At the end of the 4,000 iterations, SafeWater MCBC outputs the expected value as well as the 90 percent CI for each cost metric (*i.e.,* bounded by the 5th and 95th percentile estimates for each cost component). Detailed information on the data used to model uncertainty is provided in appendices A and L of USEPA (2024e).

Additionally, the EPA characterized sources of uncertainty in its analysis of potential benefits resulting from changes in PFAS levels in drinking water. The analysis reports uncertainty bounds for benefits estimated in each health endpoint category modeled for the final rule. Each lower (upper) bound value is the 5th (95th) percentile of the category-specific benefits estimate distribution represented by 4,000 Monte Carlo draws.

Table 75 provides an overview of the specific sources of uncertainty that the EPA quantified in the benefits analysis. In addition to these sources of uncertainty, reported uncertainty bounds also reflect the following upstream sources of uncertainty: baseline PFAS occurrence, affected population size and demographic composition, and the magnitude of PFAS concentration reductions. These analysis-specific sources of uncertainty are further described in appendix L of USEPA (2024e).

Table 75: Quantified Sources of Uncertainty in Benefits Estimates

Source	Description of Uncertainty
Health effect-serum PFAS slope factors	The slope factors that express the effects of serum PFOA and serum PFOS on health outcomes (birth weight, CVD [1], and RCC) are based either on the EPA meta-analyses or medium- or high-confidence studies that provide a central estimate and a CI for the slope factors. The EPA assumed that the slope factors would have a normal distribution within their range.
RCC risk reduction cap	The EPA implemented a cap on the cumulative RCC risk reductions due to reductions in serum PFOA based on the population attributable fraction (PAF) estimates for a range of cancers and environmental contaminants. This parameter is treated as uncertain; its uncertainty is characterized by a log-uniform distribution with a minimum set at the smallest PAF estimate identified in the literature and a maximum set at the largest PAF estimate identified in the literature. The central estimate for the PAF is the mean of this log-uniform distribution.

Note:

1 The slope factors contributing to the CVD benefits analysis include the relationship between TC and PFOA and PFOS, the relationship between HDLC and PFOA and PFOS, and the relationship between blood pressure and PFOS.

XIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094 Modernizing Regulatory Review

1. Significant Regulatory Action

This action is a ''significant regulatory action,'' as defined under section 3(f)(1) of Executive Order (E.O.) 12866, as amended by E.O. 14094. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for E.O. 12866 review. Documentation of any changes made in response to E.O. 12866 review is available in the docket. The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, the Economic Analysis (EA; USEPA, 2024g), is also available in the docket and is summarized in section XII of this preamble.

2. Additional Analysis Under E.O. 12866

The EPA evaluated commenters recommendations summarized in this section to quantify the greenhouse gas (GHG) impacts associated with the rule in light of E.O. 12866, Regulatory Planning and Review, and E.O. 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. For the final rule, the EPA has conducted an additional analysis of the disbenefits associated with operation of treatment technologies to comply with the standard. This analysis is summarized here and detailed in the EA for the Final per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR; USEPA, 2024g).

a. Proposed Rule

In the proposed rule, the EPA did not quantify and monetize potential GHG emissions impacts that would occur as a result of operating treatment technologies to comply with the proposed rule because quantification of such impacts is not required for the Health Risk Reduction and Cost Analysis (HRRCA) under the Safe Drinking Water Act (SDWA). The EPA evaluated commenters recommendations and summarized that the EPA should quantify and monetize the GHG emissions impacts associated with the rule in light of E.O. 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis.

b. Summary of Major Public Comments and EPA Responses

Several commenters recommend ''. . . that the agency consider the social costs of carbon as part of any PFAS rule's cost analysis to be comprehensive as well as to understand how this rule may have unintended consequences like increased social costs relating to carbon dioxide emissions.'' Commenters asserted that ''[n]ot including the social costs of carbon and other social costs hinders the Administrator from having all necessary information to set the perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) drinking water standard at a level that maximizes health risk reduction benefits at a cost that is justified, given those benefits.'' Commenters pointed to the GHG emissions associated with production, reactivation, and delivery of treatment media, focusing on granular activated carbon (GAC) in particular; construction associated with the installation of the treatment technology at the entry point (EP); electricity used to operate treatment technologies; and transportation and disposal of drinking water treatment residuals to comply with the PFAS NPDWR. Two commenters provided their own quantified estimates for some aspects of CO_2 emissions. One commenter estimated that the climate disbenefits from CO_2 emissions associated with increased electricity use for additional pumping, lighting, and ventilation in

treatment plants would be ''$2.5M to $6.8M at 2.5 and 1.5 percent discount rates, respectively, in 2026; and $3.6M to $8.6M at 2.5 and 1.5 percent discount rates, respectively, in 2046.'' Another commenter used a life cycle analysis paper that provides one estimate for the carbon footprint of producing and using GAC and estimates that the climate damages from the CO_2 emissions associated with increased GAC media use ''. . . could have a social cost of more than $160 million annually.'' One commenter stated that the EPA has performed this analysis in other rulemakings, specifically a 2023 proposed air rulemaking (88 FR 25080), and notes that in that regulatory impact analysis (RIA; USEPA, 2023u), ''EPA included the social cost of carbon for the electricity required to operate the air pollution controls.''

The EPA disagrees with commenters that SDWA requires the EPA to quantify and consider the climate disbenefits associated with GHG emission increases from this final rule in the HRRCA. The HRRCA requirements of SDWA 1412 (b)(3)(C) require the agency to analyze ''quantifiable and nonquantifiable costs . . . that are likely to occur *solely* as a result of compliance with the maximum contaminant level'' (emphasis added). Therefore, the EPA considered as part of its HRRCA analysis the compliance costs to facilities, including the costs to purchase electricity required to operate the treatment technologies. Since the climate disbenefits from GHG emissions associated with producing electricity necessary to operate the treatment technologies account for climate impacts associated with the CO_2 emissions and associated costs to society, they do not qualify as compliance costs to public water systems (PWSs) that are part of the required HRRCA analysis under SDWA. For this reason, the EPA included compliance costs to PWSs but not climate disbenefits from GHG emissions associated with the production, reactivation, and delivery of treatment media; construction associated with the installation of the treatment technology at EP; electricity used to operate treatment technologies; and transportation and disposal of drinking water treatment residuals in the cost consideration for the final PFAS NPDWR.

The EPA is committed to understanding and addressing climate change impacts in carrying out the agency's mission of protecting human health and the environment. While the EPA is not required by SDWA 1412(b)(3)(C) to consider climate disbenefits under the HRRCA the agency has estimated the potential climate disbenefits caused by increased on-site electricity demand associated with removing PFAS from drinking water. As explained in section V of this preamble, the EPA's final rule is based on the EPA's record-based analysis of the statutory factors in SDWA 1412(b), and this disbenefits analysis is presented solely for the purpose of complying with E.O. 12866. Circular A–4 states ''[l]ike other benefits and costs, an effort should be made to quantify and monetize additional effects when feasible and appropriate'' (OMB, 2023). The scope of the monetized climate disbenefits analysis is limited to the climate impacts associated with the CO_2 emissions from increased electricity to operate the treatment technologies that will be installed to comply with the PFAS NPDWR.

The EPA did not quantify the potential CO_2 emissions changes associated with the production and delivery of treatment media, construction required for the installation of treatment technology, and transportation and disposal of treatment residuals. The EPA recognizes that many activities directly and indirectly associated with drinking water treatment produce GHG emissions; however, the agency determined that it could not accurately quantify all the potential factors that could increase and decrease greenhouse gas emissions that are not solely attributable to the direct onsite operations of the plant beyond increased electricity use at the plant. The EPA has information, to varying degrees, that the agency could use to potentially estimate emissions from some of these activities. To accurately understand the total potential climate disbenefits of this rule, the EPA should consider GHG emissions in the baseline scenario where the agency also takes no action. However, the EPA lacks the data needed to consider the potentially significant climate disbenefits and other costs to society of the EPA taking no action (*i.e.,* not finalizing the PFAS NPDWR). If the EPA were to not finalize the rule, this could likely trigger other activities that would increase GHG emissions. For example, significant climate disbenefits may be realized from the public increasing purchases of bottled water in an effort to avoid PFAS exposure from drinking water provided by PWSs. More members of the public switch to drinking bottled water if they do not trust the safety of their utility supplied drinking water (Grupper et al. 2021, Levêque and Burns, 2017). Bottled water has a substantially larger carbon footprint than the most highly treated tap water, including the significant energy necessary to produce plastic bottles and transport water from where it is bottled to the point of consumption (Gleick and Cooley, 2009). This carbon footprint can be hundreds of times greater than tap water on a per volume basis (*e.g.,* see Botto, 2009). In addition, this is the first drinking water regulation in which the EPA has estimated disbenefits associated with increases or reductions in GHG emissions. The EPA expects that the approach for quantifying such benefits or disbenefits will continue to evolve as our understanding of the potential relationships between quality of drinking water treatment, impacts on consumer behavior, and other factors influencing GHG emissions improves. Considering the limitations described above and consistent with past EPA rulemakings,[27] the EPA is limiting the scope of the analysis to the major sources of emissions from the direct operation of treatment technologies. The EPA did not quantify the CO_2 emissions associated with production of treatment technologies, construction, transportation, and disposal, as these activities are not solely attributable to the direct onsite operations of the plant and are beyond the scope of this analysis.

Furthermore, while some data exists to inform an estimate of the CO_2 emissions associated with production and reactivation of GAC, the EPA did not do so in this analysis due to significant uncertainties associated with the future CO_2 emissions associated with these technologies. The carbon footprint of GAC is likely to reduce over time, as research continues on novel applications for PFAS removal (*e.g.,* advanced reduction/oxidation processes, novel sorbents, foam fractionation, sonolysis, among others), alternative sources of materials to produce GAC (*e.g.,* biomass and other waste materials), and use of carbon capture technology expands in the future. Given these compounding uncertainties, the EPA did not quantify the climate disbenefits of GAC production and reactivation.

In this rule, the EPA determined that increased electricity use is the major source of emissions from the direct operation of treatment technologies to

[27] Recent examples include *New Source Performance Standards (NSPS) for the SOC Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants (NESHAP) for the SOC Manufacturing Industry and Group I and Group II polymers and Resins Industry, NESHAP Gasoline Distribution NRPM, Supplemental Effluent Limitations Guidelines (ELGs)* and *Standards for the Steam Electric Power Generating Point Source Category.*

remove PFAS. In this analysis conducted pursuant to E.O. 12866, the EPA first quantified the CO_2 emissions from the additional electricity that is expected to be used for pumping, building lighting, heating, ventilation, and operation of other technology-specific equipment to remove PFAS. The EPA then monetized the climate disbenefits resulting from these CO_2 emissions by applying the social cost of carbon dioxide (SC–CO_2) estimates recommended by the commenter, as described in the following paragraphs.

After considering public comments that recommended the EPA consider the climate disbenefits of the rule, the EPA conducted an analysis similar to the one recommended by one commenter. As suggested by the commenter, the EPA used the estimates of consumption of purchased electricity available from the EPA's peer reviewed work breakdown structure (WBS) cost models to estimate the national electricity use associated with operation of PFAS removal treatment technologies. The EPA deviated from the commenter's suggested approach when estimating associated CO_2 emissions over time from producing electricity. The commenter estimates carbon emissions in a single year and presents that value as a constant reoccurring annual cost. Instead, the EPA estimated how CO_2 emissions would change through 2070, the calendar year to which the EPA has estimated CO_2 emissions from electricity production. The EPA applied readily available information from the latest reference case of the EPA's Integrated Planning Model (IPM) to represent CO_2 emissions associated with electricity production over time.[28] Given that emissions from producing electricity are expected to significantly decrease over time, this is a logical application consistent with other agency rulemakings estimating future emissions from the power sector including the EPA's final *Good Neighbor Plan* (USEPA, 2023q) and the EPA's *New Source Performance Standards for GHG Emissions from New, Modified, and Reconstructed Electric Utility Generating Units* (USEPA, 2023r). Finally, the EPA monetized the climate disbenefits resulting from the estimated CO_2 emissions by applying the SC–CO_2 estimates presented in the regulatory impact analysis of the EPA's December 2023 Final Rule, ''Standards of Performance for New, Reconstructed, and Modified Sources and Emissions Guidelines for Existing Sources: Oil and Natural Gas Sector Climate Review'' (USEPA 2023s). These are the same SC–CO_2 estimates the EPA presented in a sensitivity analysis in the RIA for the agency's December 2022 supplemental proposed Oil and Gas rulemaking that the commenter recommended for use in this action. The SC–CO_2 estimates incorporate recent research addressing recommendations of the National Academies of Science, Engineering, and Medicine (NASEM 2017), responses to public comments on the December 2022 supplemental proposed Oil and Gas rulemaking, and comments from a 2023 external peer review of the accompanying technical report. The methodology underlying the SC–CO_2 estimates is described in the agency's technical report *Report on the Social Cost of Greenhouse Gases: Estimates Incorporating Recent Scientific Advances* (USEPA, 2023t), and is included in the docket for this final rule. For additional details on the climate disbenefits analysis see chapter 9.1 of the EPA's EA for the final PFAS NPDWR.

c. Final Analysis

The EPA did not include an estimate of the monetized climate disbenefits from increased GHG emissions associated with the rule in the HRRCA as recommended by commenters because under the SDWA, the EPA only analyzes compliance costs to PWSs solely as a result of the Maximum Contaminant Level (MCL). The EPA analyzed the climate disbenefits of CO_2 emissions associated with the increased electricity use at PWSs as a result of compliance with the PFAS NPDWR, the EPA estimates annualized climate disbenefits associated with this rule of $5.5 million per year[29] (under a 2 percent near term discount rate[30]), which constitutes less than 0.4 percent of the monetized benefits of the rule at a 2 percent discount rate. As noted earlier, the EPA's action is justified based on the statutory factors in SDWA section 1412(b) and this disbenefits analysis is presented solely for the purposes of complying with E.O. 12866.

B. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for approval to the Office of Management and Budget under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned the EPA ICR number 2732.02 and OMB control number 2040–0307. You can find a copy of the ICR in the docket for this rule at *https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114*, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The monitoring information collected as a result of the final rule should allow primacy agencies and the EPA to determine appropriate requirements for specific systems and evaluate compliance with the NPDWR. For the first three-year period following rule promulgation, the major information requirements concern primacy agency activities to implement the rule including adopting the NPDWR into state regulations, providing training to state and PWS employees, updating their monitoring data systems, and reviewing system monitoring data and other requests. Certain compliance actions for drinking water systems, specifically initial monitoring, would be completed during the three years following rule promulgation. Other compliance actions for drinking water systems (including ongoing compliance monitoring, administration, and treatment costs) would not begin until after three years due to the MCL compliance date of this rule. More information on these actions is described in section XII of this preamble and in chapter 9 from the EA of the Final PFAS NPDWR (USEPA, 2024g).

Respondents/affected entities: The respondents/affected entities are PWSs and primacy agencies.

Respondent's obligation to respond: The collection requirements are mandatory under SDWA (42 U.S.C. 300g–7).

Estimated number of respondents: For the first three years after publication of the rule in the **Federal Register**, information requirements apply to an average of 33,594 respondents annually, including 33,538 PWSs and 56 primacy agencies.

Frequency of response: During the initial three-year period, PWSs will conduct one-time startup activities. The one-time burden associated with reading and understanding the rule and adopting the rule is estimated to be an average of 4 hours per system. The one-time burden associated with attending one-time training provided by primacy agencies is an average of 16 hours for systems serving ≤3,300 people and 32 hours for systems serving >3,300 people. The burden associated with initial sampling requirements is an estimated 207,000 hours. The total burden for these activities, for the three-year period, for all systems is estimated to be 1,519,000 hours. During the initial

[28] See *https://www.epa.gov/power-sector-modeling.*

[29] Disbenefits are annualized over the years 2024–2080.

[30] See the EPA's EA for the Final PFAS NPDWR for results at all discount rates.

three-year period, primacy agencies will incur burdens associated with one-time startup activities. The burden associated with reading and understanding the rule, adopting the regulatory requirements, and training internal staff is estimated to be an average of 4,320 hours per primacy agency. The burden associated with primacy agency review of initial monitoring data is 207,000 hours. The total burden for these activities, for the three-year period, for all 56 primacy agencies is estimated to be 533,000 hours.

Total estimated burden: For the first three years after the final rule is published, water systems and primacy agencies will implement several requirements related to one-time startup activities and monitoring. The total burden hours for public water systems are 1,519,000 hours. The total burden for primacy agencies is 533,000 hours. The total combined burden is 2,052,000 hours.

Total estimated cost: The total costs over the three-year period is $176.8 million, for an average of $58.9million per year (simple average over three years).

An agency may not conduct or sponsor, and a person is not required to respond to, a collected for information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to sections 603 and 609(b) of the RFA, the EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule and convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that potentially would be subject to the rule's requirements. Summaries of the IRFA and Panel recommendations are presented in the proposed rule (USEPA, 2023f).

As required by section 604 of the RFA, the EPA prepared a final regulatory flexibility analysis (FRFA) for this action. The FRFA addresses the issues raised by public comments on the IRFA for the proposed rule. The complete FRFA is available for review in section 9.4 of the EA in the docket and is summarized here.

For purposes of assessing the impacts of the final rule on small entities, the EPA considered small entities to be water systems serving 10,000 people or fewer. This is the threshold specified by Congress in the 1996 Amendments to SDWA for small water system flexibility provisions. As required by the RFA, the EPA proposed using this alternative definition in the **Federal Register** (USEPA, 1998d), sought public comment, consulted with the Small Business Administration (SBA), and finalized the small water system threshold in the agency's Consumer Confidence Report (CCR) Regulation (USEPA, 1998e). As stated in the document, the alternative definition would apply to all future drinking water regulations.

The SDWA is the core statute addressing drinking water at the Federal level. Under the SDWA, the EPA sets public health goals and enforceable standards for drinking water quality. As previously described, the final PFAS NPDWR requires water systems to reduce certain PFAS in drinking water below regulatory levels. The EPA is regulating these PFAS in drinking water to improve public health protection by reducing drinking water exposure to these and other PFAS in drinking water.

The final rule contains provisions affecting approximately 62,000 small PWSs. A small PWS serves between 25 and 10,000 people. These water systems include approximately 45,000 community water systems (CWSs) that serve the year-round residents and approximately 17,000 non-transient non-community water systems (NTNCWSs) that serve the same persons over six months per year (*e.g.,* a PWS that is an office or school). The final PFAS NPDWR includes legally enforceable regulatory standards with requirements for monitoring, public notification, and treatment or nontreatment options for water systems exceeding the regulatory standards. This final rule also includes reporting, recordkeeping, and other administrative requirements. States are required to implement operator certification (and recertification) programs under SDWA section 1419 to ensure operators of CWSs and NTNCWSs, including small water system operators, have the appropriate level of certification.

Under the final rule requirements, small CWSs and NTNCWs serving 10,000 or fewer people are required to conduct initial monitoring or demonstrate recent, previously collected monitoring data to determine the level of certain PFAS in their water system. Based on these initial monitoring results, systems are required to conduct ongoing monitoring at least every three years or as often as four times per year. Systems that exceed a drinking water standard will be required to choose between treatment and nontreatment as the compliance option. Under the final rule, the EPA estimates that approximately 16,542 small CWSs (37 percent of small CWSs) could incur annual total PFAS NPDWR related costs of more than one percent of revenues, and that approximately 8,199 small CWSs (18 percent of small CWSs) could incur annual total costs of three percent or greater of revenue. See section 9.3 of the final PFAS NPDWR EA for more information on the characterization of the impacts under the final rule.

The EPA took a number of steps to solicit small entity stakeholder input during the development of the final PFAS NPDWR. Sections XIII.E and XIII.F of this preamble contain detailed information on stakeholder outreach during the rulemaking process, including material on the Federalism and Tribal consultation processes. The EPA also specifically sought input from small entity stakeholders through the SBAR Panel process. On May 24, 2022, the EPA's Small Business Advocacy Chairperson convened the Panel, which consisted of the Chairperson, the Director of the Standards and Risk Management Division within the EPA's Office of Ground Water and Drinking Water, the Administrator of the Office of Information and Regulatory Affairs within OMB, and the Chief Counsel for Advocacy of the SBA. Detailed information on the overall panel process can be found in the panel report available in the PFAS NPDWR docket (EPA–HQ–OW–2022–0114).

In response to the proposal, the EPA received one comment specifically on the analytical approach used in the IRFA. The commenter states that ''[d]etailed analysis on the impacts to NTNCWSs should be conducted to inform the cost/benefit analysis. For example, treating PFAS with GAC at the low levels proposed is much more costly than current treatment for currently regulated contaminants, and a 2008 study is not a reliable indicator of future costs. Lack of both actual data on occurrence in these systems and reliable information on cost of compliance makes finalizing the MCL as to NTNCWSs too uncertain.'' The EPA disagrees that the agency has not analyzed the impacts of the PFAS NPDWR on NTNCWS. The EPA has used both actual data on occurrence at NTNCWSs from the third Unregulated Contaminant Monitoring Rule (UCMR 3) and state data, as well as reliable information on costs to NTNCWSs using

the WBS treatment cost models to assess the impact of the rule on NTNCWSs. As the EPA stated in the proposal, the EPA lacks information on the revenues of NTNCWS, therefore the agency does not take the same approach used for CWSs in the Significant Economic Impact on a Substantial Number of Small Entities (SISNOSE) screening analysis where costs are compared to 1 and 3 percent of revenues. Instead, the EPA used the best available data, the EPA's *Assessment of the Vulnerability of Noncommunity Water Systems to SDWA Cost Increases* (USEPA, 1998f), to find that NTNCWSs are less vulnerable to SDWA related increases than a typical CWS. The EPA proceeded with the SBAR Panel process, as previously detailed in this section.

The EPA received many comments on the rule proposal, including from the Chief Counsel for Advocacy of the SBA, on small system and IRFA related topics including lack of funding availability for small water systems, the EPA's alleged underestimation of the impacts of the rule on small systems, the EPA's alleged overestimation of reliance on Federal funding to defray compliance costs for small water systems, and ''other factors that will further deter timely compliance'' such as personnel shortages, supply chain disruptions, limited lab and disposal capacity, and availability of treatment technologies. The EPA has addressed these comments and provided for maximum flexibility for small systems while ensuring sufficient public health protection for populations served by these systems. For the EPA's response to SBA and other comments on funding availability, please see section II of this preamble. For the EPA's response to SBA and other comments on the estimated costs to small water systems, please see section XII of this preamble. For the EPA's response to SBA and other comments on lab capacity, see sections V and VIII. For the EPA's response to SBA and other comments on technology and disposal capacity, see section X. For responses to SBA's and other commenters' recommendations to the EPA to provide burden-reducing flexibilities for small water systems, including finalizing one of the regulatory alternatives and phasing in the MCL, as well as providing additional time for compliance, see section V of this preamble. For response to SBA and other commenters concerned about the EPA's concurrent proposal of a preliminary determination and a proposed regulation for four PFAS, see section III of the preamble. The FRFA, available for review in section 9.4 of the EA in the docket, also provides detailed information on the recommendations of the SBAR Panel and the EPA's actions taken to minimize the significant economic impact of the final rule on small systems.

As a mechanism to reduce the burden of the final rule requirements on small entities the EPA has promulgated compliance flexibilities for small CWSs serving 10,000 or fewer persons. These flexibilities include the use of previously collected PFAS monitoring data to satisfy initial monitoring requirements, allowing reduced initial monitoring for small groundwater systems serving 10,000 or fewer, the addition of annual monitoring to the ongoing compliance monitoring framework, and modified rule trigger levels for reduced monitoring eligibility. For more information on these flexibilities, see section VIII of this preamble. The EPA is also exercising its authority under SDWA section 1412(b)(10) to implement a nationwide two-year capital improvement extension to comply with MCL. The agency notes that SDWA section 1416(a) and (b)(2)(C) describe how the primacy agencies may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. PWSs that meet the minimum criteria outlined in the SDWA section 1416 may be eligible for an exemption of up to three years. Exemptions for smaller water systems (≤3,300 population), meeting certain specified criteria may be renewed for one or more two-year periods, but not to exceed six years. States exercising primacy enforcement responsibility must have adopted the 1998 Variance and Exemption Regulation for a water system to be eligible for an exemption in that state. Finally, the EPA notes that if point-of-use (POU) devices are certified to meet the NPDWR standard in the future, this could reduce the economic impact of the final regulation on small PWSs, particularly on water systems in the smallest size category (*e.g.,* those serving between 25 and 500 people).

The EPA also assessed the degree to which the final PFAS NPDWR small system flexibilities would mitigate compliance costs. The EPA estimates that the use of previously collected PFAS monitoring data will reduce the economic burden on small systems nationally by $7 million dollars per year for three years. The EPA expects that reduced monitoring for small groundwater systems will reduce the economic burden on small systems nationally by $21 million per year for three years. The EPA estimates that under the final rule approximately 4,300 to 7,000 small PWSs may have regulated PFAS occurrence between the trigger levels and the MCLs, and therefore may be eligible for annual monitoring following four consecutive quarterly samples demonstrating they are ''reliably and consistently'' below the MCLs. The EPA anticipates further compliance cost mitigations stemming from the decision to set the reduced monitoring trigger levels at one-half of the MCLs, rather than one-third of the MCLs as proposed. While the MCL compliance period extension does not change the treatment or non- treatment actions that small systems will be compelled to undertake, it will reduce the compliance burden faced by small water systems by allowing for more time for them to obtain and install capital improvements. Finally, the EPA recognizes the possibility of small system compliance cost reduction particularly for very small water systems should POU certifications be updated in the future and POUs meet the small system compliance technology (SSCT) criteria for the final NPDWR. See chapter 9, section 9.3.4 of the final PFAS NPDWR EA (USEPA, 2024g) for more information on the characterization of the impacts under the final rule.

In addition, the EPA is preparing a Small Entity Compliance Guide to help small entities comply with this rule. The EPA expects the *Small System Compliance Guide* will be developed in the first three years after rule promulgation and will be made available on the EPA's PFAS NPDWR website.

D. Unfunded Mandates Reform Act (UMRA)

This action contains a Federal mandate under UMRA, 2 U.S.C. 1531–1538, that may result in expenditures of $100 million or more for state, local, and Tribal governments, in the aggregate, or the private sector in any one year. Accordingly, the EPA has prepared a written statement required under section 202 of UMRA that is included in the docket for this action (see chapter 9 of the EA for the Final PFAS NPDWR) and briefly summarized here.

Consistent with UMRA section 205, the EPA identified and analyzed a reasonable number of regulatory alternatives to determine the MCL requirement in the final rule. The agency notes, however, that the provisions of section 205 do not apply when they are inconsistent with applicable law; in the case of NPDWRs, the UMRA section 205 requirement to adopt the least costly, most cost-

effective, or least burdensome option is inconsistent with SDWA regulatory development requirements. See section XII of this preamble and chapter 9 of the EA for the Final PFAS NPDWR (USEPA, 2024g) for alternative options that were considered. Consistent with the intergovernmental consultation provisions of UMRA section 204, the EPA consulted with governmental entities affected by this rule. The EPA describes the government-to-government dialogue and comments from state, local, and Tribal governments in sections XIII.E. (E.O. 13132: Federalism) and XIII.F. (E.O. 13175: Consultation and Coordination with Indian Tribal Governments) of this document.

This action may significantly or uniquely affect small governments. The EPA consulted with small governments concerning the regulatory requirements that might significantly or uniquely affect them. The EPA describes this consultation in the RFA, section XIII.C. of this preamble.

E. Executive Order 13132: Federalism

The EPA has concluded that this action has federalism implications because it imposes substantial direct compliance costs on state or local governments, and the Federal Government will not provide the funds necessary to pay those costs. However, the EPA notes that the Federal Government will provide a potential source of funds necessary to offset some of those direct compliance costs through the Bipartisan Infrastructure Law (BIL). The EPA estimates that the net change in primacy agency related cost for state, local, and Tribal governments in the aggregate to be $4.7 million.

The EPA provides the following federalism summary impact statement. The EPA consulted with state and local governments early in the process of developing the proposed action to allow them to provide meaningful and timely input into its development. The EPA held a federalism consultation on February 24, 2022. The EPA invited the following national organizations representing state and local elected officials to a virtual meeting on February 24, 2022: The National Governors' Association, the National Conference of State Legislatures, the Council of State Governments, the National League of Cities, the U.S. Conference of Mayors, the National Association of Counties, the International City/County Management Association, the National Association of Towns and Townships, the County Executives of America, and the Environmental Council of States. Additionally, the EPA invited the Association of State Drinking Water Administrators (ASDWA), the Association of Metropolitan Water Agencies (AMWA), the National Rural Water Association (NRWA), the American Water Works Association (AWWA), the American Public Works Association, the Western Governors' Association, the Association of State and Territorial Health Officials, the National Association of Country and City Health Officials, and other organizations to participate in the meeting. In addition to input received during the meeting, the EPA provided an opportunity to receive written input within 60 days after the initial meeting. A summary report of the views expressed during federalism consultations is available in the rule docket (EPA–HQ–OW–2022–0114). The EPA also received public comments from some of these organizations during the public comment period following the rule proposal. These individual organization comments are available in the docket.

Comments provided by the organizations during both the consultation and public comment periods covered a range of topics. The overarching comments from multiple organizations related to the NPDWR compliance timeframe and implementation flexibilities, the proposed MCLs for PFOA and PFOS and the Hazard Index PFAS, the EPA's estimated costs of the NPDWR and funding considerations, PFAS treatment disposal, and other EPA actions to address PFAS in the environment. Specifically, several of these organizations expressed that the EPA should allow an extended compliance timeframe to comply with the MCLs due to supply chain disruptions and availability of treatment materials, as well as maximize the implementation flexibilities for water systems and primacy agencies, including those related to monitoring. Regarding rule costs, some organizations contended that the EPA's costs were underestimated, and that the EPA should consider the disposal of PFAS treatment residuals and associated costs particularly if determined to be hazardous wastes in the future under other EPA statutes such as the Resource Conservation and Recovery Act (RCRA). A couple of organizations requested that the EPA should provide more direct funding for local governments to comply with the NPDWR noting the available BIL funding would not be sufficient to cover the rule costs and these funds cannot be used for certain rule compliance costs. A few organizations suggested that the agency should raise the proposed PFOA and PFOS MCLs, with some of these commenters offering that the EPA should not move forward with the Hazard Index MCL for perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA), and perfluorobutane sulfonic acid (PFBS). Finally, several organizations provided that the agency should focus on addressing PFAS holistically and expedite its efforts on source water protection and other actions to address PFAS in the environment beyond drinking water. The EPA considered these organizations' concerns and has taken this input to address many of these in the final PFAS NPDWR while ensuring sufficient public health protection those served by PWSs.

Related to compliance timeline and other rule implementation flexibilities, the EPA is exercising its authority under SDWA section 1412(b)(10) to implement a nationwide two-year capital improvement extension to comply with MCL. The agency notes that SDWA section 1416(a) and (b)(2)(C) describe how the EPA or states may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. See section XI.D for more information on extensions and exemptions. The EPA has promulgated compliance flexibilities for monitoring implementation including the use of previously collected PFAS monitoring data to satisfy initial monitoring requirements and allowing reduced initial monitoring for small groundwater systems serving 10,000 or fewer. Other monitoring implementation flexibilities include the addition of annual monitoring to the ongoing compliance monitoring framework and higher rule trigger levels for reduced monitoring eligibility. For more information on these flexibilities, see section VIII of this preamble.

For the final rule, the EPA has evaluated the concerns related to the rule costs and maintains that the estimated benefits of the rule justify the costs. Regarding financial costs to water systems if regulated PFAS were to be required to be disposed of as hazardous waste in the future, the EPA reaffirms that no PFAS are currently listed, or proposed to be listed, as hazardous wastes under RCRA. However, the EPA has included a sensitivity analysis to determine the impact on this action should be PFAS-containing treatment materials be considered RCRA

regulatory or characteristic hazardous waste in the future (see section X.C. for more detail). For funding concerns and information, the EPA has provided information, detailed further in section II.G. of this preamble related to potential funding opportunities, particularly those available through BIL funds including the EPA's Emerging Contaminants in Small or Disadvantaged Communities (EC–SDC) grants program.

For organizations recommending that the EPA raise the proposed PFOS and PFOS MCLs, with some of these organizations suggesting that the Hazard Index MCL is not justified and should not be finalized, as described in section V of this preamble, the EPA has demonstrated these levels are justified under the requirements of SDWA. Therefore, the agency is maintaining these MCLs for the final rule but has offered compliance flexibilities as described previously.

Lastly, several organizations provided that the agency should focus on addressing PFAS through source water protection efforts beyond drinking water, under the agency's *PFAS Strategic Roadmap* and associated actions, the EPA is swiftly working to address PFAS contamination in the environment and reduce human health PFAS exposure through all pathways. While beyond the scope of this rulemaking, the EPA is making progress implementing many of the commitments in the *Roadmap,* including those that may significantly reduce PFAS source water concentrations.

In addition to the federalism consultation, regarding state engagement more specifically, the EPA notes there were multiple meetings held by ASDWA where the EPA gathered input from state officials and utilized this input to inform this rule. The EPA also considered all comments provided by individual states and state organizations provided during the public comment period and used these comments to inform the final rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has Tribal implications, it imposes direct compliance costs on Tribal governments, and the Federal Government will not provide funds necessary to pay those direct compliance costs. However, the EPA notes that the Federal Government will provide a potential source of funds necessary to offset some of those direct compliance costs through the BIL.

The EPA has identified 998 PWSs serving Tribal communities, 84 of which are federally owned. The EPA estimates that Tribal governments will incur PWS compliance costs of $9.0 million per year attributable to monitoring, treatment or nontreatment actions to reduce PFAS in drinking water, and administrative costs, and that these estimated impacts will not fall evenly across all Tribal systems. The final PFAS NPDWR does offer regulatory relief by providing flexibilities for all water systems to potentially utilize pre-existing monitoring data in lieu of initial monitoring requirements and for groundwater CWSs and NTNCWSs serving 10,000 or fewer to reduce initial monitoring from quarterly monitoring during a consecutive 12-month period to only monitoring twice during a consecutive 12-month period. These flexibilities may result in implementation cost savings for many Tribal systems since 98 percent of Tribal CWSs and 94 percent of NTNCWs serve 10,000 or fewer people.

Accordingly, the EPA provides the following Tribal summary impact statement as required by section 5(b) of E.O. 13175. The EPA consulted with federally recognized Tribal governments early in the process of developing this action to permit them to have meaningful and timely input into its development. The EPA conducted consultation with Indian Tribes beginning on February 7, 2022, and ending on April 16, 2022. The consultation included two national webinars with interested Tribes on February 23, 2022, and March 8, 2022, where the EPA provided proposed rulemaking information and requested input. A total of approximately 35 Tribal representatives participated in the two webinars. Updates on the consultation process were provided to the National Tribal Water Council and the EPA Region 6's Regional Tribal Operations Committee upon request at regularly scheduled monthly meetings during the consultation process. As part of the consultation, the EPA received written comments from the following Tribes: Little Traverse Bay Bands of Odawa Indians and Sault Ste. Marie Tribe of Chippewa Indians. In addition to the comments from these Tribal governments, the EPA received comments the National Tribal Water Council. A summary report of the consultation, webinars, and views expressed during the consultation is available in the Docket (EPA–HQ–OW–2022–0114).

The EPA received a variety of comments from Tribal officials and representatives during both the consultation and public comment periods. These comments can be found in more detail within the Docket through the individual public comments and within the consultation summary report. Specifically, comments included those related to initial monitoring requirements, use of monitoring waivers, concerns related to treatment options and disposal of treatment materials, particularly if determined to be hazardous in the future, as well as funding concerns. The EPA has addressed these officials' comments through finalizing monitoring requirements which allow for small systems flexibilities including the use of previously collected monitoring data to be used to satisfy initial monitoring requirements and not allowing the use of monitoring waivers (see section VIII) of this preamble. Related to treatment considerations, the EPA has identified best available technologies (BATs) as described in section X which have been shown to reduce regulated PFAS levels, but also allows for other treatment technologies not identified as BATs to be used to address MCL exceedances if they can remove PFAS to the regulatory standards. Additionally, the EPA has developed a sensitivity cost analysis to describe the additional financial costs to water systems if the regulated PFAS were to be required to be disposed of as hazardous waste in the future (see appendix N, section 2 of the EA for additional detail). For funding concerns, the EPA has provided information, detailed further in section II of this preamble, related to potential funding opportunities, particularly those available through the EPA's EC–SDC grants program.

The EPA reviewed these comments received from Tribal groups, the estimated cost data, and the quantified and nonquantifiable benefits associated with the PFAS NPDWR and determined that the regulatory burden placed on Tribes is outweighed by the positive benefits. Given that the majority of Tribal systems serve fewer than 10,000 persons, as noted previously, the EPA has provided regulatory relief in the form of small system compliance flexibilities related to monitoring requirements. For additional information on these compliance flexibilities and their estimated impacts see sections VIII of this preamble and chapter 9.4, of the final PFAS NPDWR EA (USEPA, 2024g).

As required by section 7(a) of E.O. 13175, the EPA's Tribal Official has certified that the requirements of the E.O. have been met in a meaningful and timely manner. A copy of the

certification is included in the docket for this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is subject to E.O. 13045 because it is a significant regulatory action under section 3(f)(1) of E.O. 12866, and the EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children. Accordingly, the EPA has evaluated the environmental health or safety effects of the regulated PFAS found in drinking water on children and estimated the risk reduction and health endpoint impacts to children associated with adoption of treatment or nontreatment options to reduce these PFAS in drinking water. The results of these evaluations are contained in the EA of the Final PFAS NPDWR (USEPA, 2024g) and described in section XII of this preamble. Copies of the EA of the Final PFAS NPDWR and supporting information are available in the Docket (EPA–HQ–OW–2022–0114).

Furthermore, the EPA's *Policy on Children's Health* also applies to this action. Information on how the Policy was applied is available in section II.B. of this preamble.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The public and private water systems affected by this action do not, as a rule, generate power. This action does not regulate any aspect of energy distribution as the water systems that are proposed to be regulated by this rule already have electrical service. Finally, the EPA has determined that the incremental energy used to implement the identified treatment technologies at drinking water systems in response to the regulatory requirements is minimal. The EPA estimates that the final rule will result in an increased electricity use of approximately 229 GWh per year, for more information see section XIII.A; total U.S. electricity consumption in 2022 was approximately 4.05 million GWh (USEIA, 2023). Therefore, the electricity consumed as a result of the final rule represents approximately 0.005 percent of total U.S. electricity consumption. Based on these findings, the EPA does not anticipate that this rule will have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act of 1995

This action involves technical standards. The rule could involve voluntary consensus standards in that it requires monitoring for regulated PFAS, and analysis of the samples obtained from monitoring based on required methods. As part of complying with this final rule, two analytical methods are required to be used for the identification and quantification of PFAS in drinking water. The EPA Methods 533 and 537.1 incorporate quality control criteria which allow accurate quantitation of PFAS. Additional information about the analytical methods is available in section VII of this preamble. The EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the U.S. Environmental Protection Agency Drinking Water Docket, William Jefferson Clinton West Building, 1301 Constitution Ave. NW, Room 3334, Washington, DC 20460, call (202) 566–2426.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

1. Proposal

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice (EJ) concerns. Consistent with the agency's *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (USEPA, 2016f), for the proposed rule, the EPA conducted an EJ analysis to assess the demographic distribution of baseline PFAS drinking water exposure and impacts anticipated to result from the proposed PFAS NPDWR. The EPA conducted two separate analyses: an EJ exposure analysis using the agency's EJSCREENbatch R package, which utilizes data from EJScreen, the agency's Environmental Justice Screening and Mapping Tool (USEPA, 2019e), and from the U.S. Census Bureau's American Community Survey (ACS) 2015–2019 five-year sample (United States Census Bureau, 2022), and an analysis of the EPA's proposed regulatory option and alternatives using SafeWater Multi-Contaminant Benefit Cost Model (MCBC; detailed in section XII of this preamble). The EPA's analyses examined EJ impacts on a subset of PWSs across the country, based on availability of PFAS occurrence data and information on PWS service area boundaries. In the EPA's analysis, results for income, race, and ethnicity groups were generally summarized separately due to how underlying ACS statistics are aggregated at the census block group level; for more information, please see: *https://www.census.gov/data/developers/data-sets/acs-5year.html* (United States Census Bureau, 2022). Additional information on both analyses can be found in chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e).

The EPA's EJ exposure analysis using the EJSCREENbatch R package utilized hypothetical regulatory scenarios, which differed from the EPA's proposed option and regulatory alternatives presented in the proposed rule. The EPA's analysis demonstrated that across hypothetical regulatory scenarios evaluated, elevated baseline PFAS drinking water exposures, and thus greater anticipated reductions in exposure, were estimated to occur in communities of color and/or low-income populations. For this analysis, the EPA examined individuals served by PWSs with modeled PFAS exposure above baseline concentration thresholds or a specific alternative policy threshold. The EPA also summarized population-weighted average concentrations in the baseline as well as reductions that would accrue to each demographic group from hypothetical regulatory scenarios.

The EPA's analysis in SafeWater MCBC evaluated the demographic distribution of health benefits and incremental household costs anticipated to result from the PFAS NPDWR. The EPA's proposed option and all regulatory alternatives were anticipated to provide benefits across all health endpoint categories for all race/ethnicity groups. Across all health endpoints, communities of color were anticipated to experience the greatest reductions in adverse health effects associated with PFAS exposure, resulting in the greatest quantified benefits associated with the EPA's proposed rule, likely due to disproportionate baseline exposure. When examining costs anticipated to result from the rule, the EPA found that cost differences across demographic

groups were typically small, with no clear unidirectional trend in cost differences based on demographic group. In some cases, the EPA found that communities of color were anticipated to bear minimally increased costs but in other cases, costs to communities of color were anticipated to be lower than those across all demographic groups. In general, incremental household costs to all race/ethnicity groups were found to decrease with increasing system size, an expected result due to economies of scale.

Additionally, on March 2, 2022, and April 5, 2022, the EPA held public meetings related to EJ and the development of the proposed NPDWR. The meetings provided an opportunity for the EPA to share information and for communities to offer input on EJ considerations related to the development of the proposed rule. During the meetings and in subsequent written comments, the EPA received public comment on topics including establishing an MCL for PFAS, affordability of PFAS abatement options, limiting industrial discharge of PFAS, and the EPA's relationship with community groups. For more information on the public meetings, please refer to the *Environmental Justice Considerations for the Development of the Proposed PFAS Drinking Water Regulation Public Meeting Summary* for each of the meeting dates in the public docket at *https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114*. Additionally, the written public comments are included within the public docket.

2. Summary of Major Public Comments and EPA Responses

Many commenters expressed support for the rule and the EPA's EJ analysis, underscoring the rule's alignment with the administration's commitment to advancing EJ. Commenters point to evidence which suggests that PFAS exposure disproportionately affects communities with EJ concerns. Further, commenters state that these communities are particularly vulnerable to PFAS exposure and the associated health outcomes. Several commenters also assert that the rule is anticipated to benefit these communities with EJ concerns who are at a higher risk of PFAS exposure. Through this rule, the EPA reaffirms the importance of EJ considerations in agency activities, including rulemaking.

Many commenters expressed concern about potential EJ implications of the final rule and urged the EPA to further consider these implications prior to final rule promulgation. Specifically, commenters presented concerns that the rule will disproportionately impact communities that already are overburdened with sociodemographic and environmental stressors. Additionally, several commenters voiced EJ concerns associated with implementation of the rule. Many commenters asserted that communities with EJ concerns may not have sufficient financial capacity to implement the rule (*e.g.,* install treatment) and that this may further exacerbate existing disparities associated with PFAS exposure. Additionally, commenters stated that additional resources would likely be needed for communities with EJ concerns to successfully implement the rule, including targeted monitoring and sampling in these areas.

The EPA acknowledges commenters' concerns regarding potential EJ implications of the rule. Under E.O. 14096, the EPA is directed to identify, analyze, and address disproportionate and adverse human health or environmental effects of agency actions on communities with environmental justice concerns (USEPA, 2023v). The EPA believes that its EJ analysis accompanying the final rule has achieved this directive, as the EPA has assessed the demographic distribution of baseline PFAS exposure in drinking water as well as the anticipated distribution of benefits and costs that will result from the rule. For more information on the EPA's EJ analysis, please see chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e). The EPA acknowledges the potential for implementation challenges for communities with EJ concerns; however, there may be opportunities for many communities to utilize external funding streams to address such challenges. The BIL, the Low-Income Water Household Assistance Program through the American Rescue Plan, and other funding sources may be able to provide financial assistance for addressing emerging contaminants. In particular, the BIL funding has specific allocations for disadvantaged and/or small communities to address emerging contaminants, including PFAS. For example, the *Emerging Contaminants in Small or Disadvantaged Communities (EC–SDC) grants program,* which does not have a cost-sharing requirement, will provide states and territories with $5 billion to provide grants to public water systems in small or disadvantaged communities to address emerging contaminants, including PFAS. Grants will be awarded non-competitively to states and territories.

Many commenters stated that the costs of the rule will disproportionately fall on communities with EJ concerns. Additionally, some commenters asserted that the EPA's EJ analysis does not appropriately consider the distributional impacts of rule costs, with one commenter incorrectly stating that the analysis ''fails to consider how these increased compliance costs will impact EJ communities, as required by Executive Order 12898''. Commenters recommended that the EPA revise its analysis to reflect the impact that compliance costs of the rule will have on communities with potential EJ concerns.

The EPA disagrees with commenters that the EPA has failed to appropriately consider the impact that costs required to implement the rule may have on communities with potential EJ concerns. The agency has fulfilled its commitments in this rulemaking by conducting an analysis consistent with E.O. 14096 and has shared information on the demographic distribution of impacts evaluated in its EJ analysis to facilitate the public's understanding on potential environmental justice impacts of the rule. In section 8.4.2.2 of its EJ Analysis (found in chapter 8 of the HRRCA (USEPA, 2024l)), the EPA estimated the distribution of annualized incremental household costs across different race/ethnicity groups. As described in section XIII.J.1 above, the EPA found that cost differences across demographic groups are typically small, with no clear unidirectional trend in cost differences based on demographic group. In some cases, the EPA found that communities of color are anticipated to bear minimally increased costs but in other cases, costs to communities of color are lower than those across all demographic groups. In response to commenters, the EPA has updated its analysis to also examine the distribution of benefits and costs across income groups. With respect to the distribution of costs, the EPA found that, similar to its findings based on race/ethnicity group, differences in annual incremental household costs across income groups were small with no unidirectional trend in cost differences based on income level.

Additionally, one commenter recommended that the EPA disaggregate Asian and Pacific Islander data in its EJ analysis, asserting that the ''EPA must comply with OMB Statistical Directive 15''. The EPA disagrees that its EJ analysis must disaggregate Asian and Pacific Islander data in order to comply with OMB Statistical Directive 15 (SPD 15). SPD 15 establishes standards for maintaining, collecting, and presenting

Federal data on race and ethnicity and applies to ''all Federal reporting purposes'' (OMB, 1977). This term is not defined and does not clearly apply to analyses developed to support rulemaking efforts. SPD 15 is targeted primarily toward data collection efforts, the development of data for public consumption, and the enforcement of civil rights laws. As SPD 15 is not applicable in the context of rulemakings, the EPA is not required to revise its EJ analysis in accordance with the standards for data disaggregation set forth in the OMB directive. However, the EPA acknowledges that reporting results separately for these groups can help to reveal potential disparities that may exist across Asian and Pacific Islander subpopulations. In response to this comment, the EPA has added a qualitative summary of the literature provided by the commenter and has updated its analysis to include separate Asian and Pacific Islander demographic groups. These updates are reflected in chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e) for the public's information and understanding.

3. Final Rule

The EPA's EJ exposure analysis for the final rule demonstrates that some communities of color are anticipated to experience elevated baseline PFAS drinking water exposures compared to the entire sample population. The percentage of non-Hispanic Black and Hispanic populations with PFAS in drinking water detected above baseline thresholds is greater than the percentage of the total population served with PFAS exposure above these thresholds for all PFAS analytes examined in the EPA's analysis. Similarly, when results are separately analyzed by system size, non-Hispanic Black and Hispanic populations are more likely to be served by large systems with PFAS detected above baseline thresholds compared to the percentage of the total population served across all demographic groups. For small systems, non-Hispanic Asian and non-Hispanic Black populations are more likely to be served by systems with PFAS concentrations above baseline thresholds for some PFAS analytes compared to the total population served across all demographic groups.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. Across all hypothetical regulatory thresholds, elevated exposure—and thus reductions in exposure under the hypothetical regulatory scenarios—is anticipated to occur in communities of color and/or low-income populations. The EPA estimates that the most notable reductions in exposure would be experienced by Hispanic populations, specifically when using UCMR 5 minimum reporting level values as hypothetical regulatory thresholds. Hispanic populations are estimated to experience exposure rates that are at least two percentage points higher than exposure for the total population served across all demographic groups and for all PFAS analytes included in this analysis. Hispanic populations are therefore also expected to have greater reductions in exposure compared to the entire sample population. In addition, under hypothetical regulatory thresholds set at the UCMR 5 minimum reporting levels, the EPA anticipates some of the largest reductions in exposure to PFOA and PFHxS occur for non-Hispanic Native American or Alaska Native and non-Hispanic Pacific Islander populations due to relatively high concentration levels when these PFAS are detected at PWSs serving these groups. For more information on the results of this EJ exposure analysis, see chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e).

For the final rule, the EPA has updated its EJ exposure analysis to include separate Asian and Pacific Islander demographic groups, which were previously combined for the proposed rule. Additionally, the EPA has updated the demographic categories utilized in the EJ exposure analysis to ensure that consistent information is used or applied throughout the PFAS NPDWR EA to the extent possible and to reduce double counting across demographic categories. For the proposed rule, the EPA's EJ exposure analysis used different demographic categories than its distributional analysis conducted in SafeWater, with the former partly including racial groups that were inclusive of Hispanic individuals and the latter including racial groups that were exclusive of Hispanic individuals. Because the EPA's EJ exposure analysis for the proposed rule employed some demographic categories that were inclusive of Hispanic individuals (*e.g.,* American Indian or Alaska Native) and others that were not (*e.g.,* non-Hispanic White), this introduced double counting across groups in the analysis, which complicated making comparisons of exposure across populations of concern. This issue was described in the EJ analysis at proposal, and the EPA solicited comment on alternative methods for defining affected population groups.

Additionally, after considering public comments, the EPA has also updated its EJ analysis conducted in SafeWater MCBC to include an assessment of the distribution of benefits and costs anticipated to result from the final rule across income groups. Findings from the EPA's EJ analysis conducted in SafeWater MCBC for the final rule reaffirm the conclusions of the assessment of the distribution of benefits and costs conducted for the proposed rule across demographic groups. Across all health endpoints evaluated by the EPA, communities of color (*i.e.,* Hispanic, non-Hispanic Black, and/or Other race/ethnicity groups) are anticipated to experience the greatest reductions in adverse health effects associated with PFAS exposure, resulting in the greatest quantified benefits associated with the final rule. For instance, non-Hispanic Black populations are expected to experience 7.48 avoided non-fatal ischemic stroke (IS) cases and 3.90 avoided cardiovascular disease (CVD) deaths per 100,000 people per year, as compared to 3.78 avoided non-fatal IS cases and 1.26 avoided CVD deaths per 100,000 people per year for non-Hispanic White populations. Additionally, under the final rule, while in most cases the difference in cases of illnesses and deaths avoided across income groups is small, quantified health benefits are higher for low-income communities (*i.e.,* populations with income below twice the poverty level) across all health endpoints evaluated, compared to populations with income above twice the poverty level.

As found in its analysis for the rule proposal, when examining costs anticipated to result from the final rule, the EPA found that cost differences across both race/ethnicity and income groups are typically small, with no clear unidirectional trend in cost differences based on demographic group. In some cases, the EPA found that communities of color and low-income communities are anticipated to bear minimally increased costs but in other cases, costs to communities of color and low-income communities are anticipated to be lower than those across all race/ethnicity groups or populations with income above twice the poverty level, respectively. Additionally, incremental household costs to all race/ethnicity and income groups generally decrease as system size increases, which is expected due to economies of scale. This is especially true if systems serving these communities are required to install treatment to comply with the final rule. For example, systems serving 3,300 to 10,000 people that will be required to install treatment to comply with the

final rule have substantially higher costs than systems in all larger size categories, irrespective of demographic group. To alleviate potential cost disparities identified by the EPA's analysis, there may be an opportunity for many communities to utilize BIL (Pub. L. 117–58) funding to provide financial assistance for addressing emerging contaminants. BIL funding has specific allocations for both disadvantaged and/or small communities and emerging contaminants, including PFAS.

The information supporting this E.O. 12898 review is contained in chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e) and is available in the public docket for this action. This documentation includes additional detail on the methodology, results, and conclusions of the EPA's EJ analysis.

K. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with sections 1412(d) and 1412(e) of the SDWA, the agency consulted with the National Drinking Water Advisory Council (NDWAC, or the Council); the Secretary of U.S. Department of Health and Human Services (HHS); and with the EPA Science Advisory Board (SAB).

1. Science Advisory Board

The SAB PFAS Review Panel met virtually via a video meeting platform on December 16, 2021, and then at three (3) subsequent meetings on January 4, 6, and 7, 2022, to deliberate on the agency's charge questions. Another virtual meeting was held on May 3, 2022, to discuss their draft report. Oral and written public comments were considered throughout the advisory process. The EPA sought guidance from the SAB on how best to consider and interpret life stage information, epidemiological and biomonitoring data, the agency's physiologically based pharmacokinetic (PBPK) analyses, and the totality of PFAS health information to derive an MCLG for PFOA and PFOS, combined toxicity framework, and CVD. The documents sent to SAB were the EPA's *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335–67–1) in Drinking Water* (USEPA, 2021i); the EPA's *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763–23–1) in Drinking Water* (USEPA, 2021j); the EPA's *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* (USEPA, 2021e); and the EPA's Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water. On May 3 and July 20, 2022, the EPA received input from SAB, summarized in the report *Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS* (USEPA, 2022i).

In response to the EPA's request that the SAB review the EPA's four draft documents listed above, the SAB identified subject matter experts to augment the SAB Chemical Assessment Advisory Committee (CAAC) and assembled the SAB PFAS Review Panel to conduct the review.

In general, the SAB recognized the time constraints for completing the rulemaking process and was supportive of the EPA's efforts to the utilize the latest scientific finding to inform their decisions. The SAB applauded the agency's efforts to develop new approaches for assessing the risk of PFAS mixtures and the benefits arising from reducing exposure to these chemicals as adopted by the EPA in the Hazard Index approach in this rule. In general, the SAB agreed with many of the conclusions presented in the assessments, framework, and analysis. The SAB also identified many areas that would benefit from further clarification to enhance their transparency and increase their utility. The SAB provided numerous recommendations which can be found in the SAB's final report (USEPA, 2022i) and some highlights are outlined in the following section.

a. Approaches to the Derivation of Draft MCLGs for PFOA and PFOS

The primary purpose of the *Proposed Approaches to the Derivation of Draft MCLGs for PFOA and PFOS* (USEPA, 2021i; USEPA, 2021j) was to develop Maximum Contaminant Level Goals (MCLGs) based on the best available health effects information for PFOA and PFOS. Each MCLG draft document includes derivation of an updated chronic oral reference dose (RfD), cancer slope factor (CSF) when relevant data were available, and a relative source contribution (RSC) for SAB review. The health effects information used to derive these toxicity values and RSC values built upon the information in the 2016 EPA PFOA and PFOS Health Effects Support Documents (HESDs; USEPA, 2016c; USEPA, 2016d). The EPA has considered all SAB consensus advice in the development of the final values derived in this health effects assessment and subsequently derived MCLGs for the NPDWRs for PFOA and PFOS based on the best available science and the EPA guidance and precedent. Please see section IV of this preamble for discussions on the process for derivation of the MCLGs and the resulting proposed MCLG values for this final action.

The SAB charge questions for the MCLG draft documents addressed the systematic review study identification and inclusion, non-cancer hazard identification, cancer hazard identification and slope factor, toxicokinetic (TK) modeling, RfD derivation, and RSC. The complete list of charge questions was included in the EPA's documents prepared for the SAB (USEPA, 2022i). The SAB provided numerous specific recommendations to consider alternative approaches, expand the systematic review steps for the health effects assessment, and to develop additional analyses in order to improve the rigor and transparency of the EPA's documents. The complete list of SAB consensus advice is described in their final report (USEPA, 2022i).

Regarding the approaches to deriving MCLG draft documents, the SAB stated that the systematic review methods could be more transparent and complete. Specifically, study identification and criteria for inclusion could be improved. The EPA made revisions to the systematic review description and process by updating and expanding the scope of the literature search; providing greater transparency regarding the study inclusion criteria; and adding additional systematic review steps and transparently describing each of these steps in the PFOA and PFOS systematic review protocols.

In the charge questions, the EPA sought advice on the noncancer health assessment, and the SAB recommended that the EPA separate hazard and dose-response assessment systematic review steps. In response, the EPA made revisions to the noncancer hazard identification by expanding systematic review steps beyond study quality evaluation to include evidence integration to address the need to separate hazard identification and dose-response assessment and to ensure consistent hazard decisions; and strengthening rationales for selection of points of departure for the noncancer health outcomes. Additionally, the SAB advised the EPA to focus on the health endpoints with the strongest evidence (*i.e.,* liver, immune, serum lipids, development, and cancer).

The EPA consulted with the SAB on the cancer risk assessment. On the cancer Hazard Index and CSF, the SAB agreed that PFOA was a ''likely''

designation but recommended undertaking and describing a more structured and transparent discussion of the ''weight of evidence'' for both PFOA and PFOS. The EPA revised this assessment by following the structured approach in the EPA cancer guidelines (USEPA, 2005a) to develop a weight of evidence narrative for cancer, to consider the data for selecting the cancer classification, evaluating and integrating mechanistic information, and strengthening the rationales for decisions.

With respect to the TK model for which the EPA sought advice, SAB requested more details on the TK modeling including model code and parameters and recommended that the EPA consider expressing the RfD in water concentration equivalents to better account for possible life-stage specific differences in exposure rates and TKs. The EPA considered the alternate approach suggested by SAB and made revisions by evaluating alternative TK models and further validating the selected model.

The EPA also sought advice on the draft RfD derivation. The SAB advised that the EPA consider multiple human and animal studies for a variety of endpoints and populations. The SAB also stated a need for stronger and more transparent justification of BMR selections and asked the EPA to consider adopting a probabilistic framework to calculate risk-specific doses. SAB also recommended that the EPA clearly state that RfDs apply to both short-term and chronic exposure. The EPA made revisions based on these recommendations by providing additional descriptions and rationale for the selected modeling approaches and conducting new dose-response analyses of additional studies and endpoints.

On the RSC charge question, SAB supported the selection of a 20 percent RSC, but asked that the EPA provide clarity and rationale to support the value. To address this recommendation, the EPA added clarifying language related to the RSC determination from the EPA guidance (USEPA, 2000d), including the relevance of drinking water exposures and the relationship between the RfD and the RSC.

b. Combined Toxicity Framework

The EPA sought advice from the SAB on the *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* document (USEPA, 2021e). The main purpose of this document was to provide a data-driven framework for estimating human health risks associated with oral exposures to mixtures of PFAS. The charge questions for the SAB pertaining to the framework draft documents included whether the EPA provided clear support for the assumption of dose additivity, and application of the Hazard Index, relative potency factor (RPF), and mixtures benchmark dose (BMD) approaches for the evaluation of mixtures of PFAS. The full list of charge questions was included in the EPA's documents prepared for the SAB (USEPA, 2022i). The SAB agreed in general with dose additivity at the level of common health effect, and application of the Hazard Index, RPF and mixture BMD approaches for the evaluation of mixtures of PFAS. The SAB identified instances in which the communication of the analyses and approaches in the EPA's framework document could be improved to be clearer.

On the EPA's charge question for dose additivity, the SAB agreed with the use of the dose additivity assumption when evaluating PFAS mixtures that have similar effects and concluded that this approach was health protective. The SAB recommended a more thoroughly and clearly presented list of the uncertainties associated with dose additivity along with information supporting this approach. The EPA made revisions that added clarity to the text by expanding upon the uncertainties and including additional support for using dose additivity.

The SAB panel agreed with the use of the Hazard Index as a screening method and decision-making tool. The SAB advised that the EPA should consider using a menu-based framework to support selection of fit-for-purpose approaches, rather than a tiered approach as described in the draft mixtures document. Based on this feedback, the EPA has since reorganized the approach to provide a data-driven ''menu of options'' to remove the tiered logic flow and is adding text to clarify the flexibility in implementation.

The EPA sought the SAB's opinion on the RPF approach for estimating health risks associated with PFAS mixtures and the SAB panel considered the RPF approach to be a reasonable methodology for assessing mixtures. On the mixture BMD, the SAB agreed that the mixture BMD approach was a reasonable methodology for estimating a mixture-based point of departure (POD). For both the RPF and mixture BMD approach, the SAB recommended that the EPA's approach be strengthened by the use of PODs from animal studies that are based on HEDs rather than administered doses. The SAB also requested clarification as to the similarities and differences among the RPF and mixture BMD approaches. The SAB also asked the EPA to provide additional information on how the proposed mixtures BMD approach would be applied in practice. To address these recommendations, the EPA made revisions to provide better context and delineation about the applicability of the data across these approaches.

c. Cardiovascular Disease Analysis

The EPA consulted with the SAB on the agency's methodology to determine the avoided cases of CVD events (*e.g.,* heart attack, stroke, death from coronary heart disease) associated with reductions in exposure to PFOA and PFOS in drinking water to support a benefits analysis. Specifically, the EPA sought SAB comment on the extent to which the approach to estimating reductions in CVD risk is scientifically supported and clearly described. The EPA posed specific charge questions on the exposure-response information used in the analysis, the risk model and approach used to estimate the avoided cases of CVD events, and the EPA's discussion of limitations and uncertainties of the analysis. Overall, the SAB supported the EPA's approach to estimating reductions in CVD risk associated with reductions in exposure to PFOA and PFOS in drinking water. The SAB provided feedback on several areas of the analysis; main points of their feedback and the EPA's responses are discussed in this section.

The SAB noted a discrepancy between the draft CVD document's focus on CVD risk, and the draft MCLG documents' conclusions that the evidence of CVD was not sufficient to form the basis of a RfD. Based on SAB feedback on the draft MCLG document's assessment of CVD related risks, the EPA has developed an RfD for total cholesterol (TC). (For more information see USEPA, 2024c; USEPA, 2024d.) The derivation of an RfD for this endpoint addresses the SAB's concerns about inconsistency between the two documents. The SAB also recommended that the EPA ensure that recommendations for the draft MCLG documents relating to evidence identification and synthesis are applied to the CVD endpoint. All studies in the EPA's CVD benefits analysis were evaluated for risk of bias, selective reporting, and sensitivity as applied in the EPA's *Public Comment Draft—Toxicity Assessment and Proposed MCLGs for PFOA and PFOS in Drinking Water* (USEPA, 2023g; USEPA, 2023h).

The SAB recommended that the EPA provide more discussion as to the rationale for selecting CVD for risk reduction analysis and that the

approach follows the pathway that links cholesterol to cardiovascular events rather than looking at the reported effects of PFAS directly on CVD. The SAB also recommended that the EPA consider risk reduction analyses for other endpoints. In section 6.5 of the EA, the EPA discusses the rationale for quantifying CVD and analytical assumptions. Sections 6.4 and 6.6 discusses the agency's quantified risk reduction analyses for other adverse health effects, including infant birthweight effects and renal cell carcinoma (RCC), respectively. In section 6.2.2, the EPA assesses the qualitative benefits of other adverse health effects of PFAS.

Although the SAB generally agreed with the meta-analysis, life table and risk estimation methods, the SAB recommended that the EPA provide additional clarity as to the application of these approaches and conduct additional sensitivity analyses. In response to these comments, the EPA expanded documentation and conducted additional sensitivity analyses to evaluate the impact of inclusion or exclusion of certain studies in the meta-analyses of exposure-response estimates. Further, the EPA expanded documentation and conducted additional sensitivity analyses to assess the effects of using a key single study approach versus the meta-analysis approach to inform the exposure-response estimates. The EPA identified two suitable key studies for use in the single study approach. The EPA found that the single study approach resulted in increased benefits, and this trend was driven by the larger estimates of PFAS–TC slope factors and inverse associations in the high-density lipoprotein cholesterol (HDLC) effect for one or both contaminants in the key single studies. The EPA elected to retain the meta-analysis approach in the benefits analysis because the agency identified several studies on adults in the general population with large numbers of participants and low risk of bias, and in this case the meta-analytical approach offers an increased statistical power over the single study approach. While the single study approach is common for RfD derivations, the meta-analysis pooled estimate provides a slope factor that represents the average response across a larger number of studies, which is useful in evaluating benefits resulting from changes in CVD risk on a national scale.

The SAB also recommended that the EPA evaluate how inclusion of HDLC effects would influence the results and provide further justification for the inclusion or exclusion of HDLC and blood pressure effects. The EPA found that, as expected, inclusion of HDLC effects decreases annualized CVD benefits and inclusion of blood pressure effects slightly increases annualized CVD benefits. Because HDLC was shown to have a stronger effect than blood pressure on annualized CVD benefits, inclusion of blood pressure and HDLC effects together decreases annualized CVD benefits. For more information see sensitivity analyses evaluating these effects in appendix K of the EA. Inclusion of HDLC effects into the national analysis would reduce national benefits estimates but would not change the EPA's bottom-line conclusion that the quantifiable and nonquantifiable benefits of the rule justify the quantifiable and nonquantifiable costs. After further examination of the evidence for HDLC and blood pressure effects, the EPA elected to include blood pressure effects because the findings from a single high confidence study and several medium confidence studies conducted among the general population provided consistent evidence of an association between PFOS exposure and blood pressure. The EPA did not include HDLC effects in the national benefits analysis because available evidence of associations between PFOS exposures and HDLC levels is inconsistent and there is no evidence of an association between PFOA exposures and HDLC levels.

Finally, the SAB noted that while the Atherosclerotic Cardiovascular Disease (ASCVD) model is a reasonable choice for estimating the probability of first time CVD events, it is not without limitations. The panel recommended that the EPA include more discussion of the accuracy of its predictions, particularly for sub-populations. The EPA expanded its evaluation of the ASCVD model's limitations, including a comparison of the ASCVD model predictions with race/ethnicity and sex-specific CVD incidence from Centers for Disease Control and Prevention's (CDC's) public health surveys (See section 6.5.3.2 and appendix G of the EA for details). Results show that the ASCVD model coefficients for the non-Hispanic Black model are more consistent with data on CVD prevalence and mortality for Hispanic and non-Hispanic other race subpopulations than the ASCVD model coefficients for the non-Hispanic White model.

Comments on the SAB consultation and review were raised by public commenters. As a result, the comments have been addressed by the EPA in the final rule, supporting documents in the record, and throughout this preamble, specifically in sections III.B, IV, and XII.A.

2. National Drinking Water Advisory Council (NDWAC)

The agency consulted with the NDWAC prior to the rule proposal during the Council's April 19, 2022, virtual meeting. During the meeting, the EPA provided information related to the development of the proposed rule. A summary of the NDWAC input from that meeting is available in the *NDWAC, Fall 2022 Meeting Summary Report* (NDWAC, 2022) and the docket.

On August 8, 2023, the EPA consulted with the NDWAC prior to the final rule during a virtual meeting where the EPA presented on the proposed PFAS NPDWR, including the proposed MCLs, monitoring and PN requirements, and treatment and economic considerations. The EPA reiterated that the PFAS NPDWR was developed with extensive consultation from state, local and Tribal partners to identify avenues that would reduce PFAS in drinking water and reaffirmed its commitment to working with these partners on rule implementation. The EPA carefully considered the information provided by the NDWAC during the development of a final PFAS NPDWR. A summary of the NDWAC input from that meeting is available in the *NDWAC Summary Report* (NDWAC, 2023) and the docket.

3. Department of Health and Human Service

On September 28, 2022, the EPA consulted with the Department of HHS on the proposed PFAS NPDWR. On November 2, 2023, the EPA consulted with the HHS on the final rule. The EPA received and considered comments from the HHS for both the proposed and final rules through the interagency review process described in section XIII.A.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action meets the criteria set forth in 5 U.S.C.804(2).

XIV. Severability

The purpose of this section is to clarify the EPA's intent with respect to the severability of provisions of this rule. Each Maximum Contaminant Level (MCL) is independent of the others and can be implemented on its own. For that reason, if any individual or Hazard Index MCL is determined by judicial review or operation of law to be invalid, the EPA intends that the partial invalidation will not render any other

MCL invalid. In addition, each per- and polyfluoroalkyl substance (PFAS) included in the Hazard Index is independent from any other PFAS included in the Hazard Index. As a result, if any PFAS regulation is determined by judicial review or operation of law to be invalid, that partial invalidation should not render any other PFAS regulation included in the Hazard Index or the Hazard Index PFAS MCL invalid. Moreover, the Hazard Index approach and Hazard Index PFAS MCL can remain operable and applicable so long as there are at least two contaminants subject to the Hazard Index as a mixture because the EPA's definition of mixture in this final rule is of two or more of the Hazard Index PFAS. In addition, each individual Maximum Contaminant Level Goal (MCLG) is independent of each of the other MCLGs and, because they perform different functions under the Act, of each of the MCLs. As a result, if an MCL is determined to be invalid, that partial invalidation should not render the associated MCLG invalid. The monitoring requirements are independent and capable of operating without any MCLs. Likewise, if any provision of this rule other than the MCLGs, or MCLs, is determined to be invalid (such as monitoring waivers or the capital improvements extension), the remainder of the rule can still be sensibly implemented; as a result, the EPA intends that the rest of the rule (such as monitoring requirements) remain operable and applicable.

XV. Incorporation by Reference

In this action, the EPA requires that systems must only use the analytical methods specified to demonstrate compliance with the rule. EPA Method 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry, November 2019, 815–B–19–020, and EPA Method 537.1,Version 2.0: Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS), March 2020, EPA/600/R–20/006, are incorporated by reference in this final rule and are publicly available in the EPA's Docket ID No. EPA–HQ–OW–2022–0114. The EPA Method 533 and EPA Method 537.1, Version 2.0 are solid phase extraction liquid chromatography-tandem mass spectrometry methods for the detection and determination of select per-and polyfluoroalkyl substances in drinking water. In addition to being available in the aforementioned rule docket, both methods can be accessed online at *https://www.epa.gov/pfas/epa-pfas-drinking-water-laboratory-methods*.

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List of Subjects

40 CFR Part 141

Environmental protection, Incorporation by reference, Indians—lands, Intergovernmental relations, Monitoring and analytical requirements, Per- and polyfluoroalkyl substances, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Indians—lands, Intergovernmental relations, Monitoring and analytical requirements, Per- and polyfluoroalkyl substances, Reporting and recordkeeping requirements, Water supply.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR parts 141 and 142 as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 2. Amend § 141.2 by adding in alphabetical order the definitions for ''Hazard Index (HI)'', ''Hazard quotient (HQ)'', ''Health-based water concentration (HBWC)'', ''HFPO–DA or GenX chemicals'', ''PFBS'', ''PFHxS'', ''PFNA'', ''PFOA'', and ''PFOS'' to read as follows:

§ 141.2 Definitions.

* * * * *

Hazard Index (HI) is the sum of component hazard quotients (HQs), which are calculated by dividing the measured regulated PFAS component contaminant concentration in water (*e.g.,* expressed as parts per trillion (ppt) or nanograms per liter (ng/l)) by the associated health-based water concentration (HBWC) expressed in the same units as the measured concentration (*e.g.,* ppt or ng/l). For PFAS, a mixture Hazard Index greater than 1 (unitless) is an exceedance of the MCL.

Hazard quotient (HQ) means the ratio of the measured concentration in drinking water to the health-based water concentration (HBWC).

Health-based water concentration (HBWC) means level below which there are no known or anticipated adverse health effects over a lifetime of

exposure, including sensitive populations and life stages, and allows for an adequate margin of safety.

HFPO–DA or *GenX chemicals* means Chemical Abstract Service registration number 122499–17–6, chemical formula C6F11O3-, International Union of Pure and Applied Chemistry preferred name 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

* * * * *

PFBS means Chemical Abstract Service registration number 45187–15–3, chemical formula C4F9SO3-, perfluorobutane sulfonate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

PFHxS means Chemical Abstract Service registration number 108427–53–8, chemical formula C6F13SO3-, perfluorohexane sulfonate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

PFNA means Chemical Abstract Service registration number 72007–68–2, chemical formula C9F17O2-, perfluorononanoate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

PFOA means Chemical Abstract Service registration number 45285–51–6, chemical formula C8F15O2-, perfluorooctanoate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

PFOS means Chemical Abstract Service registration number 45298–90–6, chemical formula C8F17SO3–, perfluorooctanesulfonate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

* * * * *

■ 3. Amend § 141.6 by revising paragraph (a) and adding paragraph (l) to read as follows:

§ 141.6 Effective dates.

(a) Except as provided in paragraphs (b) through (l) of this section the regulations set forth in this part take effect on June 24, 1977.

* * * * *

(l) The regulations pertaining to the per- and polyfluoroalkyl substances (PFAS) chemicals set forth in subpart Z of this part are effective June 25, 2024. See § 141.900 for the compliance dates for provisions under subpart Z. Compliance with reporting requirements under subpart Z, in accordance with subparts O (the consumer confidence rule) and Q (the public notification rule) of this part are required on April 26, 2027, except for notification requirements in § 141.203 related to violations of the MCLs. The compliance date for the PFAS MCLs in § 141.61, as specified in § 141.60, and for § 141.203 notifications of violations of the PFAS MCLs is April 26, 2029.

■ 4. Amend § 141.24 by revising paragraph (h) introductory text to read as follows:

§ 141.24 Organic chemicals, sampling and analytical requirements.

* * * * *

(h) Analysis of the contaminants listed in § 141.61(c) for the purposes of determining compliance with the maximum contaminant level shall be conducted as follows, with the exceptions that this paragraph (h) does not apply to regulated PFAS (see § 141.902) and no monitoring is required for aldicarb, aldicarb sulfoxide, or aldicarb sulfone:

* * * * *

■ 5. Amend § 141.28 by revising paragraph (a) to read as follows:

§ 141.28 Certified laboratories.

(a) For the purpose of determining compliance with §§ 141.21 through 141.27, 141.40, 141.74, 141.89, 141.402, 141.901, and 141.902, samples may be considered only if they have been analyzed by a laboratory certified by EPA or the State except that measurements of alkalinity, disinfectant residual, orthophosphate, pH, silica, temperature, and turbidity may be performed by any person acceptable to the State.

* * * * *

■ 6. Amend § 141.50 by:

■ a. Adding periods at the ends of paragraphs (a)(1) through (23);

■ b. Adding paragraphs (a)(24) and (25); and

■ c. In the table to paragraph (b), revising the heading for the second column and adding in numerical order the entries ''(34),'' ''(35),'' ''(36),'' and ''(37)'' and footnote 1.

The additions and revision read as follows:

§ 141.50 Maximum contaminant level goals for organic contaminants.

(a) * * *

(24) PFOA.

(25) PFOS.

(b) * * *

Contaminant	MCLG in mg/l (unless otherwise noted)
* * * * * * *	
(34) Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA)	1 (unitless).[1]
(35) HFPO–DA	0.00001.
(36) PFHxS	0.00001.
(37) PFNA	0.00001.

[1] The PFAS Mixture Hazard Index (HI) is the sum of component hazard quotients (HQs), which are calculated by dividing the measured component PFAS concentration in water by the corresponding contaminant's health-based water concentration (HBWC) when expressed in the same units (shown in ng/l). The HBWC for PFHxS is 10 ng/l; the HBWC for HFPO–DA is 10 ng/l; the HBWC for PFNA is 10 ng/l; and the HBWC for PFBS is 2000 ng/l. A PFAS Mixture Hazard Index greater than 1 (unitless) indicates an exceedance of the health protective level and indicates potential human health risk from the PFAS mixture in drinking water.

$$\text{Hazard Index} = \left(\left[\frac{\text{HFPO–DA}_{\text{water}}\ \text{ng/l}}{10\ \text{ng/l}}\right] + \left[\frac{\text{PFBS}_{\text{water}}\ \text{ng/l}}{2000\ \text{ng/l}}\right] + \left[\frac{\text{PFNA}_{\text{water}}\ \text{ng/l}}{10\ \text{ng/l}}\right]\right) + \left(\frac{\text{PFHxS}_{\text{water}}\ \text{ng/l}}{10\ \text{ng/l}}\right)$$

HBWC = health-based water concentration

HQ = hazard quotient

ng/l = nanograms per liter

$\text{PFAS}_{\text{water}}$ = the concentration of a specific PFAS in water

■ 7. Amend § 141.60 by adding paragraph (a)(4) to read as follows:

§ 141.60 Effective dates.

(a) * * *

(4) The effective date for paragraphs (c)(34) through (40) of § 141.61 (listed in table 4 to paragraph (c)) is April 26, 2029.

* * * * *

■ 8. Amend § 141.61 by:

■ a. In paragraph (a), revising the introductory text and adding a table heading;

■ b. In paragraph (b), revising the introductory text and the table heading;

■ c. Revising and republishing paragraph (c); and

■ d. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 141.61 Maximum contaminant levels for organic contaminants.

(a) The following maximum contaminant levels for volatile organic contaminants apply to community and non-transient, non-community water systems.

TABLE 1 TO PARAGRAPH (a)—MAXIMUM CONTAMINANT LEVELS FOR VOLATILE ORGANIC CONTAMINANTS

* * * * *

(b) The Administrator, pursuant to section 1412 of the Act, hereby identifies as indicated in table 2 to this paragraph (b) granular activated carbon (GAC), packed tower aeration (PTA), or oxidation (OX) as the best technology, treatment technique, or other means available for achieving compliance with the maximum contaminant level for organic contaminants identified in paragraphs (a) and (c) of this section, except for per- and polyfluoroalkyl substances (PFAS).

TABLE 2 TO PARAGRAPH (b)—BAT FOR ORGANIC CONTAMINANTS IN PARAGRAPHS (a) AND (c) OF THIS SECTION, EXCEPT FOR PFAS

* * * * *

(c) The following maximum contaminant levels (MCLs) in tables 3 and 4 to this paragraph (c) for synthetic organic contaminants apply to community water systems and non-transient, non-community water systems; table 4 also contains health-based water concentrations (HBWCs) for selected per- and poly-fluoroalkyl substances (PFAS) used in calculating the Hazard Index.

TABLE 3 TO PARAGRAPH (c)—MCLS FOR SYNTHETIC ORGANIC CONTAMINANTS, EXCEPT FOR PFAS

CAS No.	Contaminant	MCL (mg/l)
(1) 15972–60–8	Alachlor	0.002
(2) 116–06–3	Aldicarb	0.003
(3) 1646–87–3	Aldicarb sulfoxide	0.004
(4) 1646–87–4	Aldicarb sulfone	0.002
(5) 1912–24–9	Atrazine	0.003
(6) 1563–66–2	Carbofuran	0.04
(7) 57–74–9	Chlordane	0.002
(8) 96–12–8	Dibromochloropropane	0.0002
(9) 94–75–7	2,4–D	0.07
(10) 106–93–4	Ethylene dibromide	0.00005
(11) 76–44–8	Heptachlor	0.0004
(12) 1024–57–3	Heptachlor epoxide	0.0002
(13) 58–89–9	Lindane	0.0002
(14) 72–43–5	Methoxychlor	0.04
(15) 1336–36–3	Polychlorinated biphenyls	0.0005
(16) 87–86–5	Pentachlorophenol	0.001
(17) 8001–35–2	Toxaphene	0.003
(18) 93–72–1	2,4,5–TP	0.05
(19) 50–32–8	Benzo[a]pyrene	0.0002
(20) 75–99–0	Dalapon	0.2
(21) 103–23–1	Di(2-ethylhexyl) adipate	0.4
(22) 117–81–7	Di(2-ethylhexyl) phthalate	0.006
(23) 88–85–7	Dinoseb	0.007
(24) 85–00–7	Diquat	0.02
(25) 145–73–3	Endothall	0.1
(26) 72–20–8	Endrin	0.002
(27) 1071–53–6	Glyphosate	0.7
(28) 118–74–1	Hexacholorbenzene	0.001
(29) 77–47–4	Hexachlorocyclopentadiene	0.05
(30) 23135–22–0	Oxamyl (Vydate)	0.2
(31) 1918–02–1	Picloram	0.5
(32) 122–34–9	Simazine	0.004
(33) 1746–01–6	2,3,7,8–TCDD (Dioxin)	3×10^{-8}

TABLE 4 TO PARAGRAPH (c)—MCLS AND HBWCS FOR PFAS

CAS. No.	Contaminant	MCL (mg/l) (unless otherwise noted)	HBWC (mg/l) for hazard index calculation
(34) Not applicable	Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA).	1 (unitless) [1]	Not applicable
(35) 122499–17–6	HFPO–DA	0.00001	0.00001
(36) 45187–15–3	PFBS	No individual MCL	0.002
(37) 108427–53–8	PFHxS	0.00001	0.00001
(38) 72007–68–2	PFNA	0.00001	0.00001
(39) 45285–51–6	PFOA	0.0000040	Not applicable

TABLE 4 TO PARAGRAPH (c)—MCLS AND HBWCS FOR PFAS—Continued

CAS. No.	Contaminant	MCL (mg/l) (unless otherwise noted)	HBWC (mg/l) for hazard index calculation
(40) 45298–90–6	PFOS	0.0000040	Not applicable

[1] The PFAS Mixture Hazard Index (HI) is the sum of component hazard quotients (HQs), which are calculated by dividing the measured component PFAS concentration in water by the relevant health-based water concentration when expressed in the same units (shown in ng/l for simplification). The HBWC for PFHxS is 10 ng/l; the HBWC for HFPO–DA is 10 ng/l; the HBWC for PFNA is 10 ng/l; and the HBWC for PFBS is 2000 ng/l.

$$\text{Hazard Index} = \left(\frac{[\text{HFPO–DA}_{\text{water}}\ \text{ng/l}]}{[10\ \text{ng/l}]}\right) + \left(\frac{[\text{PFBS}_{\text{water}}\ \text{ng/l}]}{[2000\ \text{ng/l}]}\right) + \left(\frac{[\text{PFNA}_{\text{water}}\ \text{ng/l}]}{[10\ \text{ng/l}]}\right) + \left(\frac{[\text{PFHxS}_{\text{water}}\ \text{ng/l}]}{[10\ \text{ng/l}]}\right)$$

HBWC = health-based water concentration
HQ = hazard quotient
ng/l = nanograms per liter
$\text{PFAS}_{\text{water}}$ = the concentration of a specific PFAS in water

(d) The Administrator, pursuant to section 1412 of the Act, hereby identifies in table 5 to this paragraph (d) the best technology, treatment technique, or other means available for achieving compliance with the maximum contaminant levels for all regulated PFAS identified in paragraph (c) of this section:

TABLE 5 TO PARAGRAPH (d)—BEST AVAILABLE TECHNOLOGIES FOR PFAS LISTED IN PARAGRAPH (c) OF THIS SECTION

Contaminant	BAT
Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA)	Anion exchange, GAC, reverse osmosis, nanofiltration.
HFPO–DA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFHxS	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFNA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFOA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFOS	Anion exchange, GAC, reverse osmosis, nanofiltration.

(e) The Administrator, pursuant to section 1412 of the Act, hereby identifies in table 6 to this paragraph (e) the affordable technology, treatment technique, or other means available to systems serving 10,000 persons or fewer for achieving compliance with the maximum contaminant levels for all regulated PFAS identified in paragraph (c) of this section:

TABLE 6 TO PARAGRAPH (e)—SMALL SYSTEM COMPLIANCE TECHNOLOGIES (SSCTS) FOR PFAS

Small system compliance technology [1]	Affordable for listed small system categories [2]
Granular Activated Carbon.	All size categories.
Anion Exchange	All size categories.
Reverse Osmosis, Nanofiltration [3].	3,301–10,000.

[1] Section 1412(b)(4)(E)(ii) of SDWA specifies that SSCTs must be affordable and technically feasible for small systems.

[2] The Act (ibid.) specifies three categories of small systems: (i) those serving 25 or more, but fewer than 501, (ii) those serving more than 500, but fewer than 3,301, and (iii) those serving more than 3,300, but fewer than 10,001.

[3] Technologies reject a large volume of water and may not be appropriate for areas where water quantity may be an issue.

■ 9. Amend § 141.151 by revising paragraph (d) to read as follows:

§ 141.151 Purpose and applicability of this subpart.

* * * * *

(d) For the purpose of this subpart, detected means: at or above the levels prescribed by § 141.23(a)(4) for inorganic contaminants, at or above the levels prescribed by § 141.24(f)(7) for the contaminants listed in § 141.61(a), at or above the levels prescribed by § 141.24(h)(18) for the contaminants listed in § 141.61(c) (except PFAS), at or above the levels prescribed by § 141.131(b)(2)(iv) for the contaminants or contaminant groups listed in § 141.64, at or above the levels prescribed by § 141.25(c) for radioactive contaminants, and at or above the levels prescribed in § 141.902(a)(5) for PFAS listed in § 141.61(c).

* * * * *

■ 10. Amend § 141.153 by adding paragraph (c)(3)(v) to read as follows:

§ 141.153 Content of the reports.

* * * * *

(c) * * *

(3) * * *

(v) *Hazard Index or HI.* The Hazard Index is an approach that determines the health concerns associated with mixtures of certain PFAS in finished drinking water. Low levels of multiple PFAS that individually would not likely result in adverse health effects may pose health concerns when combined in a mixture. The Hazard Index MCL represents the maximum level for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS allowed in water delivered by a public water system. A Hazard Index greater than 1 requires a system to take action.

* * * * *

■ 11. Amend appendix A to subpart O, under the Contaminant heading ''Synthetic organic contaminants including pesticides and herbicides:'', by adding in alphabetical order entries for ''Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA) (unitless)'', ''HFPO–DA (ng/l)'', ''PFHxS (ng/l)'', ''PFNA (ng/l)'', ''PFOA (ng/l)'', and ''PFOS (ng/l)'' to read as follows:

Appendix A to Subpart O of Part 141—Regulated Contaminants

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
*	*	*	*	*	*	*
Synthetic organic contaminants including pesticides and herbicides:	*	*	*	*	*	*
*	*	*	*	*	*	*
Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA) (unitless).	1 (unitless)	.....	1	1	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Per- and polyfluoroalkyl substances (PFAS) can persist in the human body and exposure may lead to increased risk of adverse health effects. Low levels of multiple PFAS that individually would not likely result in increased risk of adverse health effects may result in adverse health effects when combined in a mixture. Some people who consume drinking water containing mixtures of PFAS in excess of the Hazard Index (HI) MCL may have increased health risks such as liver, immune, and thyroid effects following exposure over many years and developmental and thyroid effects following repeated exposure during pregnancy and/or childhood.
*	*	*	*	*	*	*
HFPO–DA (ng/l).	0.00001	1,000,000	10	10	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing HFPO–DA in excess of the MCL over many years may have increased health risks such as immune, liver, and kidney effects. There is also a potential concern for cancer associated with HFPO–DA exposure. In addition, there may be increased risks of developmental effects for people who drink water containing HFPO–DA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
*	*	*	*	*	*	*
PFHxS (ng/l)	0.00001	1,000,000	10	10	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing PFHxS in excess of the MCL over many years may have increased health risks such as immune, thyroid, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFHxS in excess of the MCL following repeated exposure during pregnancy and/or childhood.
PFNA (ng/l) ...	0.00001	1,000,000	10	10	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing PFNA in excess of the MCL over many years may have increased health risks such as elevated cholesterol levels, immune effects, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFNA in excess of the MCL following repeated exposure during pregnancy and/or childhood.
PFOA (ng/l) ...	0.0000040	1,000,000	4.0	0	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing PFOA in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including kidney and testicular cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
PFOS (ng/l) ...	0.0000040	1,000,000	4.0	0	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing PFOS in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including liver cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOS in excess of the MCL following repeated exposure during pregnancy and/or childhood.
*	*	*	*	*	*	*

* * * * *

■ 12. Amend appendix A to subpart Q by:

■ a. Adding under the Contaminant heading ''D. Synthetic Organic Chemicals (SOCs)'' entries for ''31'', ''32'', ''33'', ''34'', ''35'', and ''36'' in numerical order;

■ b. Adding, immediately before footnote 1, footnote *; and

■ c. Adding footnote 23 at the end of the table.

The additions read as follows:

Appendix A to Subpart Q of Part 141—NPDWR Violations and Other Situations Requiring Public Notice [1]

Contaminant	MCL/MRDL/TT violations [2]		Monitoring & testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
* * * * *	*		*	*
D. Synthetic Organic Chemicals (SOCs)				
* * * * *	*		*	*
31. Hazard Index PFAS	[23] *2	141.61(c)	3	141.905(c)
32. HFPO–DA	*2	141.61(c)	3	141.905(c)
33. PFHxS	*2	141.61(c)	3	141.905(c)
34. PFNA	*2	141.61(c)	3	141.905(c)
35. PFOA	*2	141.61(c)	3	141.905(c)
36. PFOS	*2	141.61(c)	3	141.905(c)
* * * * *	*		*	*

Appendix A—Endnotes

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*Beginning April 26, 2029.

[1] Violations and other situations not listed in this table (*e.g.,* failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (*e.g.,* Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under § 141.202(a) and § 141.203(a).

[2] MCL—Maximum contaminant level, MRDL—Maximum residual disinfectant level, TT—Treatment technique.

* * * * * * *

[23] Systems that violate the Hazard Index MCL and one or more individual MCLs based on the same contaminants may issue one notification to satisfy the public notification requirements for multiple violations pursuant to § 141.203.

■ 13. Amend appendix B to subpart Q by redesignating entries ''55'' through ''89'' as entries ''61'' through ''95'' and adding new entries ''55'' through ''60'' under the heading ''E. Synthetic Organic Chemicals (SOCs)'' to read as follows:

Appendix B to Subpart Q of Part 141—Standard Health Effects Language for Public Notification

Contaminant	MCLG [1] mg/L	MCL [2] mg/L	Standard health effects language for public notification
*	*	*	* * * * *
E. Synthetic Organic Chemicals (SOCs)			
*	*	*	* * * * *
55. Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA).	1 (unitless)	1 (unitless)	Per- and polyfluoroalkyl substances (PFAS) can persist in the human body and exposure may lead to increased risk of adverse health effects. Low levels of multiple PFAS that individually would not likely result in increased risk of adverse health effects may result in adverse health effects when combined in a mixture. Some people who consume drinking water containing mixtures of PFAS in excess of the Hazard Index (HI) MCL may have increased health risks such as liver, immune, and thyroid effects following exposure over many years and developmental and thyroid effects following repeated exposure during pregnancy and/or childhood.
56. HFPO–DA	0.00001	0.00001	Some people who drink water containing HFPO–DA in excess of the MCL over many years may have increased health risks such as immune, liver, and kidney effects. There is also a potential concern for cancer associated with HFPO–DA exposure. In addition, there may be increased risks of developmental effects for people who drink water containing HFPO–DA in excess of the MCL following repeated exposure during pregnancy and/or childhood.
57. PFHxS	0.00001	0.00001	Some people who drink water containing PFHxS in excess of the MCL over many years may have increased health risks such as immune, thyroid, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFHxS in excess of the MCL following repeated exposure during pregnancy and/or childhood.
58. PFNA	0.00001	0.00001	Some people who drink water containing PFNA in excess of the MCL over many years may have increased health risks such as elevated cholesterol levels, immune effects, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFNA in excess of the MCL following repeated exposure during pregnancy and/or childhood.
59. PFOA	Zero	0.0000040	Some people who drink water containing PFOA in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including kidney and testicular cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOA in excess of the MCL following repeated exposure during pregnancy and/or childhood.
60. PFOS	Zero	0.0000040	Some people who drink water containing PFOS in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including liver cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOS in excess of the MCL following repeated exposure during pregnancy and/or childhood.
*	*	*	* * * * *
*	*	*	* * * * *

[1] MCLG—Maximum contaminant level goal.
[2] MCL—Maximum contaminant level.

* * * * *

■ 14. Amend appendix C to subpart Q by adding entries for the acronyms ''HI'' and ''PFAS'' in alphabetical order to read as follows:

Appendix C to Subpart Q of Part 141—List of Acronyms Used in Public Notification Regulation

* * * * *

HI Hazard Index

* * * * *

PFAS Per- and Polyfluoroalkyl Substances

* * * * *

■ 15. Add subpart Z to read as follows:

Subpart Z—Control of Per- and Polyfluoroalkyl Substances (PFAS)

Sec.

Subpart Z—Control of Per- and Polyfluoroalkyl Substances (PFAS)

§ 141.900 General requirements.

(a) The requirements of this subpart constitute the national primary drinking water regulations for PFAS. Each community water system (CWS) and non-transient, non-community water system (NTNCWS) must meet the requirements of this subpart including the maximum contaminant levels for the PFAS identified in § 141.61(c).

(b) The deadlines for complying with the provisions of this subpart are as follows:

(1) Each system must meet the analytical requirements in § 141.901 by June 25, 2024.

(2) Each system must report the results of initial monitoring, as described in § 141.902(b)(1), to the State by April 26, 2027.

(3) Each system must meet the compliance monitoring requirements in § 141.902(b)(2) by April 26, 2027.

(4) Each system must meet the MCL compliance requirements in § 141.903 by April 26, 2029.

(5) Each system must meet the reporting and recordkeeping requirements in § 141.904 by April 26, 2027.

(6) Violations described in § 141.905 include monitoring and reporting violations and violations of MCLs. Monitoring and reporting violations may be assessed beginning on April 26, 2027. MCL violations may be assessed beginning on April 26, 2029.

§ 141.901 Analytical requirements.

(a) *General.* (1) Systems must use only the analytical methods specified in this section to demonstrate compliance with the requirements of this subpart.

(2) The following documents are incorporated by reference with the approval of the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the EPA and at the National Archives and Records Administration (NARA). Contact the EPA's Drinking Water Docket at: 1301 Constitution Avenue NW., EPA West, Room 3334, Washington, DC 20460; phone: 202–566–2426. 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*. The material may be obtained from the EPA at 1301 Constitution Avenue NW, the EPA West, Room 3334, Washington, DC 20460; phone: 202–566–2426; website: *https://www.epa.gov/pfas/epa-pfas-drinking-water-laboratory-methods*.

(i) EPA Method 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry, 815–B–19–020, November 2019.

(ii) Method 537.1, Version 2.0: Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS), EPA/600/R–20/006, March 2020.

(b) *PFAS*–(1) *Analytical methods.* Systems must measure regulated PFAS by the methods listed in the following table:

TABLE 1 TO PARAGRAPH (b)(1)—ANALYTICAL METHODS FOR PFAS CONTAMINANTS

Contaminant	Methodology	EPA method (incorporated by reference, see paragraph (a) of this section)
Perfluorobutane Sulfonate (PFBS)	SPE LC–MS/MS	533, 537.1, version 2.0.
Perfluorohexane Sulfonate (PFHxS)	SPE LC–MS/MS	533, 537.1, version 2.0.
Perfluorononanoate (PFNA)	SPE LC–MS/MS	533, 537.1, version 2.0.
Perfluorooctanesulfonic Acid (PFOS)	SPE LC–MS/MS	533, 537.1, version 2.0.
Perfluorooctanoic Acid (PFOA)	SPE LC–MS/MS	533, 537.1, version 2.0.
2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy)propanoate (HFPO–DA or GenX Chemicals).	SPE LC–MS/MS	533, 537.1, version 2.0.

(2) *Laboratory certification.* Analyses under this section for regulated PFAS must only be conducted by laboratories that have been certified by EPA or the State. To receive certification to conduct analyses for the regulated PFAS, the laboratory must:

(i) Analyze Performance Evaluation (PE) samples that are acceptable to the State at least once during each consecutive 12-month period by each method for which the laboratory desires certification.

(ii) Beginning June 25, 2024, achieve quantitative results on the PE sample analyses that are within the following acceptance limits:

TABLE 2 TO PARAGRAPH (b)(2)(ii)—ACCEPTANCE LIMITS FOR PFAS PERFORMANCE EVALUATION SAMPLES

Contaminant	Acceptance limits (percent of true value)
Perfluorobutane Sulfonate (PFBS)	70–130
Perfluorohexane Sulfonate (PFHxS)	70–130
Perfluorononanoate (PFNA)	70–130
Perfluorooctanesulfonic Acid (PFOS)	70–130
Perfluorooctanoic Acid (PFOA)	70–130
2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy)propanoate (HFPO–DA or GenX Chemicals)	70–130

(iii) For all samples analyzed for regulated PFAS in compliance with § 141.902, beginning June 25, 2024, report data for concentrations as low as the trigger levels as defined in § 141.902(a)(5).

§ 141.902 Monitoring requirements.

(a) *General requirements.* (1) Systems must take all samples during normal operating conditions at all entry points to the distribution system.

(2) If the system draws water from more than one source and the sources are combined before distribution, the system must sample at an entry point to the distribution system during periods of representative operating conditions.

(3) Systems must use only data collected under the provisions of this subpart to qualify for reduced monitoring.

(4) All new systems that begin operation after, or systems that use a new source of water after April 26, 2027, must demonstrate compliance with the MCLs within a period of time specified by the State. A system must also comply with initial sampling frequencies required by the State to ensure that the system can demonstrate compliance with the MCLs. Compliance monitoring frequencies must be conducted in accordance with the requirements in this section.

(5) For purposes of this section, the trigger levels are defined as shown in the following table.

TABLE 1 TO PARAGRAPH (a)(5)—TRIGGER LEVELS FOR PFAS CONTAMINANTS

Contaminant	Trigger level
Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, PFNA).	0.5 (unitless).
HFPO–DA	5 nanograms per liter (ng/l).
PFHxS	5 ng/l.
PFNA	5 ng/l.
PFOA	2.0 ng/l.
PFOS	2.0 ng/l.

(6) Based on initial monitoring results, for each sampling point at which a regulated PFAS listed in § 141.61(c) is detected at a level greater than or equal to the trigger level, the system must monitor quarterly for all regulated PFAS beginning April 26, 2027, in accordance with paragraph (b)(2) of this section.

(7) For purposes of this section, each water system must ensure that all results provided by a laboratory are reported to the State and used for determining the required sampling frequencies. This includes values below the practical quantitation levels defined in § 141.903(f)(1)(iv); zero must not be used in place of reported values.

(b) *Monitoring requirements for PFAS*—(1) *Initial monitoring.* (i) Groundwater CWS and NTNCWS serving greater than 10,000 persons and all surface water CWS and NTNCWS must take four consecutive samples 2 to 4 months apart within a 12-month period (quarterly samples) for each regulated PFAS listed in § 141.61(c).

(ii) All groundwater CWS and NTNCWS serving 10,000 or fewer persons must take two samples for each regulated PFAS listed in § 141.61(c) five to seven months apart within a 12-month period.

(iii) All groundwater under the direct influence of surface water (GWUDI) CWS and NTNCWS must follow the surface water CWS and NTNCWS monitoring schedule in paragraph (b)(1)(i) of this section.

(iv) All systems that use both surface water and groundwater must apply the requirements in paragraphs (b)(1)(i) through (iii) of this section depending on the source(s) of water provided at a given entry point to the distribution system (EPTDS). If the EPTDS provides surface water, the requirements for a surface water CWS/NTNCWS apply. If the EPTDS provides groundwater, the requirements for a groundwater CWS/NTNCWS apply, based on system size. If an EPTDS provides a blend of surface water and groundwater, the requirements for a surface water system apply. For systems that change the source water type at an EPTDS during the initial monitoring period (*i.e.,* one part of the year it is surface water and the remaining part of the year it is groundwater), the sampling requirements for a surface water system apply.

(v) Systems must monitor at a frequency indicated in the following table, though a State may require more frequent monitoring on a system-specific basis:

TABLE 2 TO PARAGRAPH (b)(1)(v)—INITIAL MONITORING REQUIREMENTS

Type of system	Minimum monitoring frequency	Sample location
Groundwater CWS and NTNCWS serving greater than 10,000 persons, all surface water CWS and NTNCWS, and all GWUDI systems.	Four consecutive quarters of samples per entry point to the distribution system (EPTDS) within a 12-month period, unless the exception in paragraph (b)(1)(viii) of this section applies. Samples must be taken two to four months apart..	Sampling point for EPTDS.
Groundwater CWS and NTNCWS serving 10,000 or fewer persons.	Two consecutive samples per EPTDS within a 12-month period, unless the exception in paragraph (b)(1)(viii) of this section applies. Samples must be taken five to seven months apart..	Sampling point for EPTDS.

(vi) A State may accept data that has been previously acquired by a water system to count toward the initial monitoring requirements if the data meet the requirements of § 141.901(b)(1), samples were collected starting on or after January 1, 2019, and otherwise meet the timing requirements specified in table 2 to paragraph (b)(1)(v) of this section. For the purposes of satisfying initial monitoring requirements, acceptable data may be reported to a concentration no greater than the MCLs. However, a system is only eligible for triennial monitoring at the start of the compliance monitoring period if the system demonstrates that concentrations in all samples it uses to satisfy the initial monitoring requirements are below the trigger levels as defined in paragraph (a)(5) of this section.

(vii) If systems have multiple years of data, the most recent data must be used.

(viii) For systems using previously acquired data that have fewer than the number of samples required in a continuous 12-month period for initial monitoring as listed in table 2 to paragraph (b)(1)(v) of this section: All surface water systems, GWUDI systems, and groundwater systems serving greater than 10,000 persons must collect in a calendar year one sample in each quarter that was not represented, two to four months apart from the months with available data; All groundwater systems serving 10,000 or fewer persons must collect one sample in the month that is five to seven months apart from the month in which the previous sample was taken.

(ix) In determining the most recent data to report, a system must include all results provided by a laboratory whether above or below the practical quantitation levels. These results must be used for the purposes of determining the frequency with which a system must monitor at that sampling point at the start of the compliance monitoring period.

(x) States may delete results of obvious sampling errors. If the State deletes a result because of an obvious sampling error and the system fails to collect another sample this is a monitoring violation as described in § 141.905(c).

(xi) Initial monitoring requirements, including reporting results to the State, must be completed by April 26, 2027.

(2) *Compliance monitoring.* (i) Based on initial monitoring results, at the start of the monitoring period that begins on April 26, 2027, systems may reduce monitoring at each sampling point at which all reported sample concentrations were below all trigger levels defined in paragraph (a)(5) of this section, unless otherwise provided for by the State. At eligible sampling points,

each water system must analyze one sample for all regulated PFAS during each three-year monitoring period, at a time specified by the State, in the quarter in which the highest analytical result was detected during the most recent round of quarterly or semi-annual monitoring. If a sampling point is not eligible for triennial monitoring, then the water system must monitor quarterly at the start of the compliance monitoring period.

(ii) If, during the compliance monitoring period, a system is monitoring triennially and a PFAS listed in § 141.61(c) is detected at a level equal to or exceeding the trigger levels defined in paragraph (a)(5) of this section in any sample, then the system must monitor quarterly for all regulated PFAS beginning in the next quarter at the sampling point. The triggering sample must be used as the first quarter of monitoring for the running annual average calculation.

(iii) For all source water types, a State may determine that all regulated PFAS at a sampling point are reliably and consistently below the MCL after considering, at a minimum, four consecutive quarterly samples collected during the compliance monitoring period. A sampling point that a State has determined to be reliably and consistently below the MCL is required to collect annual samples for at least the first three years after that determination is made. Annual samples must be collected in the quarter in which detected concentrations were highest during the most recent year of quarterly monitoring. If, after three consecutive years, annual samples all contain results that are below the trigger levels defined in paragraph (a)(5) of this section, the State may allow a system to begin triennial monitoring at the sampling point. The water system must collect triennial samples in the quarter with the highest concentrations during the most recent round of quarterly sampling. If an annual sample meets or exceeds an MCL or the State determines that the result is not reliably and consistently below the MCL for all regulated PFAS, then the system must monitor quarterly for all regulated PFAS beginning in the next quarter at the sampling point.

(iv) The three different compliance monitoring sampling schedules that may be assigned and the criteria for each are summarized in the following table:

Table 3 to paragraph (b)(2)(iv)—Compliance Monitoring Schedules and Requirements

Sampling frequency	Eligibility requirements [1]	Sample timing requirements
Triennial	At an individual sampling point, either: (1) All initial monitoring results demonstrate concentrations of all regulated PFAS below trigger levels;. (2) The most recent three consecutive annual monitoring results all demonstrated concentrations of all regulated PFAS below trigger levels; or. (3) The previous triennial sample demonstrated all regulated PFAS concentrations below trigger levels.. **Note:** After beginning compliance monitoring, a system may not transition directly from quarterly monitoring to triennial monitoring..	Sample must be collected at a time within the three-year period designated by the State, in the quarter that yielded the highest analytical result during the most recent round of quarterly sampling (or the most recent semi-annual sampling, if no quarterly sampling has occurred).
Annual	A State makes a determination that all regulated PFAS concentrations at the sampling point are reliably and consistently below PFAS MCLs, after considering, at a minimum, 4 consecutive quarterly samples collected during the compliance monitoring period..	Sample must be collected at a time designated by the State, within the quarter that yielded the highest analytical result during the most recent round of quarterly sampling.
Quarterly	At an individual sampling point, either: (1) Any regulated PFAS concentration meets or exceeds a trigger level during initial monitoring;. (2) Sampling is occurring quarterly during compliance monitoring and a State has not made a determination that all levels of regulated PFAS at the sampling point are reliably and consistently below the regulated PFAS MCLs; or. (3) A sample collected by a system required to conduct triennial monitoring contains regulated PFAS concentrations that meet or exceed trigger levels. The first of these samples meeting or exceeding the trigger level is considered the first quarterly sample.. (4) A sample collected by a system required to conduct annual monitoring contains regulated PFAS concentrations that meet or exceed an MCL. The first of these samples meeting or exceeding the MCL is considered the first quarterly sample..	Samples must be collected in four consecutive quarters, on dates designated by the State.

[1] The monitoring frequency at a sampling point must be the same for all regulated PFAS and is determined based on the most frequent sampling required for any regulated PFAS detected at a level at or exceeding the trigger level.

(v) The State may require a confirmation sample for any sampling result. If a confirmation sample is required by the State, the system must average the result with the first sampling result and the average must be used for the determination of compliance with MCLs as specified by § 141.903. A State may delete results of obvious sampling errors from the MCL compliance calculations described in § 141.903. If the State deletes a result because of an obvious sampling error and the system fails to collect another sample this is a monitoring violation as described in § 141.905(c).

(vi) The State may increase the required monitoring frequency, where necessary, to detect variations within the system (*e.g.,* fluctuations in concentration due to seasonal use, changes in water source).

(vii) Each public water system must monitor at the time designated by the State within each monitoring period.

(viii) When a system reduces its sampling frequency to annual or triennial sampling, the next compliance sample must be collected in the monitoring period that begins the calendar year following State approval of a reduction in monitoring frequency.

§ 141.903 Compliance requirements.

(a) Compliance with MCLs for regulated PFAS in § 141.61(c) must be determined based on the analytical results obtained at each sampling point.

(b) For systems monitoring quarterly, compliance with the MCL is determined by the running annual average at each sampling point.

(c) If a system fails to collect the required number of samples specified in § 141.902, this is a monitoring violation as described in § 141.905(c), and compliance calculations must be based on the total number of samples collected.

(d) Systems monitoring triennially whose sample result equals or exceeds the trigger level of 2.0 ng/l for either PFOS or PFOA, 5 ng/l for HFPO–DA, PFHxS, or PFNA, or a Hazard Index of 0.5 for the Hazard Index PFAS, must begin quarterly sampling for all regulated PFAS in the next quarter at the sampling point. Systems monitoring annually whose sample result equals or exceeds the MCL of 4.0 ng/l for either PFOS or PFOA, 10 ng/l for HFPO–DA, PFHxS, or PFNA, or a Hazard Index of 1 for the Hazard Index PFAS, must begin quarterly sampling for all regulated PFAS in the next quarter at the sampling point.

(e) Except as provided in this paragraph (e), if a sample result exceeds an MCL, the system will not be considered in violation of the MCL until it has completed one year of quarterly sampling at the sampling point with the triggering sample used as the first quarter of monitoring for the running annual average calculation. However, whenever a sample result in any quarter (or quarterly average, if more than one compliance sample is available in a quarter because a confirmation sample was required by the State) causes the running annual average to exceed the MCL at a sampling point regardless of the subsequent quarterly monitoring results required to complete a full year of monitoring (*e.g.,* the results from a single sample are more than 4 times the MCL), the system is out of compliance with the MCL immediately.

(f) Systems must calculate compliance using the following method to determine MCL compliance at each sampling point:

(1) For each PFAS regulated by an individual MCL:

(i) For systems monitoring quarterly, divide the sum of the measured quarterly concentrations for each analyte by the number of quarters samples were collected for that analyte during the consecutive quarters included in the calculation. If more than one compliance sample for that analyte is available in a quarter because a confirmation sample was required by the State, systems must average all the results in a quarter then average the quarterly averages. Rounding does not occur until the end of the calculation. If the running annual average exceeds the MCL, the system is not in compliance with the MCL requirements.

(ii) For systems monitoring annually, if the concentration measured is equal to or exceeds an MCL for regulated PFAS, the system is required to initiate quarterly monitoring for all regulated PFAS beginning in the next quarter at the sampling point, with the triggering sample result used as the first quarter of monitoring for the running annual average calculation.

(iii) For systems monitoring triennially, if the concentration measured is equal to or exceeds the trigger level, the system is required to initiate quarterly monitoring for all regulated PFAS beginning in the next quarter at the sampling point, with the triggering sample result used as the first quarter of monitoring for the running annual average calculation.

(iv) For the purpose of calculating MCL compliance, if a sample result is less than the practical quantitation level (PQL) for a regulated PFAS, in accordance with the following table, zero is used for that analyte solely to calculate the running annual average.

TABLE 1 TO PARAGRAPH (f)(1)(iv)—PRACTICAL QUANTITATION LEVELS (PQLS) FOR PFAS CONTAMINANTS

Contaminant	PQL (in parts per trillion)
HFPO–DA	5.0
PFBS	3.0
PFHxS	3.0
PFNA	4.0
PFOA	4.0
PFOS	4.0

(2) For each PFAS regulated under the Hazard Index MCL:

(i) For systems monitoring quarterly, divide the observed sample analytical result for each analyte included in the Hazard Index by the corresponding HBWC listed in § 141.61(c) to obtain a hazard quotient for each analyte for each sampling event at each sampling point. Sum the resulting hazard quotients together to determine the Hazard Index for the quarter. If the State requires a confirmation sample for an analyte in the quarter, systems must average these results for each analyte in that quarter and then determine the hazard quotient(s) from those average values, then sum the hazard quotients. Once the Hazard Indices for the individual quarters are calculated, they are averaged to determine a running annual average. If the running annual average Hazard Index exceeds the MCL and two or more Hazard Index analytes had an observed sample analytical result at or above the PQL in any of the quarterly samples collected to determine the running annual average, the system is in violation of the Hazard Index MCL. No rounding occurs until after the running annual average Hazard Index is calculated.

(ii) If the Hazard Index calculated using the results of an annual sample equals or exceeds the Hazard Index MCL, the system must initiate quarterly sampling for all regulated PFAS beginning in the next quarter at the sampling point, with the triggering sample result used as the first quarter of monitoring.

(iii) If the Hazard Index calculated using the results of a triennial sample equals or exceeds the Hazard Index trigger level, the system must initiate quarterly sampling for all regulated PFAS beginning in the next quarter at the sampling point, with the triggering sample result used as the first quarter of monitoring.

(iv) If a sample result is less than the practical quantitation level for a regulated PFAS, in accordance with the table 1 to paragraph (f)(1)(iv) of this section, zero is used for that analyte solely to calculate the running annual average.

§ 141.904 Reporting and recordkeeping requirements.

Systems required to sample must report to the State according to the timeframes and provisions of § 141.31 and retain records according to the provisions in § 141.33.

(a) Systems must report the information from initial monitoring specified in the following table:

TABLE 1 TO PARAGRAPH (a)—DATA TO REPORT FROM INITIAL MONITORING

If you are a . . .	You must report . . .
System monitoring for regulated PFAS under the requirements of § 141.902(b)(1) on a quarterly basis.	1. All sample results, including the locations, number of samples taken at each location, dates, and concentrations reported. 2. Whether a trigger level, defined in § 141.902(a)(5), was met or exceeded in any samples.
System monitoring for regulated PFAS under the requirements of § 141.902(b)(1) less frequently than quarterly.	1. All sample results, including the locations, number of samples taken at each location, dates, and concentrations reported. 2. Whether a trigger level, defined in § 141.902(a)(5), was met or exceeded in any samples.

(b) Systems must report the information collected during the compliance monitoring period specified in the following table:

TABLE 2 TO PARAGRAPH (b)—DATA TO REPORT FROM COMPLIANCE MONITORING

If you are a . . .	You must report . . .
System monitoring for regulated PFAS under the requirements of § 141.902(b)(2) on a quarterly basis.	1. All sample results, including the locations, number of samples taken at each location, dates, and concentrations during the previous quarter. 2. The running annual average at each sampling point of all compliance samples. 3. Whether a trigger level, defined in § 141.902(a)(5), was met or exceeded in any samples. 4. Whether an MCL for a regulated PFAS in § 141.61(c) was met or exceeded in any samples. 5. Whether, based on § 141.903, an MCL was violated.
System monitoring for regulated PFAS under the requirements of § 141.902(b)(2) less frequently than quarterly.	1. All sample results, including the locations, number of samples taken at each location, dates, and concentrations during the previous monitoring period. 2. Whether a trigger level, defined in § 141.902(a)(5), was met or exceeded in any samples. 3. Whether an MCL for a regulated PFAS in § 141.61(c) was met or exceeded in any samples. 4. Whether, based on § 141.903, an MCL was violated (*e.g.,* the results from a single sample are more than 4 times the MCL).

§ 141.905 Violations.

(a) PFAS MCL violations, both for the individual PFOA, PFOS, HFPO–DA, PFHxS, and PFNA MCLs, as well as the Hazard Index MCL, as listed in § 141.61(c), are based on a running annual average, as outlined under § 141.903.

(b) Compliance with § 141.61(c) must be determined based on the analytical results obtained at each sampling point. If one sampling point is in violation of an MCL, the system is in violation of the MCL.

(c) Each failure to monitor in accordance with the requirements under § 141.902 is a monitoring violation.

(d) Failure to notify the State following a MCL violation and failure to submit monitoring data in accordance with the requirements of §§ 141.904 and 141.31 are reporting violations.

(e) Results for PFAS with individual MCLs as listed in § 141.61(c) are compared to their respective MCLs, and results for mixtures of two or more of the Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA) are compared to the Hazard Index MCL as listed in § 141.61(c). For determining compliance with the Hazard Index MCL, if only PFBS is reported at any concentration and no other regulated PFAS are in the mixture, it is not violation of the Hazard Index MCL. If only one of the other PFAS within the Hazard Index (HFPO–DA, PFHxS, and PFNA) is detected and the level of this PFAS exceeds its MCL as determined by § 141.903(f)(1)(i), only an individual MCL violation is assessed for the individual PFAS detected, and it is not a violation of the Hazard Index MCL. Exceedances of the Hazard Index caused by two or more of the Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA) and exceedances of one or more individual MCLs can result in multiple MCL exceedances. However, in this instance, for purposes of public notification under appendix A to subpart Q of this part, a PWS must only report the Hazard Index MCL exceedance.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

■ 16. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 17. Amend § 142.16 by adding paragraph (r) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(r) *Requirements for States to adopt 40 CFR part 141, subpart Z, PFAS.* In addition to the general primacy requirements elsewhere in this part, including the requirements that State regulations be at least as stringent as Federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subpart Z, must contain the following, in lieu of meeting the requirements of paragraph (e) of this section:

(1) The State's procedures for reviewing the water system's use of pre-existing data to meet the initial

monitoring requirements specified in § 141.902, including the criteria that will be used to determine if the data are acceptable. This paragraph (r)(1) is no longer applicable after the initial monitoring period ends on April 26, 2027.

(2) The State's procedures for ensuring all systems complete the initial monitoring period requirements that will result in a high degree of monitoring compliance by the regulatory deadlines. This paragraph (r)(2) is no longer applicable after the initial monitoring period ends on April 26, 2027.

(3) After the initial monitoring period, States establish the initial monitoring requirements for new public water systems and existing public water systems that plan to use a new source. States must explain their initial monitoring schedules and how these monitoring schedules ensure that new public water systems and existing public water systems that plan to use new sources comply with MCLs and monitoring requirements. States must also specify the time frame in which a new system or existing system that plans to use a new source must demonstrate compliance with the MCLs.

■ 18. Amend § 142.62 by revising and republishing paragraph (a) to read as follows:

§ 142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals.

(a) The Administrator, pursuant to section 1415(a)(1)(A) of the Act, hereby identifies the technologies listed in tables 1 and 2 to this paragraph (a) as the best available technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for the organic chemicals, including per- and polyfluoroalkyl substances (PFAS), listed in § 141.61(a) and (c) of this chapter, for the purposes of issuing variances and exemptions. A list of small system compliance technologies for the regulated PFAS for the purposes of providing variances and exemptions is provided in table 3 to this paragraph (a); for the purpose of this paragraph (a), small system is defined as a system serving 10,000 persons or fewer.

TABLE 1 TO PARAGRAPH (a)—BATS FOR PFAS LISTED IN § 141.61(c)

Contaminant	BAT
Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA)	Anion exchange, GAC, reverse osmosis, nanofiltration.
HFPO–DA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFHxS	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFNA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFOA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFOS	Anion exchange, GAC, reverse osmosis, nanofiltration.

TABLE 2 TO PARAGRAPH (a)—BATS FOR OTHER SYNTHETIC ORGANIC CONTAMINANTS LISTED IN § 141.61(c) AND VOLATILE ORGANIC CHEMICALS LISTED IN § 141.61(a)

Contaminant	Best available technologies		
	PTA [1]	GAC [2]	OX [3]
(1) Benzene	X	X	
(2) Carbon tetrachloride	X	X	
(3) 1,2-Dichloroethane	X	X	
(4) Trichloroethylene	X	X	
(5) para-Dichlorobenzene	X	X	
(6) 1,1-Dichloroethylene	X	X	
(7) 1,1,1-Trichloroethane	X	X	
(8) Vinyl chloride	X		
(9) cis-1,2-Dichloroethylene	X	X	
(10) 1,2-Dichloropropane	X	X	
(11) Ethylbenzene	X	X	
(12) Monochlorobenzene	X	X	
(13) o-Dichlorobenzene	X	X	
(14) Styrene	X	X	
(15) Tetrachloroethylene	X	X	
(16) Toluene	X	X	
(17) trans-1,2-Dichloroethylene	X	X	
(18) Xylense (total)	X	X	
(19) Alachlor		X	
(20) Aldicarb		X	
(21) Aldicarb sulfoxide		X	
(22) Aldicarb sulfone		X	
(23) Atrazine		X	
(24) Carbofuran		X	
(25) Chlordane		X	
(26) Dibromochloropropane	X	X	
(27) 2,4-D		X	
(28) Ethylene dibromide	X	X	
(29) Heptachlor		X	
(30) Heptachlor epoxide		X	
(31) Lindane		X	
(32) Methoxychlor		X	
(33) PCBs		X	
(34) Pentachlorophenol		X	

TABLE 2 TO PARAGRAPH (a)—BATS FOR OTHER SYNTHETIC ORGANIC CONTAMINANTS LISTED IN § 141.61(c) AND VOLATILE ORGANIC CHEMICALS LISTED IN § 141.61(a)—Continued

Contaminant	Best available technologies		
	PTA [1]	GAC [2]	OX [3]
(35) Toxaphene		X	
(36) 2,4,5-TP		X	
(37) Benzo[a]pyrene		X	
(38) Dalapon		X	
(39) Dichloromethane	X		
(40) Di(2-ethylhexyl)adipate	X	X	
(41) Di(2-ethylhexyl)phthalate		X	
(42) Dinoseb		X	
(43) Diquat		X	
(44) Endothall		X	
(45) Endrin		X	
(46) Glyphosate			X
(47) Hexachlorobenzene		X	
(48) Hexachlorocyclopentadiene	X	X	
(49) Oxamyl (Vydate)		X	
(50) Picloram		X	
(51) Simazine		X	
(52) 1,2,4-Trichlorobenzene	X	X	
(53) 1,1,2-Trichloroethane	X	X	
(54) 2,3,7,8-TCDD (Dioxin)		X	

[1] Packed Tower Aeration.
[2] Granular Activated Carbon.
[3] Oxidation (Chlorination or Ozonation).

TABLE 3 TO PARAGRAPH (a)—LIST OF SMALL SYSTEM COMPLIANCE TECHNOLOGIES (SSCTS) [1] FOR PFAS LISTED IN § 141.61(c)

Small system compliance technologies	Affordable for listed small system categories [2]
Anion Exchange	All size categories.
GAC	All size categories.
Reverse Osmosis,[3] Nanofiltration [3].	3,301–10,000.

[1] Section 1412(b)(4)(E)(ii) of SDWA specifies that SSCTs must be affordable and technically feasible for small systems.
[2] The Act (ibid.) specifies three categories of small systems: (i) those serving 25 or more, but fewer than 501, (ii) those serving more than 500, but fewer than 3,301, and (iii) those serving more than 3,300, but fewer than 10,001.
[3] Technologies reject a large volume of water and may not be appropriate for areas where water quantity may be an issue.

* * * * *

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Part III

Department of Transportation

14 CFR Parts 259, 260, 262, et al.
Refunds and Other Consumer Protections; Final Rule

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 259, 260, 262, and 399

[Docket No. DOT–OST–2022–0089 and DOT–OST–2016–0208]

RIN 2105–AF04

Refunds and Other Consumer Protections

AGENCY: Office of the Secretary (OST), Department of Transportation.

ACTION: Final rule.

SUMMARY: The U.S. Department of Transportation (Department or DOT) is requiring automatic refunds to consumers when a U.S. air carrier or a foreign air carrier cancels or makes a significant change to a scheduled flight to, from, or within the United States and the consumer is not offered or rejects alternative transportation and travel credits, vouchers, or other compensation. These automatic refunds must be provided promptly, *i.e.,* within 7 business days for credit card payments and within 20 calendar days for other forms of payment. To ensure consumers know when they are entitled to a refund, the Department is requiring carriers and ticket agents to inform consumers of their right to a refund if that is the case before making an offer for alternative transportation, travel credits, vouchers, or other compensation in lieu of refunds. Also, the Department is defining, for the first time, the terms ''significant change'' and ''cancellation'' to provide clarity and consistency to consumers with respect to their right to a refund. The Department is also requiring refunds to consumers for fees for ancillary services that passengers paid for but did not receive and for checked baggage fees if the bag is significantly delayed. For consumers who are unable to or advised not to travel as scheduled on flights to, from, or within the United States because of a serious communicable disease, the Department is requiring that carriers provide travel vouchers or credits that are transferrable and valid for at least 5 years from the date of issuance. Carriers may require consumers to provide documentary evidence demonstrating that they are unable to travel or have been advised not to travel to support their request for a travel voucher or credit, unless the Department of Health and Human Services (HHS) publishes guidance declaring that requiring such documentary evidence is not in the public interest.

DATES: This rule is effective June 25, 2024. Upon OMB approval of the information collection established in this final rule, the Department will publish a separate notice announcing the effective date of the collection.

FOR FURTHER INFORMATION CONTACT: Clereece Kroha or Blane Workie, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC, 20590, 202–366–9342 (phone), *clereece.kroha@dot.gov* or *blane.workie@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

Executive Summary

(1) Purpose of the Regulatory Action

The purpose of this final rule is to ensure that consumers are treated fairly when they do not receive service that they paid for or are unable or advised not to travel because of a serious communicable disease. This rule responds to Executive Order 14036 on Promoting Competition in the American Economy (E.O. 14036), which was issued on July 9, 2021.[1] The Executive Order launched a whole-of-government approach to strengthen competition and requires the Department to take various actions to promote the interests of American consumers, workers, and businesses.

Section 5, paragraph(m)(i)(C) of E.O. 14036 directs the Department to submit a report to the White House Competition Council on the progress of its investigatory and enforcement activities to address the failure of airlines to provide timely refunds for flights cancelled as a result of the COVID–19 pandemic. The Department submitted its report to the White House in September 2021.[2] In that report, the Department explained that the lack of definition regarding cancelled or significantly changed flights had resulted in inconsistency among carriers on when passengers are entitled to a refund. The Department also noted that approximately 20% of the refund complaints received during the first 18 months of the COVID–19 pandemic involved instances in which passengers with non-refundable tickets chose not to travel given the COVID–19 pandemic and stated that it planned to address protections for these consumers in a rulemaking.[3]

The Executive Order in Section 5, paragraph(m)(i)(D) further directs the Department to publish a notice of proposed rulemaking requiring airlines to refund baggage fees when a passenger's luggage is substantially delayed and to refund other ancillary fees when passengers pay for a service that is not provided.

(2) Background

The FAA Extension, Safety, and Security Act of 2016 (FAA Extension Act or Act) requires the Department to issue a rule mandating that airlines provide refunds to passengers for any fee charged to transport a checked bag if the bag is delayed as specified in the Act.[4] On October 31, 2016, the Department published an advance notice of proposed rulemaking (ANPRM) seeking comment on various issues related to the requirement for airlines to refund checked baggage fees when they fail to deliver the bags in a timely manner as provided by the FAA Extension Act.[5] On July 21, 2021, the Department published a notice of proposed rulemaking titled ''Refunding Fees for Delayed Checked Bags and Ancillary Services That Are Not Provided'' (Ancillary Fee Refund NPRM).[6] Among other things, the Ancillary Fee Refund NPRM proposed that U.S. and foreign air carriers refund the baggage fee paid for a checked bag when they fail to deliver the bag to the passenger within 12 hours of the arrival of a domestic flight and within 25 hours of the arrival of an international flight. This NPRM further proposed ways to measure the length of the baggage delivery delay for the purpose of determining whether a refund is due. In addition, the Ancillary Fee Refund NPRM also proposed to implement a provision in the FAA Reauthorization Act of 2018 regarding refunding fees for ancillary services that are paid for but not provided.[7]

The Department received a total of 29 comments on the Ancillary Fee Refund NPRM—three comments from consumer rights advocacy groups,[8] 16 comments from U.S. and foreign airlines and airline trade associations,[9] three

[1] Exec. Order No. 14036, 86 FR 36987 (Jul. 9, 2021).

[2] Report to the White House Competition Council: U.S. Department of Transportation's Investigatory, Enforcement and Other Activities Addressing Lack of Timely Airline Ticket Refunds Associated with the COVID–19 Pandemic (Refund Report) (September 9, 2021) at *https://www.transportation.gov/individuals/aviation-consumer-protection/dot-report-airline-ticket-refunds.*

[3] Refund Report at pages 11–12.

[4] See FAA Extension, Safety, and Security Act of 2016, Pub. L. 114–190, July 15, 2016; 49 U.S.C. 41704 note.

[5] 81 FR 75347 (October 31, 2016).

[6] 86 FR 38420 (July 21, 2021).

[7] 49 U.S.C. 42301 note prec.

[8] Business Travel Coalition et. al., FlyersRights.org, and Travelers United.

[9] Airlines for America, International Air Transport Association, Arab Air Carriers'

comments from ticket agent trade associations,[10] five comments from individual consumers, one comment from the Colorado Attorney General, and one comment from an ancillary service provider.[11] Overall, the commenters provided various suggestions on how the Department should interpret and implement the statutory mandate. Airlines asserted they would face challenges to comply with certain aspects of the proposed baggage delivery deadlines and other requirements, while consumers and ticket agents supported a more stringent standard under which a refund of baggage fees is due.

In a separate effort to enhance air travel consumer protection, on August 22, 2022, the Department published in the **Federal Register** a notice of proposed rulemaking titled ''Airline Ticket Refunds and Consumer Protections'' (Ticket Refund NPRM) to propose measures to enhance protections for consumers when airlines cancel or make significant changes to the scheduled itineraries to, from, or within the United States.[12] Currently, the Department's regulations in 14 CFR part 259 require that airlines provide prompt refunds ''when ticket refunds are due.'' Further, the Department's regulations in 14 CFR part 399 require that ticket agents ''make proper refunds promptly when service cannot be performed as contracted.'' The Department's Office of Aviation Consumer Protection has interpreted these requirements and its statutory authority to prohibit unfair and deceptive practices as mandating airlines and ticket agents provide prompt refunds to passengers of both the airfare and fees for prepaid ancillary service fees if a flight is cancelled or significantly changed and the passenger does not continue his or her travel. The Ticket Refund NPRM proposed to codify the interpretation that when carriers cancel flights or make significant changes to flight itineraries and the contracted service is not provided, ticket refunds are due if consumers do not accept the alternative transportation offered by carriers or ticket agents. It also proposed to define ''significant change of flight itinerary'' and ''cancelled flight'' to protect consumers and ensure consistency among carries and ticket agents regarding when passengers are entitled to refunds.

The Ticket Refund NPRM also proposed to require airlines and ticket agents to issue non-expiring travel credits or vouchers, and under certain circumstances, refunds in lieu of the travel credits or vouchers, to consumers when they: (1) are restricted or prohibited from traveling by a governmental entity due to a serious communicable disease (*e.g.,* as a result of a stay at home order, entry restriction, or border closure); (2) are advised by a medical professional or determine consistent with public health guidance issued by the Centers for Disease Control and Prevention (CDC), comparable agencies in other countries, or the World Health Organization (WHO) not to travel during a public health emergency to protect themselves from a serious communicable disease; or (3) are advised by a medical professional or determine consistent with public health guidance issued by CDC, comparable agencies in other countries, or WHO not to travel, irrespective of any declaration of a public health emergency, because they have or may have contracted a serious communicable disease and their condition would pose a direct threat to the health of others. Under the Department's current regulations, there is no requirement for an airline or a ticket agent to issue a refund or travel credit to a passenger holding a non-refundable ticket when the airline operated the flight and the passenger does not travel, regardless of the reason that the passenger does not travel. The Ticket Refund NPRM's proposals were intended to protect consumers' financial interests when the disruptions to their travel plans were caused by public health concerns beyond their control, and also to promote safe and adequate air transportation by incentivizing individuals to postpone travel when they are advised by a medical professional or determine, consistent with public health guidance, not to travel to protect themselves from a serious communicable disease or because they have or may have a serious communicable disease that would pose a threat to others.

Between August 2022 and January 2023, the Aviation Consumer Protection Advisory Committee (ACPAC) [13] devoted substantial time in three separate meetings to discuss the Ticket Refund NPRM. At an all-day public meeting on August 22, 2022, the ACPAC heard the perspectives of consumer advocates, airline and ticket agent representatives, and members of the public. Then, on December 9, 2022, the ACPAC identified and deliberated on potential recommendations on the Ticket Refund NPRM. The ACPAC voted on these recommendations at a meeting held on January 12, 2023.

The Department initially provided a comment period of 90 days on the Ticket Refund NPRM (*i.e.,* until November 21, 2022). In September 2022, Airlines for America (A4A), the International Air Transport Association (IATA), the Travel Technology Association (Travel Tech), the American Society of Travel Advisors (ASTA), and the Travel Management Coalition requested an extension of the comment period.[14] The Department extended the comment period to December 16, 2022. In extending the comment period for an additional 25 days, the Department acknowledged that the NPRM raised important issues that required in-depth analysis and consideration by the stakeholders. The Department also noted that the ACPAC was expected to meet on December 9 to deliberate on what, if any, recommendations it would make to the Department regarding this rulemaking and its belief that extending the comment period of the NPRM for one week after the ACPAC meeting would provide the public an opportunity to consider and provide comment on any recommendations of the ACPAC.

On December 16, 2022, A4A and IATA filed a petition to request a public hearing on the NPRM pursuant to the Department's regulation on discretionary rulemaking relating to unfair and deceptive practices at 14 CFR 399.75. The Department granted the request and conducted a public hearing on March 21, 2023, to afford A4A, IATA, and other stakeholders an opportunity to present certain factual

Association, Association of Asian Pacific Airlines, National Air Carrier Association, Regional Airline Association, Allegiant Air, Air New Zealand, Condor Flugdienst GmbH, COPA Airlines, Emirates, Kuwait Airways, Qatar Airways, Spirit Airlines, United Airlines, and Virgin Atlantic.

[10] American Society of Travel Advisors and Travel Technology Association (Travel Technology Association submitted two comments).

[11] Panasonic Avionics Corporation.

[12] 87 FR 51550 (August 22, 2022). Prior to publication in the **Federal Register**, on August 3, 2022, the NPRM was publicly available at *https://www.transportation.gov/airconsumer/latest-news* and at *https://www.regulations.gov,* docket number DOT–OST–2022–0089.

[13] The ACPAC is a statutorily required Federal advisory committee that evaluates current aviation consumer protection programs. It also provides recommendations to the Secretary for improving and establishing additional consumer protection programs that may be needed. Information about ACPAC is available at *https://www.regulations.gov/docket/DOT-OST-2018-0190.*

[14] In the request for extension of comment period by the airline representatives, they included various questions arising from the NPRM for which they sought clarifications from the Department. The Department responded to these questions and placed the responses in the docket for this rulemaking at DOT–OST–2022–0089.

issues that they asserted are pertinent to the Department's decision on the rulemaking. At the hearing, the Department heard from various stakeholders and subject matter experts on three issues regarding the Ticket Refund NPRM: (1) whether consumers can make reasonable self-determinations regarding contracting a serious communicable disease; (2) whether the documentation requirement (medical attestation and/or public health guidance) is sufficient to prevent fraud; and (3) how to determine whether a downgrade of amenities or travel experiences qualifies as a ''significant change of flight itinerary.'' The Department reopened the comment period for seven days after the hearing to allow the public the opportunity to provide comments on issues discussed at the hearing.

The Department received over 5,300 comments on the Ticket Refund NPRM from consumer rights advocacy groups, airlines and airline trade associations, ticket agents and ticket agent trade associations, academic researchers, State attorneys general, and individual consumers. Of the 5,300 comments, approximately 4,600 comments are from individual consumers or consumer organizations, while approximately 24 comments are from airline representatives and 650 comments are from those representing ticket agents. Almost all consumer commenters expressed strong support of the Department's proposals to enhance aviation consumer protection. The industry commenters raised various concerns about the NPRM proposals, supporting some while urging the Department to reconsider or revise others.

The Department has carefully reviewed and considered the comments on the Ancillary Fee Refund NPRM and the Ticket Refund NPRM received in the rulemaking dockets, as well as comments received during the March 2023 hearing and the recommendations of the ACPAC. The Department is now issuing a combined final rule for the Ticket Refunds NPRM and the Ancillary Fee Refund NPRM to significantly strengthen protections for consumers seeking refunds of: (1) airline tickets when an airline cancels or significantly changes a flight, and the consumer rejects or is not offered alternative transportation; (2) checked bag fees when bags are significantly delayed; and (3) ancillary services fees when consumers pay for services, such as Wi-Fi, that are not provided. In addition, this final rule provides protections for consumers who are unable or advised not to travel because of a serious communicable disease by requiring that carriers provide these consumers travel vouchers or credits that are transferrable and valid for at least 5 years from the date of issuance.

(3) Summary of Major Provisions

Subject	Final rule
Definition of Cancelled Flight	Amend 14 CFR part 399 and add 14 CFR part 260 to define cancelled flight as a flight that was published in a carrier's Computer Reservation System (CRS) at the time of the ticket sale but not operated by the carrier.
Definition of Significant Change of Flight Itinerary.	Amend 14 CFR part 399 and add 14 CFR part 260 to define significant change of flight itinerary as a change to the itinerary made by a carrier where: (1) the passenger is scheduled to depart from the origination airport three hours or more (for domestic itineraries) or six hours or more (for international itineraries) earlier than the original scheduled departure time; (2) the passenger is scheduled to arrive at the destination airport three hours or more (for domestic itineraries) or six hours or more (for international itineraries) later than the original scheduled arrival time; (3) the passenger is scheduled to depart from a different origination airport or arrive at a different destination airport; (4) the passenger is scheduled to travel on an itinerary with more connection points than that of the original itinerary; (5) the passenger is downgraded to a lower class of service; (6) the passenger with a disability is scheduled to travel through one or more connecting airports that differ from the original itinerary; or (7) the passenger with a disability is scheduled to travel on a substitute aircraft that results in one or more accessibility features needed by the passenger being unavailable.
Entity Responsible for Refunding Airline Tickets	Add 14 CFR part 260 to require U.S. and foreign air carriers that are the merchants of record[15] of the ticket transactions to provide prompt refunds when they are due, including for codeshare and interline itineraries. Amend 14 CFR part 399 to require ticket agents that are merchants of record of the airline ticket transactions to provide prompt ticket refunds when they are due.[16]
Notification of Right to Refund	Amend 14 CFR parts 259 and 399 to require U.S. and foreign airlines and ticket agents inform consumers that they are entitled to a refund of the ticket if that is the case before making an offer for alternative transportation or travel credits, vouchers, or other compensation in lieu of refunds. Add 14 CFR part 260 to require U.S. and foreign airlines to provide prompt notifications to consumers affected by a cancelled or significantly changed flight of their right to a refund of the ticket and ancillary fees due to airline-initiated cancellations or significant changes, any offer of alternative transportation or travel credit, vouchers, or other compensation in lieu of a refund, and airline policies on refunds and rebooking when consumers do not respond to carriers' offers of alternative transportation or travel credit, vouchers, or other compensation in lieu of a refund.
''Prompt'' Ticket Refund	Amend 14 CFR parts 259 and 399 and add 14 CFR part 260 to specify ''prompt'' ticket refund means: (1) Airlines and ticket agents provide refunds for tickets purchased with credit cards within 7 business days of refunds becoming due; and (2) Airlines and ticket agents refund tickets purchased with payments other than credit cards within 20 calendar days of refunds becoming due. Define ''business days'' to mean Monday through Friday excluding Federal holidays in the United States.

Subject	Final rule
Automatic Refunds of Airline Tickets	Add 14 CFR part 260 to require carriers who are the merchants of record to provide automatic ticket refunds when: (1) a carrier cancels a flight and does not offer alternative transportation or travel credits, vouchers, or other compensation for the canceled flight in lieu of a refund; (2) a carrier significantly changes a flight and the consumer rejects the significantly changed flight itinerary and the carrier does not offer alternative transportation or offer travel credits, vouchers, or other compensation in lieu of a refund; (3) a consumer rejects the significantly changed flight or alternative transportation offered as well as travel credits, vouchers, or other compensation offered for a canceled flight or a significantly changed flight itinerary in lieu of a refund; (4) a carrier offers a significantly changed flight or alternative transportation for a significantly changed flight itinerary or a canceled flight, but the consumer does not respond to the transportation offered on or before a response deadline set by the carrier and does not accept any offer of travel credits, vouchers, or other compensation, and the carrier's policy is to treat a lack of a response as a rejection of the alternative transportation offered; (5) a carrier does not offer a significantly changed flight or alternative transportation for a significantly changed flight itinerary or a canceled flight but offers travel credits, vouchers, or other compensation in lieu of a refund, and the consumer does not respond to the alternative compensation offered on or before a reasonable response date in which case the lack of a response is deemed a rejection; or (6) a carrier offers a significantly changed flight or alternative transportation for a significantly changed flight itinerary or a canceled flight and offers travel credits, vouchers, or other compensation in lieu of a refund and the carrier has not set a deadline to respond, the consumer does not respond to the alternatives offered, and the consumer does not take the flight. Carriers may set a reasonable deadline for a consumer to accept or reject a significant change to a flight or an offer of alternative transportation following a significant change or a cancellation. Carriers that set a deadline must establish, publish, and adhere to a policy regarding whether consumers not responding to a significant change or an offer of alternative transportation following a significant change or cancellation before the carrier's deadline would: (1) have their reservations cancelled and receive a refund; or (2) maintain their reservations and forfeit the right to a refund.
Refunding Fees for Significantly Delayed Bags	Add 14 CFR part 260 to require U.S. and foreign airlines that are merchants of record for the checked bag fee or if a ticket agent is the merchant of record for the checked bag fee, the carrier that operated the last flight segment to provide automatic refunds of checked baggage fees when they fail to deliver checked bags in a timely manner: (1) For domestic itineraries, a refund of baggage fee is due when an airline fails to deliver the checked bag within 12 hours of the consumer's flight arriving at the gate and the consumer has filed a Mishandled Baggage Report. (2) For international itineraries where the flight duration of the segment between the United States and a point in a foreign country is 12 hours or less, a refund of baggage fee is due when the airline fails to deliver the checked bag within 15 hours of the consumer's flight arriving at the gate and the consumer has filed a Mishandled Baggage Report. (3) For international itineraries where the flight duration of the segment between the United States and a point in a foreign country is over 12 hours, a refund of baggage fee is due when the airline fails to deliver the checked bag within 30 hours of the consumer's flight arriving at the gate and the consumer has filed a Mishandled Baggage Report.
Refunding Ancillary Services Fees for Services Not Provided.	Add 14 CFR part 260 to require U.S. and foreign airlines that are merchants of record for the ancillary service or if a ticket agent is the merchant of record for the ancillary service, the carrier that failed to provide the ancillary service to provide automatic refunds of ancillary service fees when a passenger pays for an ancillary service that the airlines fail to provide.
Providing Travel Credits or Vouchers to Consumers Affected by a Serious Communicable Disease.	Add 14 CFR part 262 to require U.S. and foreign airlines that are merchants of record for the ticket transaction or if a ticket agent is the merchant of record, the carrier that operated the flight to issue travel credits or vouchers, valid for at least five years from the date of issuance and transferrable, when: (1) a consumer is advised by a licensed treating medical professional not to travel during a public health emergency to protect himself/herself from a serious communicable disease, the consumer purchased the airline ticket before a public health emergency was declared, and the consumer is scheduled to travel during the public health emergency to or from the area affected by the public health emergency; (2) a consumer is prohibited from travel or is required to quarantine for a substantial portion of the trip by a governmental entity in relation to a serious communicable disease and the consumer purchased the airline ticket before a public health emergency for that area was declared or, if there is no declaration of a public health emergency, before the government prohibition or restriction for travel to or from that area is imposed; or (3) a consumer is advised by a licensed treating medical professional not to travel, irrespective of a public health emergency, because the consumer has or is likely to have contracted a serious communicable disease and would pose a direct threat to the health of others.
Documentation Requirement for Receiving Credits or Vouchers.	Add 14 CFR part 262 to allow U.S. and foreign airlines to require consumers requesting a credit or voucher for a non-refundable ticket when the flight is still scheduled to be operated without significant change to provide, as appropriate:

Subject	Final rule
	(1) the applicable government order or other document relating to a serious communicable disease demonstrating how the passenger is prohibited from travel or is required to quarantine at the destination for a substantial portion of the trip; or (2) a written statement from a licensed treating medical professional, attesting that it is the medical professional's opinion, based on current medical knowledge concerning a serious communicable disease such as guidance issued by CDC or WHO and the passenger's health condition, that the passenger should not travel to protect the passenger from a serious communicable disease or the passenger would pose a direct threat to the health of others if the passenger traveled. This medical statement may only be required in the absence of HHS guidance declaring that requiring such documentation is not in the public interest.
Service Fees by Ticket Agents for Issuing Tickets.	Amend 14 CFR part 399 to allow ticket agents to retain the service fee charged when issuing the original ticket if the service provided is for more than processing payment for a flight that the consumer found and so long as the fee is on a per-passenger basis and the existence, amount, and the non-refundable nature of the fee if this is the case, is clearly and prominently disclosed to consumers at the time they purchase the airfare.
Processing Fees for Issuing Refunds, Credits, or Vouchers.	*Retaining Processing Fee for Required Refunds:* Add 14 CFR part 260 to prohibit carriers from retaining a processing fee for issuing required refunds when the carrier cancels or significantly changes a flight. *Processing Fee for Issuing Required Credits or Vouchers:* Add 14 CFR part 262 to allow airlines to retain a processing fee from the value of a required travel credit or voucher provided to a passenger due to a serious communicable disease. Airlines (not ticket agents) are responsible for issuing travel credits or vouchers to eligible consumers whose travel is affected by a serious communicable disease.

(4) Costs and Benefits

The final rule will reduce inconsistencies in granting consumers airline ticket refunds that stem from the lack of universal definitions for cancellation and significant itinerary change. As such, the rule is expected to reduce the resources consumers need to expend to obtain the refunds they are owed. Consumer time savings are estimated to be about $3.8 million annually. The rule also implements 2016 and 2018 statutory mandates pertaining to refunds of fees for delayed baggage and ancillary services that a consumer does not receive. The expected economic impacts of the fee refund provisions consist of $16.0 million annually in increased refunds to consumers and $7.1 million annually in administrative costs for the airlines.

The rule also requires airlines to provide five-year transferable travel credits or vouchers to passengers who cancel travel for reasons related to a serious communicable disease. Expected societal benefits, which were not quantified, are from infected air passengers who cancel air travel due the option of receiving the five-year travel credit and the reduction in exposure of uninfected passengers to serious contagious disease. Estimated annual costs range from $3.4 million to $482.0 million.

[15] Merchants of records are the entities shown in the consumer's financial charge statements such as debit or credit card charge statements.

[16] Comments from ticket agents assert that ticket agents appear as merchants of records in less than 10 percent of transactions addressed in this final rule.

Statutory Authority

The Department is issuing this rulemaking under its authority to prohibit unfair or deceptive practices or unfair methods of competition in air transportation or the sale of air transportation pursuant to 49 U.S.C. 41712, its authority to require safe and adequate interstate transportation pursuant to 49 U.S.C. 41702, its authority to mandate that airlines refund checked baggage fees to passengers when they fail to deliver checked bags in a timely manner pursuant to 49 U.S.C. 41704 note, and its authority to mandate that airlines promptly provide a refund to a passenger of any ancillary fees paid for services related to air travel that the passenger does not receive pursuant to 49 U.S.C. 42301 note prec.

Under the Department's procedural rule regarding rulemakings relating to unfair and deceptive practices, 14 CFR 399.75, the Department is required to provide its reasoning for concluding that a certain practice is unfair or deceptive to consumers, as defined in 14 CFR 399.79, when issuing aviation consumer protection rulemakings that are not specifically required by statute and are based on the Department's general authority to prohibit unfair or deceptive practices under 49 U.S.C. 41712. A practice is ''unfair'' to consumers if it causes or is likely to cause substantial injury, which is not reasonably avoidable, and the harm is not outweighed by benefits to consumers or competition.[17] Proof of intent is not necessary to establish unfairness.[18] The elements of unfairness are further elaborated by the Department in its guidance document. [19]

The Department has determined that it is an unfair business practice in violation of section 41712 for airlines or ticket agents to refuse to refund passengers when an airline cancels or significantly changes a flight and passengers do not accept the offered alternative transportation or compensation (*e.g.,* airline credits or vouchers) in lieu of a refund, regardless of whether the passenger purchased a non-refundable ticket. A practice by airlines or ticket agents of not providing refunds in such situations substantially harms consumers because consumers paid money for services that were not provided when the airline cancelled or significantly changed the flight. This harm is not reasonably avoidable by consumers as cancellations or significant changes to their flights are outside of their control. A reasonable consumer would not expect that he or she must pay more to purchase a refundable ticket to be able to recoup the ticket price when the airline fails to provide the service through no action or fault of the consumer. Also, the tangible and significant harm to consumers of not receiving a refund is not outweighed by benefits to consumers or competition. The Department acknowledges that consumers may benefit from the availability of lower cost nonrefundable tickets but does not expect that this requirement would result in airlines no longer offering

[17] 14 CFR 399.79(b)(1).

[18] 14 CFR 399.79(c).

[19] 87 FR 52677 (August 28, 2022).

nonrefundable tickets as the term nonrefundable has generally been understood not to apply in cases where airlines cancel or make a significant change in the service provided.

For airlines, this prohibited unfair practice includes a carrier's retention of a fee to process a required refund or of a booking fee (*i.e.,* a fee for processing payment for a flight that the consumer found) because it is the carrier's flight that is significantly changed or canceled; the Department is deferring decision on whether the same prohibition should apply to ticket agents because ticket agents do not operate the flight. Further, the Department has determined that it is an unfair and deceptive practice in violation of section 41712 for airlines and ticket agents to not inform consumers that they are entitled to a refund of the ticket and ancillary fees if that is the case before making an offer for travel credits, vouchers, or other compensation in lieu of refunds. Also, it is an unfair and deceptive practice to not provide proper disclosures and notifications to consumers with respect to: the limitations, restrictions, and conditions on any travel credits, vouchers, or other compensation offered in lieu of refunds; consumers' rights to automatic refunds under certain circumstances; and any airline-imposed requirements on accepting or rejecting alternative transportation. Additionally, to ensure that consumers who purchased their airline tickets from a ticket agent receive refunds that are due in a timely manner, the Department has determined that it is an unfair practice for airlines to not confirm a consumer's refund eligibility in a timely manner. The Department's analysis on why these actions by airlines or ticket agents violate section 41712 will be provided in each section that discusses these matters in substance.

Similarly, the Department considers it to be an unfair practice for an airline to not provide travel credits or vouchers when (1) a consumer is advised by a licensed treating medical professional not to travel to protect himself/herself from a serious communicable disease and the consumer purchased the airline ticket before a public health emergency affecting the origination or destination of the consumer's itinerary was declared and is scheduled to travel to or from that area during the public health emergency; (2) a consumer is prohibited from traveling or is required to quarantine for a substantial portion of the trip by a governmental entity due to a serious communicable disease (*e.g.,* as a result of a stay-at-home order, border closure) affecting the origination or destination of the consumer's itinerary and the consumer purchased the airline ticket before a public health emergency was declared or, if there is no declaration of a public health emergency, before the government prohibition or restriction for travel to the consumer's destination or from the consumer's origination; or (3) a consumer is advised by a licensed treating medical professional consistent with public health guidance (*e.g.,* CDC guidance) not to travel to protect others from a serious communicable disease. Consumers are substantially harmed when they pay for a service that they are unable to use because they were directed or advised by governmental entities or a medical professional not to travel to protect themselves or others from a serious communicable disease, and the airline does not provide a travel credit or voucher. More specifically, the loss of the value of their tickets is a substantial harm that is not reasonably avoidable when consumers purchased their tickets before the declaration of a public health emergency and the only way to avoid the loss of the ticket value is to disregard a medical professional's advice not to travel and risk inflicting serious health consequences on themselves. This loss is also not reasonably avoidable when consumers purchased their tickets before the declaration of a public health emergency that results in the issuance of communicable disease-related travel prohibition or restriction or, if there is no declaration of a public health emergency, before the government prohibition or restriction for travel due to a serious communicable disease and the only way to avoid the loss of the ticket value is to disregard direction from governmental entities. Finally, this loss of the value of their tickets is not reasonably avoidable when the only way to avoid the loss of the ticket value is to disregard medical professionals' advice not to travel and risk inflicting serious health consequences on others. The tangible and significant harm to consumers of losing the value of their ticket is not outweighed by potential benefits to consumers or competition because the requirement to provide travel credits or vouchers would have minimal, if any, impact on nonrefundable fares. A public health emergency affecting travel to, within, and from the United States in a large scale is infrequent, and this requirement applies only to consumers who have been advised or directed not to travel by a medical professional or governmental entity in relation to a serious communicable disease.

In addition, the Department considers it to be an unfair practice for airlines to not provide travel credits or vouchers to consumers who are advised by a medical professional not to travel because they have or are likely to have contracted a serious communicable disease, *regardless of whether there is a public health emergency.* Infected passengers who are unwilling to incur a financial loss for the airline tickets may choose to travel despite the infection, which is likely to cause substantial harm to other passengers on the flight by significantly increasing the likelihood of these passengers, especially those seated within close proximity of the infected passenger, being infected by the communicable disease. Such harm cannot be reasonably avoided by these passengers because they are assigned to sit close to the infected passenger and may have no knowledge about the infection by that passenger. The harm to these passengers' health is not outweighed by any benefits to consumers or competition. The Department believes there would not be any benefit to consumers or competition among airlines in infected or potentially infected travelers possibly choosing to travel by air and infecting other passengers.

Further, the Department relies on its authority in 49 U.S.C. 41702 to require U.S. air carriers to ''provide safe and adequate interstate air transportation'' to establish the requirement that an airline provide travel credits or vouchers to consumers who are unable or advised not travel due to a serious communicable disease. This final rule promotes safe and adequate air transportation by reducing incentives to travel for individuals who have been advised against traveling because they have or are likely to have contracted a serious communicable disease or individuals who are particularly vulnerable to a serious communicable disease by allowing them to retain the value of their tickets in travel credits and postpone travel.

The Department has received comments from the airlines, ticket agents, and their trade associations disputing the Department's authority to promulgate the regulation relating to providing travel credits or vouchers to passengers whose travel is impacted by a serious communicable disease. Those comments and the Department's responses are provided in Section IV.1 of this rule preamble.

The requirements in this final rule regarding airlines refunding baggage fees when significantly delayed and refunding ancillary service fees when

the paid for services are not provided are specifically required by statute. The requirement for airlines to refund fees for checked bags that are significantly delayed is issued pursuant to the Department's authority in 49 U.S.C. 41704 note, which was enacted as part of the FAA Extension Act (Pub. L. 114–90) and requires the Department to promulgate a regulation that mandates that airlines refund checked baggage fees to passengers when they fail to deliver checked bags in a timely manner.[20] The requirement to refund ancillary fees for air travel related services that passengers paid for but did not receive is issued pursuant to the Department's authority in 49 U.S.C. 42301 note prec., which was enacted as part of the FAA Reauthorization Act of 2018 (Pub. L. 115–254) and requires the Department to promulgate a rule that mandates that airlines promptly provide a refund to a passenger of any ancillary fees paid for services related to air travel that the passenger does not receive.[21]

Comments and Responses

I. Refunding Airline Tickets for Cancelled or Significantly Changed Flights

1. Covered Entities, Flights, and Consumers

The NPRM: The existing requirement under 14 CFR 259.5 for carriers to adopt and adhere to a customer service plan, which includes a commitment to provide prompt ticket refunds to passengers when a refund is due, applies to all scheduled flights of a certificated or commuter air carrier [22] if the carrier operates passenger service using any aircraft originally designed to have a passenger capacity of 30 or more seats, and to all scheduled flights to and from the United States of a foreign carrier if the carrier operates passenger service to and from the United States using any aircraft originally designed to have a passenger capacity of 30 or more seats. The Ticket Refund NPRM proposed to expand the applicability of the requirement to provide prompt refunds to a certificated or commuter air carrier that operates scheduled passenger service to, within, and from the United States using aircraft *of any size,* and to a foreign carrier that operates scheduled passenger service to or from the United States using aircraft *of any size*. The Department sought comments on whether the proposed expansion of the regulation in section 259.5 to include smaller carriers is reasonable, and what obstacles, if any, these smaller carriers may encounter to compliance.

As for ticket agents,[23] the Department's rule in 14 CFR 399.80(l) requires that ticket agents of any size ''make proper refunds promptly when service cannot be performed as contracted.'' The Ticket Refund NPRM proposed that, like the existing rule on ticket agents providing refunds, the proposed refund requirements would apply to ticket agents of any size but specified that it would only apply to ticket agents that sell directly to consumers for scheduled passenger service to, from, or within the United States.

In the NPRM, the Department also considered whether the applicability of DOT's proposed refund requirements should be limited to sellers of air transportation located in the United States and whether the beneficiaries should be limited to aviation consumers who are residents of the United States based on its review of Regulation Z of the Consumer Financial Protection Bureau (CFPB), as codified in 12 CFR part 1026, and the airline refund regulation in 14 CFR part 374, which implements the requirement of Regulation Z with respect to airlines. The Department recognized that the regulated entities covered by Regulation Z for airline ticket transactions with credit cards may be limited to sellers located in the United States and that the protection afforded by Regulation Z may be limited to consumers who are residents of the United States with credit card accounts located in the United States. The Department also noted its broad and independent authority to prohibit unfair or deceptive practices in air transportation or sale of air transportation,[24] which enables it to cover flights to, within, and from the United States, irrespective of whether the consumer holding reservations on those flights is a resident of the United States, whether the seller of the airline ticket is located in the United States, or whether the transaction takes place in the United States. The Department asked for comment on the applicability of the proposed requirement.

The Department also sought comments on applicability of the rule to certain flight segments between two foreign points if they are on the same itinerary or ticket with flights to, from, or within the United States. If adopting the same itinerary/ticket standard, the Ticket Refund NPRM asked whether the refund requirement should only apply when the entire itinerary/ticket is sold under a U.S. carrier's code or whether it should also apply to itineraries/tickets that combine flight segments sold under a U.S. carrier's code and flight segments sold under a foreign carrier code pursuant to an interline agreements.

Comments Received: The Department received one comment from an individual stating that including small carriers operating flights to, from, or within the United States solely using aircraft originally designed to have a passenger capacity of fewer than 30 seats in these regulatory proposals would place a considerable burden on these carriers, potentially drive many of the smaller carriers that provide access to more remote and distant parts of the country out of business. The Department received no comments on the proposed scope of covered ticket agents in the Ticket Refund NPRM, which incorporates the current scope of ticket agents refund rule in 14 CFR 399.80(l), and the definition for ''ticket agent'' in 49 U.S.C. 40102(a)(45).

For the covered tickets/itineraries/flights under the Ticket Refund NPRM, IATA and several foreign carriers raised two concerns. First, they suggested that applying the rule to all scheduled flights to, from, or within the United States is incompatible with regulations from other jurisdictions such as the European Union and Canada. They further argued that the rule should only apply to flight segments departing a U.S. airport. Air Canada argued that the scope of the refund regulation, as proposed, would cause confusion as refund rules in other jurisdictions typically apply to itineraries departing that jurisdiction to a foreign destination. Air Canada contended that the Department's proposal represents a misalignment with Canada's Air Passenger Protection Regulations (APPR) when both sets of rules apply to the same itinerary. Air Canada provides an example that in the

[20] See Section 2305 of the FAA Extension, Safety, and Security Act of 2016, Public Law 114–190 (July 15, 2016)).

[21] See Section 421 of the FAA Reauthorization Act of 2018, Public Law 115–254 (October 5, 2018).

[22] A certificated air carrier is an air carrier holding a certificate issued under 49 U.S.C. 41102. A commuter air carrier is an air carrier as established by 14 CFR 298.3(b) that carries passengers on at least five round trips per week on at least one route between two or more points according to a published flight schedule, using small aircraft—*i.e.,* aircraft originally designed with the capacity for up to 60 passenger seats. See 14 CFR 298.2. Commuter air carriers, along with air taxi operators, operating under 14 CFR part 298 are exempted from the certification requirements of 49 U.S.C. 41102.

[23] A ''ticket agent'' is defined in 49 U.S.C. 40102(a)(45) to mean a person (except an air carrier, a foreign air carrier, or an employee of an air carrier or foreign air carrier) that as a principal or agent sells, offers for sale, negotiates for, or holds itself out as selling, providing, or arranging for, air transportation.

[24] Air transportation means foreign air transportation, interstate air transportation, or the transportation of mail by aircraft. See 49 U.S.C. 40102 (a)(5).

case of uncontrollable event such as winter storm causing a cancellation, the APPR only requires a carrier to refund if the carrier is not able to rebook the passenger within 48 hours from the departure time, whereas the Department's proposed rule would require a refund offer upon flight cancellation. Second, IATA and several foreign carriers objected to applying the rule to certain flight segments between two foreign points, raising extraterritoriality concerns. Air Canada argued that the Department's attempt to apply its refund rule extraterritorially would violate the longstanding principles of comity and reciprocity of international aviation agreements and the bilateral air transport agreement [25] between the United States and Canada.

Consumers and their representatives are largely in support of a broad scope of the Ticket Refund NPRM. Travelers United stated that the European regulation, EU261, applies to the scheduled flights of all carriers departing the European Union to the United States but only applies to the scheduled flights of EU carriers departing the United States to the European Union. Travelers United pointed out that, as such, a consumer traveling from the United States to the European Union on a flight by a U.S. carrier, for example, would not be protected by EU 261. Some individual consumer commenters argued that the Department's refund rule should cover flights between two foreign points in the same itinerary to streamline the refund process for international travel.

Ticket agents also commented on the scope of itineraries/tickets covered by the Ticket Refund NPRM. Travel Management Coalition suggested that the refund rule should apply only to ticket transactions with a point of sale in the United States. Travel Technology Association (Travel Tech) echoed the ''point of sale'' approach and added that this approach is a bright-line and widely used industry standard as the Global Distribution Systems (GDSs) denote the point of sale on all their ticket transactions. Travel Tech suggested that this approach would make the implementation of any final rules easier for the regulated entities.

U.S. Travel Association stated that the refund requirement should be limited to flights to, from, or within the United States purchased by consumers residing in the United States. It argued that this approach is consistent with CFPB's interpretation of Regulation Z and the Department's proposed rule on Transparency of Ancillary Fees, which proposes that the consumer protection measures relating to disclosure apply to websites ''marketed to United States customers'' and ''tickets purchased by consumers in the United States.''

DOT Response: The Department has determined that it is appropriate to include within the scope of covered carriers with respect to the ticket refund requirements U.S. and foreign air carriers operating scheduled flights to, from, or within the United States solely using aircraft originally designed to have a passenger capacity of fewer than 30 seats. The Department notes that the new ticket refund regulations in part 260, which provide clarity on various issues related to refunds, do not add new burdens to these carriers as they are already covered under 14 CFR part 374 with respect to refunds for credit card purchases. The applicability provision in 14 CFR 374.2 states that ''this part is applicable to all air carriers and foreign air carriers engaging in consumer credit transactions.'' Also, the Department's Office of Aviation Consumer Protection has for many years interpreted 49 U.S.C. 41712 as requiring all carriers to provide prompt refunds when due irrespective of the form of ticket purchase payment.

The Department has carefully considered airlines' argument that the proposed scope of covered flights for airline ticket refunds (*i.e.,* scheduled flights to, from, or within the United States) would potentially result in some flights being subject to refund rules of multiple jurisdictions, causing complexity to carriers' compliance and potential consumer confusion. The Department is not convinced that any potential compliance complexity or consumer confusion arising from these situations cannot be addressed by carriers offering all the accommodations required by the applicable regulations so consumers can choose the option that best suits their needs. For instance, the Department does not see any conflict of law in the example provided by Air Canada. APPR, which applies to all flights to, from, and within Canada,[26] requires airlines to provide a passenger affected by a cancellation or a lengthy delay due to a situation outside the airline's control with a confirmed reservation on the next available flight that is operated by the carrier or a partner airline, leaving within 48 hours of the departure time indicated on the passenger's original ticket; if the airline cannot provide a confirmed reservation within this 48-hour period, it will be required to provide, at the passenger's choice, a refund or rebooking. Both the APPR requirement and the Department's refund requirement would apply to a flight between the United States and Canada. Under the regulation finalized here, the carrier would be required to refund the affected passenger if the flight is cancelled or delayed for more than six hours and the consumer rejects the alternative offered or an alternative is not offered. In this situation, the carrier would be expected to offer the passenger the choice of a refund and a choice of rebooking on a flight departing within 48 hours if such flight exists. Providing consumers such choices would satisfy the requirements of both U.S. and Canadian regulations.

The Department notes that airlines operating international air transportation are subject to rules from multiple jurisdictions in many other areas, such as oversales and disability. The Department does not believe there is a conflict of law in ticket refunds which makes it impossible for carriers to comply with laws of multiple jurisdictions. The Department expects that U.S. and foreign air carriers operating scheduled flights to, from, and within the United States will fully comply with the refund regulations to which they are subject, consistent with the bilateral agreements between the United States and other countries. Such compliance will result in consumers benefiting from having more choices when their flights are canceled or significantly changed by airlines.

We have also considered the comments on the scope of ''air transportation'' for tickets that include flight segments between two foreign points. The Department has determined that the refund requirements would cover these flight segments that are on a single ticket/itinerary to or from the United States without a break in the journey. Congress has authorized the Department to prevent unfair or deceptive practices or unfair methods of competition in ''air transportation,'' 49 U.S.C. 41712(a), and ''air transportation'' is defined to include ''foreign air transportation.'' [27] The

[25] As support for its position, Air Canada references Article 12.1 of the Air Transport Agreement Between the Government of Canada and the Government of the United States, which states ''While entering, within, or leaving the territory of one Party, its laws and regulations relating to the operation and navigation of aircraft shall be complied with by the other Party's airlines.''

[26] *https://otc-cta.gc.ca/eng/publication/application-air-passenger-protection-regulations-a-guide.*

[27] Foreign air transportation ''means the transportation of passengers or property by aircraft as a common carrier for compensation, or the transportation of mail by aircraft, between a place in the United States and a place outside the United States when any part of the transportation is by aircraft.'' See 49 U.S.C. 40102(a)(23).

Department has concluded that ''foreign air transportation'' includes journeys to or from the United States with brief and incidental stopover(s) at a foreign point without breaking the journey. We believe this approach fully addresses the extraterritoriality concerns raised by some carriers and is consistent with the Department's general approach adopted in this final rule of considering domestic segments of international itineraries as a part of the international journey. While the Department is not providing an exhaustive list of what a stopover that would break the journey is, it is setting an outer limit by treating any deliberate interruption of a journey at a point between the origin and destination that is scheduled to exceed 24 hours on an international itinerary to be a break in the journey.[28]

Besides this bright-line outer limit, to determine whether a stopover under 24 hours at a foreign point breaks the journey between a point in the United States and a point in a foreign country, the Department would view factors including whether the whole itinerary was purchased in one single transaction, whether the segment between two foreign points is operated or marketed by a carrier that has no codeshare or interline agreement with the carrier operating or marketing the segment to or from the United States, and whether the stopover at a foreign point involves the passenger picking up checked baggage, leaving the airport, and continuing the next segment after a substantial amount of time.

The Department has also determined that it is appropriate to apply the refund and other consumer protection regulations finalized here to all tickets/itineraries to, from, or within the United States regardless of the point of sales or the residency of the consumers. While recognizing that Regulation Z applies only to credit card transactions that take place in the United States involving residents of the United States, the Department's authority to prohibit unfair or deceptive practices in air transportation under 49 U.S.C. 41712 goes beyond this scope with respect to the type and location of the transactions and the residency of consumers. The Department has made the policy decision to exercise its broad authority under section 41712 to ensure that its ticket and ancillary service fee refunds requirements and the protections for passengers affected by a serious communicable disease provide the maximum protections to consumers as permitted by the law. The Department also believes that this broad scope would simplify and streamline the refund process by the regulated entities and reduce consumer frustration and confusion.

2. Need for a Rulemaking

The NPRM: The NPRM is intended to prevent unfair or deceptive practices by airlines and ticket agents when airlines cancel or make significant changes to flights. Under the Department's existing regulations, airlines have an obligation to provide prompt refunds when refunds are due, but a specific reference to refunding airfare due to a canceled or significantly changed flight is not codified in the regulations. Also, today, airlines are permitted to adopt their own standards for ''cancellation'' and ''significant change,'' which has resulted in lack of consistency from airline to airline and passenger confusion about their rights, particularly during periods of significant air travel disruptions such as the COVID–19 pandemic when refund requests overwhelmed the industry. As noted in the NPRM, the Department received a significant number of complaints against airlines and ticket agents for refusing to provide a refund or for delaying processing of refunds during the COVID–19 pandemic. In issuing the NPRM, the Department explained that its existing regulations on refunds made it difficult to monitor compliance and enforce refund requirements and described benefits of strengthening protections for consumers to obtain a prompt refund when airlines cancel or significantly change flight schedules.

Comments Received: Virtually all consumers and consumer rights advocacy groups that commented on the NPRM are in support of the Department exercising its legal authority under section 41712 to codify the Department's longstanding enforcement policy requiring airlines and ticket agents to provides refunds when airlines cancel or make a significant change to a flight itinerary. They also strongly support the proposal to define ''cancellation'' and ''significant change'' to eliminate the inconsistencies among airline policies that are the main sources of consumer frustration. FlyersRights commented that some airlines' behavior during the COVID–19 pandemic to retroactively extend the length of delay that would qualify affected consumers for a refund is strong evidence for the need of rulemaking. In addition to supporting the proposals in this area, approximately 500 individual consumers expressed their view that the NPRM does not go far enough in terms of consumer protection, with over 300 commenters explicitly suggesting that the Department adopt regulation mandating airlines to compensate consumers for incidental costs (*e.g.,* meals, hotels, ground transportation) associated with airline cancellations or significant changes, similar to the European Union Regulation EC261/2004 (EC261). National Consumers League noted that this additional consumer protection measure would mitigate consumer inconveniences and incentivize airlines to invest in maintaining operations according to the published schedules.

Among airline commenters, A4A expressed support for codifying the refund policy and adopting definitions for ''cancellation'' and ''significant change'' but disagreed with some components of the proposed definitions. The National Air Carrier Association (NACA) stated that the Department should simply codify the current policy without adopting definitions for ''cancellation'' and ''significant change.'' IATA and several airline commenters asserted that it is not necessary to promulgate a new rule because airlines were already providing refunds pre-COVID–19 pandemic, as evidenced by the relatively small numbers of complaints on refunds at that time. They contended that the Department should not rely on a once-in-a-lifetime event (*i.e.,* the COVID–19 pandemic) as the justification for a rulemaking. They pointed out that airlines have issued unprecedented amounts of refunds during the pandemic and in cases where they failed to do so, the Department's enforcement actions under the current rule have proven that rulemaking is unnecessary. IATA's comment recognized that standardizing definitions would provide consistency in passenger experiences and avoid consumer confusion, although it argued that allowing airlines to define these terms provides greater flexibility, fosters competition, and helps maximize value for consumers. The Association of Asian and Pacific Airlines (AAPA) expressed its view that the refund requirement should exempt situations where cancellations and significant changes are caused by safety or security-related reasons including pandemics and when large scale disruptions or ''*force majeure*'' such as unannounced border closures and restrictions by governments occur.

Ticket agents and their trade associations are generally in support of the proposals on codification of the refund enforcement policy and adopting

[28] See definitions for common terms in air travel at *https://www.transportation.gov/sites/dot.gov/files/docs/Common%20Terms%20in%20Air%20Travel.pdf.*

definitions for ''cancellation'' and ''significant change.'' Many ticket agent commenters share the Department's view that these proposals mitigate consumer confusion caused by different airline refund policies and enhance predictability regarding refund rights. However, U.S. Travel Association, an organization representing various components of the U.S. travel industry, including some ticket agents, opposed the proposals on refunds due to airline cancellation and significant change, arguing that the proposals do not address the root causes of flight delays and cancellations and would have unintended consequences of higher costs for travel and reduced options for consumers.

The Department also received a joint comment by 32 State Attorneys General supporting the Department's proposal but also urging, among other things, that the Department: (1) work on a partnership with States to enforce consumer protection rules, (2) require airlines to sell tickets only for flights they have adequate staff to operate, (3) impose significant penalties for airline cancellations or lengthy delays not caused by weather or other unavoidable reasons, and (4) require airlines to compensate consumers affected by cancellations or delays, including compensating for the cost of meals, hotels, flights on another airline, rental cars, and issuing partial refunds to consumers who took the alternative flight that is later, longer, or otherwise of less value.

The Department's Aviation Consumer Protection Advisory Committee, after discussing the Department's proposals on refunds related to airline cancellation and significant change during several meetings, unanimously recommended that the Department codify its longstanding policy to require airlines and ticket agents to provide prompt refunds to consumers when airlines cancel or make a significant change to flight itineraries and consumers do not accept alternative transportation offered by airlines or ticket agents. The member representing airlines noted that the airlines' support on this recommendation is limited to adopting a rule that codifies the Department's current policy.

DOT Response: The Department continues to be concerned about the lack of regulatory clarity regarding airlines' obligation to provide prompt refunds when airlines cancel or make significant changes to flights and the impact that this lack of regulatory clarity has on airlines' compliance and the ability of the Department's Office of Aviation Consumer Protection to take enforcement action despite the Department's statutory authority to prohibit unfair and deceptive practices. As described in the Statutory Authority section, the Department believes that an airline's or ticket agent's practice of not providing a prompt refund when an airline cancels or significantly changes a passenger's flight and the passenger does not accept the alternative offered causes substantial harm to consumers, the harm is not reasonably avoidable, and the harm is not outweighed by benefits to consumers or competition. As such, the Department concludes that its existing regulatory structure on refunds should be enhanced to better protect consumers.

The Department also agrees with comments from ticket agent representatives and others that definitions for ''cancellation'' and ''significant change of flight itinerary'' mitigate consumer confusion caused by different airline refund policies and enhance predictability regarding refund rights. As the Department stated in the Ticket Refund NPRM, the consumer complaints received by the Department during the COVID–19 pandemic demonstrated that various airline definitions for these terms have caused a great level of consumer harm in terms of frustration and confusion. The Department agrees with FlyersRights that a lack of a uniform standard on the meaning of a cancellation and significant change has resulted in certain airlines improperly revising and applying less consumer-friendly refund policies during periods when flight cancellations and changes spike, which is strong evidence of the need of rulemaking. The Department notes, however, that the adoption of this final rule is not, as some airline commenters argue, solely based on issues arising from an unprecedented pandemic. As we have witnessed during the past two years while the air travel industry is recovering post-pandemic, disruptions in large scales continue to occur as the result of other factors such as weather, technological issues, and staffing shortages. The significant number of consumer complaints on refunds filed with the Department in recent years demonstrates the need to strengthen the current regulation on refunds.

Regarding the various comments by consumers, consumer right advocacy groups, and the State Attorneys General regarding promulgating regulations to require airlines to provide compensation to consumers when their flights are cancelled or significantly changed to cover the incidental costs such as meals, hotels, and ground transportation, the Department has initiated another consumer protection rulemaking to address these issues.[29] The Department fully recognizes that the measures finalized in this rule on airline ticket refunds are merely the first steps towards the Department's goal of strengthening overall protections to consumers affected by airline cancellations and changes.

3. Definition of a Cancelled Flight

The NPRM: The Ticket Refund NPRM proposed to define a cancelled flight to mean a covered flight that was listed in the carrier's CRS at the time the ticket was sold to a consumer but not operated by the carrier. Under this proposed definition, the reason that the flight was not operated (*e.g.,* mechanical, weather, air traffic control) would not matter. Also, the removal of a flight from a carrier's CRS would not negate the obligation to provide a refund when the alternative offered is not accepted.

Comments Received: A4A and IATA expressed support for the Department codifying a definition for ''cancelled flight'', as they believe it is necessary to provide clarity and transparency to the traveling public. They argued, however, that the definition should exclude situations that would technically qualify as a ''cancellation'' under the proposed definition but do not affect consumers, such as a simple flight number change or a flight that was delayed into the next calendar day but does not exceed the delay limits set forth in the definition for ''significant change of flight itinerary.'' They further argued that when a passenger from any cancelled flight was rebooked on a new flight that does not constitute a ''significant change of flight itinerary'' when compared to the original flight that was cancelled, consumers should not be entitled to a refund. The flight number change and overnight delay exemptions argument is supported by the Regional Airline Association (RAA) and some foreign airline commenters. The National Air Carrier Association (NACA) argued that the definition for ''cancelled flight'' should exclude cancellations due to situations outside of carriers' control. Qatar Airways argued that the definition should include only flight operations that are not operated but were listed in the carrier's CRS within seven calendar days of the scheduled departure. On a similar issue, A4A submitted that the Department should clarify that this definition is distinct from the Department's airline service quality

[29] See, *Rights of Airline Passengers When There Are Controllable Flight Delays or Cancellations, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=2105-AF20.*

reporting rule, 14 CFR part 234, and it does not change the definition for ''cancelled flight'' in that regulation.[30] Spirit Airlines stated that it accepts the Department's proposed definition for ''cancelled flight.''

Consumers and consumer rights advocacy groups fully support the Department's proposed definition for ''cancelled flight.'' National Consumers League commented that whether a flight was removed from a carrier's CRS one year or one day before its scheduled operation is irrelevant for consumers. U.S. Public Interest Research Group Education Fund filed comments supporting stronger consumer protections for air travelers. It specifically commented that by adopting the proposed definition for ''cancelled flight,'' airlines should no longer be allowed to categorize cancellations that occur more than seven days before the departure as ''discontinued'' flights therefore evading being held accountable for the true number of cancellations. It further stated that this would encourage airlines to produce more realistic flight schedules.

Ticket agent representatives' positions on this definition are split. The United States Tour Operators Association (USTOA) supported the airlines' position on exempting situations under which consumers are reaccommodated on flights that do not constitute a ''significant change of flight itinerary'' when compared to the cancelled flight. Global Business Travel Association, on the other hand, supported the Department's proposed definition.

U.S. Chamber of Commerce opposed the proposal based on its understanding that the definition would expand the current refund entitlement and hold carriers liable for cancellations due to situations beyond their control such as weather or air traffic control delays. It further argued that this definition would also entitle a passenger who is reaccommodated on another flight to a refund. It suggested that the Department reconsider the definition to exempt cancellations unforeseeable by carriers. On the other hand, the ACPAC recommended to the Department that it adopt the proposed definition for ''cancelled flight.'' [31]

DOT Responses: The Department has considered the comments suggesting the definition of ''cancelled flight'' not include a flight cancellation that has no significant impact on a consumer because the new flight offered to the consumer does not constitute a ''significant change of flight itinerary'' as compared to the original flight. The Department is concerned, however, that carving out such an exemption would lead to substantial consumer confusion as to whether a consumer is entitled to a refund after a flight cancellation, as entitlements to a refund would depend on the nature of the new flight offered to each affected consumer, a fact-specific and case-by-case analysis that is often time-consuming, and complex. For example, if two passengers from a cancelled flight were offered different alternative flights, one that would be considered a ''significant change'' compared to the cancelled flight and the other that would not be considered a ''significant change,'' the outcome is that one passenger would be entitled to rejecting the alternative flight and receiving a refund, and the other would not. The Department believes that the potential complexity and confusion associated with a case-by-case determination of when passengers are entitled to a refund of a cancelled flight outweighs its benefits. Further, the Department believes that consumers who are reaccommodated on a flight that is substantially comparable to the original flight generally would not typically refuse the re-accommodation and seek a refund. For these reasons, the Department is adopting the proposed definition of ''cancelled flight'' under which a consumer would be entitled to a refund with clarification. A cancelled flight means a flight with a specific flight number that was published in a carrier's Computer Reservation System to operate between a specific origin-destination city pair at the time of the ticket sale that was not operated. Under this definition, a flight that was operated under a different flight number would be considered a new flight and the original flight would be considered a canceled flight.

The Department further clarifies that the NPRM did not propose to amend, and this final rule does not amend, the existing definition of ''cancelled flight'' for airline reporting purposes in 14 CFR part 234. U.S. carriers will continue to apply the existing definitions for ''cancelled flight'' and ''discontinued flight'' in part 234 when reporting their on-time performance data to the Department. In response to the comment by U.S. Chamber of Commerce, the Department notes that its current policy requiring airlines to provide refunds due to flight cancellations applies irrespective of the reason for a cancellation, and this continues to be the case under this final rule. The Department further adds that the final rule adopted here does not require airlines or ticket agents to provide a refund to a passenger for a canceled flight if that passenger accepts the alternative transportation offered and is reaccommodated.

4. Definition of ''Significant Change of Flight Itinerary''

The NPRM proposed to ensure consistency on when passengers are entitled to a refund for a significantly changed flight by defining the term ''significant change of flight itinerary'' instead of relying on a case-by-case analysis on whether a flight change was significant to the consumer. The Department proposed that changes that affect departure and/or arrival times, departure or arrival airport, a change in the type of aircraft that causes a significant downgrade in the air travel experience or amenities available onboard the flight, as well as the number of connections in the itinerary, would be significant to consumers. The NPRM sought comments regarding whether this approach is reasonable and fair to passengers while not imposing undue burden on carriers and ticket agents, and whether there are any other changes to flight itineraries that airlines may make that should also be considered a ''significant change of flight itinerary.'' The NPRM also sought comments on whether there are any operational concerns from airlines and ticket agents when implementing these proposed definitions into their refund policies that should be taken into consideration.

A. Types of Significant Changes

(i) Early Departure and Late Arrival

The NPRM: The NPRM considered three options in defining the extent of early departure or delayed arrival that

[30] Under 14 CFR part 234, which sets forth the requirements that U.S. carriers must follow when submitting, among other things, on-time performance data to the Department, a ''cancelled flight'' is defined as a flight operation that was not operated, but was listed in a carrier's computer reservation system within seven calendar days of the scheduled departure.

[31] Three members representing consumer rights advocacy groups, State Attorneys General, and airports, respectively, voted for the recommendation, and the member representing A4A voted against the recommendation, stating that although A4A generally supports DOT defining the term, the proposed definition does not address several concerns that A4A mentioned in its comments to the rulemaking. According to the ACPAC Charter, a quorum must exist for any official action, including voting on a recommendation, to occur. A quorum exists whenever three of the appointed members are present, whether in person and/or virtually. In any situation involving voting, the majority vote of members will prevail, but the views of the minority will be reported as well.

would qualify as ''significant changes.'' The first option, which the NPRM proposed, is a set timeline of three hours applicable to domestic itineraries and another set timeline of six hours applicable to international itineraries that would constitute a significant departure and arrival time change. The NPRM emphasized that airlines and ticket agents would be free to apply a shorter timeframe that constitutes a significant departure or arrival change but would not be able to increase it beyond three hours for domestic flights and six hours for international flights. The NPRM described this approach to be the most straightforward, clearly defined standard that would be easily understood by airlines and consumers, making it easier to train airline and ticket agent personnel on how to respond to refund requests, and potentially streamlining and expediting the refund review and issuance process. In applying the proposed standard to a refund request, the NPRM explained that the proposal's focus is only on the departure time of the first flight segment and/or the arrival time of the final flight segment. In other words, an early departure of a connecting flight or a late arrival of a flight that is not the final flight segment, even if exceeding the proposed timeframe, may not necessarily result in a passenger being entitled to a refund. In addition, the NPRM clarified that the proposed standard for international itineraries would apply to the early departure or the late arrival of a domestic segment of those itineraries if the domestic segment is the first or the last segment and is on the same ticket as the international segment.

The second option the Department considered in the NPRM is the option of not defining the timeframes of early departure and late arrival. Under this approach, the Department would continue to use the word ''significant'' to describe the amount of time change that would justify a refund. The Department stated that it has concerns that this option of leaving the determination of refund-qualifying flight schedule time changes to individual airlines is not the best way to achieve the balance between considering all relevant factors impacting consumers on the one hand, and ensuring the efficiency, consistency, and certainty of its regulation on the other hand, and may not be in the public interest. The NPRM sought comments on whether continuing to provide airlines the flexibility to define significant flight schedule time change is a better option than the proposed approach (option 1) of defining a significant departure or arrival change to mean beyond three hours for domestic flights and six hours for international flights.

A third approach considered by the Department is to define significant departure and arrival time change through the adoption of a tiered structure based on objective factors such as the total travel time of an itinerary. The NPRM provided an example of a tiered standard using the illustration below.

Original scheduled total travel time (measured from the scheduled departure time of the first flight segment to the scheduled arrival time of the last flight segment)	Projected arrival delay or early departure as offered to passenger	Result
3 hours or less	2 hours or less	Refund Not Required.
	More than 2 hours	Refund Due.
3–6 hours	3 hours or less	Refund Not Required.
	More than 3 hours	Refund Due.
6–10 hours	4 hours or less	Refund Not Required.
	More than 4 hours	Refund Due.
More than 10 hours	5 hours or less	Refund Not Required.
	More than 5 hours	Refund Due.

The NPRM acknowledged that this approach would be more difficult for carriers to implement and for consumers to understand because a determination on whether a refund is due would be based on each individual itinerary. The NPRM asked whether the industry considers the adoption of this type of tiered standard to be practical and whether consumers believe this type of tiered standard would better reflect the inconvenience and disruption caused by a flight schedule change.

Comments Received: A4A expressed its support for adopting a set timeframe standard for determining whether a refund is due. A4A stated that, however, the standard should only include late arrivals (delays) and not early departures because it is consistent with the Department's reporting regulation for U.S. carriers. A4A further suggested that the standard should be four hours for domestic itineraries and eight hours for international itineraries. A4A also commented that a schedule change accepted by the passenger should reset the calculation for delays for the purpose of refund. RAA supported A4A's position that the standard should only cover delays but not early departures, arguing that including both would create potential conflict when the arrival time did not exceed the standard, but the departure time did. RAA also supported A4A's suggestion on calculation of delay being reset once a passenger accepts an alternative flight. RAA suggested that a flight diversion should not be treated as a significant change of flight itinerary as long as passengers are transported to their final destination because safety and security are usually the principal reason for diversions. NACA and its member Allegiant Air (Allegiant) commented that the three/six-hour standards unduly burden Ultra-Low-Cost-Carriers (ULCCs) because of their limited networks and the lack of interline agreements with the large U.S. airlines that have operated for many years. They believed that the proposal would increase operating costs and ultimately result in higher airfares. Allegiant further suggested that the Department should not require refunds when the reason for the cancellation or delay is outside of a carrier's control, as long as the carrier makes a good faith effort to rebook the passenger. Spirit Airlines, another NACA member, commented that it has a two-hour standard for both domestic and international itineraries, and it does not object to the proposed three/six-hour standards. IATA, AAPA, and Qatar Airways supported the second option, which is to allow carriers to set their own standards for flight schedule time change. IATA argued that a uniform standard harms consumers who travel with airlines that currently have a more generous policy. IATA suggested that if the Department adopts a set of uniform standards, it should be four hours for domestic itineraries and eight hours for international itineraries, with the international standard applying to all segments. Air Senegal and SATA

International—Azores Airlines, S.A. (SATA) also supported an eight-hour standard for international itineraries. AAPA stated that the proposal disregards many contributory factors impacting ultra-long-haul operations including weather, safety, security considerations, and government restrictions. Among consumer comments, National Consumers League supports the proposed three/six-hour standards. However, FlyersRights stated that the proposed standards are more lenient than many carriers' current policies. FlyersRights believes that the refund rule should count for delayed departures (as opposed to late arrivals) and the standard should be two hours for domestic and three hours for international itineraries. FlyersRights further commented that for early departures, the standard should be one hour for domestic and two hours for international itineraries. FlyersRights explained that it views early departures as being more harmful to consumers because for late departures, consumers are usually already waiting at the airports. Travelers United shared FlyersRights' view that the proposed standards are more generous to airlines than many airlines' policies and suggests that the standards should be 90 minutes. Among the over 4,500 individual consumer commenters, approximately 500 commented on the proposed three/six-hour standards, with 85% in support, and 15% suggesting shorter hours, such as two hours for domestic and four hours for international, or three hours for both.

Two ticket agent trade associations, the Destination Wedding & Honeymoon Specialists Association (DWHSA) and USTOA, expressed their support for the proposed three/six-hour standards on early departures and late arrivals. Similarly, the ACPAC recommended that the Department adopt the proposed three- and six-hour delay standard under which a refund is due.[32] The joint comment filed by 32 State Attorneys General also advocated for a three-hour delay benchmark being the floor for consumers' entitlement to refunds and stated that this floor will result in benefits for consumers on airlines with unclear or lengthier delay parameters for refunds. The comment further argued that because some airlines currently adopt a short timeframe, the Department should take steps to ensure that setting a floor does not cause these airlines to loosen their standards to the detriment of consumers. With respect to the third option proposed in the NPRM to adopt a standard with a tiered matrix based on objective factors such as the total travel time of an itinerary, several airline commenters as well as individual consumers expressed their opposition, arguing that this approach is not workable because there are too many variables.

DOT Responses: The Department appreciates the comments by stakeholders on the proposed standards for flight departure/arrival changes that would constitute ''significant changes of flight itinerary.'' The Department agrees with commenters that defining significant departure and arrival through the adoption of a tiered matrix based on an objective factor such as total travel time to determine significance is unworkable because of its complexity. Based on the support from the airline and ticket agent industries and consumers, the Department has determined that adopting a unified standard consisting of set timeframes to determine whether a flight schedule change constitutes a significant change is a preferred approach as compared to the current policy of allowing airlines to set their own timeframes. This approach provides much needed clarity and consistency to consumers with respect to their rights to refunds, no matter on which airline they travel.

The Department has further concluded that covering early departure of the initial flight segment and late arrival of the final flight segment is reasonable and workable for airlines and ticket agents, and beneficial to consumers. Commenters have varied perspectives on whether the definition of significant change should be based on early or late departure of the initial flight segment or the late arrival of the final flight segment. We have considered some airlines' comments that the timeframes should apply only to flight late arrivals (delays) but not early departures, as well as FlyersRights' comment that the timeframes should apply to change in flight departure time (early or late departures) regardless of whether consumers' arrival time is significantly changed. We disagree with these suggestions. The Department has concluded that it is important to ensure that the definition of significant change includes both early departure as consumers may not be available to take the flight significantly earlier than scheduled, and late arrivals, because arriving significantly later than scheduled may make the trip moot (*e.g.,* job interview) or severely disrupt travel plans (*e.g.,* miss embarkation of a cruise). In contrast, the Department does not believe that a late departure would cause as much disruption, so long as the consumer arrives at the final destination without substantial delay. As FlyersRights pointed out, consumers are already at the departure airport while waiting for a delayed departure flight, and the late departure alone does not add significant amount of additional time to the total time that the consumers already carved out for travel.

Regarding the timeline that would constitute a significant departure and arrival time change, the Department agrees with the comment provided by the State Attorneys General and others that the proposed three-hour timeframe for domestic itineraries and six-hour timeframe for international itineraries constitute a significant departure and arrival time change. The Department acknowledges that several airlines' current refund policies adopt shorter timeframes than the proposed three/six-hour standards, and the Department notes that these airlines are not only permitted under this final rule to continue these polices but are encouraged to do so. The Department establishes a baseline to set the minimum consumer protection requirement, and the Department expects that healthy competition in the marketplace will lead to airlines adopting consumer-friendly refund policies that go above and beyond the regulatory minimum. The Department will closely monitor airlines' implementation of this final rule and the impact on consumers to determine whether the three/six-hour timeframes are adequate to ensure that consumers who experience significant disruptions and inconveniences from airline flight schedule changes receive refunds if they so choose.

The Department is not persuaded by NACA's argument that ULCCs are unduly burdened by the three/six-hour standard and it would ultimately cause higher airfares. The fact that at least one ULCC has already implemented for some time a refund policy with a schedule delay threshold lower than the Department's minimum standard indicates that the three/six-hour standard can work well with ULCCs' unique business model and competition strategies, and it will not be detrimental to maintaining ULCCs' fare structure.

The Department is also not persuaded by comments that a schedule change accepted by the passenger should reset the calculation for delays for the purpose of refunds. Under the final rule,

[32] Three members representing consumer rights advocacy groups, State Attorneys General, and airports, respectively, voted for the recommendation, and the member representing A4A voted against the recommendation, stating that A4A supports defining ''significant delay'' but does not support the three- and six-hour timeframes.

a consumer's acceptance of the flight schedule time change when the original flight encounters expected early departure or late arrival or a consumer's acceptance of another flight when the original flight was cancelled does not reset the clock. The timeframes adopted here are measured from the *original* departure and arrival times offered to consumers when they purchased their tickets, and any deviation from those times represents a change to the product that they agreed to and paid for. By adopting these timeframes in the regulation, the Department has deemed that any change to these *original times* by three hours or more for domestic itineraries and six hours or more for international itineraries are *material and significant* to consumers and they are entitled to a refund if they do not accept the change, or any alternative transportation offered. Although the Department understands that flight schedule changes may occur multiple times before the flight's actual operation, we believe it is fundamentally unfair to consumers and it will defeat the purpose of this rule if we allow the clock to reset every time a consumer accepts the time change to a flight. In a typical rolling delay scenario, a domestic flight initially projected to arrive two hours late could actually be delayed for eight hours, with each new projection adding two more hours at a time, and if the clock resets each time, the consumer would never be entitled to a refund despite the lengthy delay.

Regarding RAA's comment that the refund requirement should exempt situations involving flight diversions due to safety or security concerns as long as passengers were ultimately transported to their destinations, the Department does not view the refund requirement as applying to these diversion situations. Typically, when a decision to divert a flight is made, the flight has already departed and from the passenger's perspective, the travel already took place. The passengers would not have the opportunity to refuse the flight. For those passengers, the issue of requesting compensation for their inconvenience caused by the diversions will be addressed in the Department's forthcoming rulemaking on Rights of Airline Passengers When There Are Controllable Flight Delays or Cancellations.[33]

[33] *See https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=2105-AF20.*

(ii) Change of Origination, Connection, or Destination Airport

The NPRM: The Department proposed to define a significant change that would entitle a consumer to a refund to include a change of the origination or destination airports. The Department reasoned that most consumers are concerned about origin and destination airports when booking a flight itinerary because of convenience and stated that a carrier-initiated change in the origination or destination airport is likely to lead to additional time and cost for consumers. The NPRM did not propose to require refunds if a carrier changes the connecting airport(s) and instead invited comments on whether a change of connecting airports should also be considered a significant change that would entitle consumers to a refund. Further, the NPRM asked whether special consideration on refund eligibility should be given in situations where passengers choose to connect at a particular airport with extended layover time for specific purposes beyond connecting to the next flight, such as conducting business or visiting family, friends, or tourist sites at that location.

Comments Received: Airline commenters generally supported including the change of an origination or destination airport as a ''significant change of flight itinerary.'' They contended, however, that the definition should exclude a change of airport involving airports located in the same metropolitan area. A4A and AAPA suggested that a change between two ''co-terminal airports,'' as defined by the Transportation Security Administration's (TSA) regulation, should be exempted.[34] Airline commenters argued that these airports are sufficiently close in proximity to each other, indicating that a change of the airport would not necessarily significantly impact consumers' travel plans. Some carriers further argue that allowing this exemption would incentivize carriers to provide greater rebooking options. Air Senegal provided long-haul international carriers' perspective by arguing that these carriers' first and foremost goal is to provide transportation between two major metropolitan gateways and a change of airport within the same metropolitan area that is necessitated by circumstances beyond the carrier's control (*e.g.,* airport staffing shortage, government public health restriction) should not trigger the refund obligation. Airline commenters also supported the position that a change of connecting airport should not be considered a ''significant change of flight itinerary.'' IATA commented that if a passenger wishes to have a longer layover at a particular airport, airlines should accommodate by rebooking on another flight to that layover airport.

Consumers, consumer rights advocacy groups, and ticket agent representatives who commented on this issue were in support of the Department's proposal. Two disability rights advocacy groups, Paralyzed Veterans of America (PVA) and United Spinal Association, commented that, from passengers with disabilities' perspective, any change to the origination, connection, and destination airport should be considered a ''significant change of flight itinerary.'' They stated that when booking flights, passengers with disabilities may rely on the specific accessibility features of an airport to select the flights and itinerary, and this may include selecting a particular connecting airport based on the accessibility features needed to accommodate their disabilities during the layover time.

DOT Responses: There is a consensus from all the comments received that a change of the origination or destination airport in general would significantly impact a passenger's travel plan and should be considered a basis for a refund if the passenger no longer wishes to travel. The Department disagrees with airlines' suggestion that the regulation should exempt changes of airports located in the same metropolitan area. In the Department's view, a change in the origination or destination airport when located in the same metropolitan area could still significantly impact passengers depending on the passenger's specific circumstances including whether the new airport is sufficiently close to their residence or the hotel so they have the flexibility to navigate to or from the new airport without substantial additional cost, whether they have the additional time needed to travel to or from the alternative airport, and whether affordable ground transportation is available for them to get to or from the alternative airport. Given the potential impact, the Department believes that the best approach is to require refunds if passengers reject the change in origin or destination airport even if in the same metropolitan area. The Department also believes that this approach would not impose a substantial negative impact on long-haul international carriers, who

[34] Co-terminal [airport] means an airport serving a multi-airport city or metropolitan area that has been approved by TSA to be used as the same point for purposes of determining application of the security service fee imposed under [49 CFR 1510.5]. *See* 49 CFR 1510.3.

stated that the main goal of their operations is to transport passengers between two major metropolitan gateways. Passengers carried on long-haul international flights who are focused on arriving at the destination city as opposed to a specific airport can accept the alternative airport offered by the carrier. The Department further notes that in the case of flights being directed to a ''co-terminal'' airport due to government restrictions, such as a requirement to funnel flights for communicable disease screening purposes, it is likely that passengers would not have a choice to travel on an alternative flight that is destined to the original airport. The Department believes that passengers should have the choice of either traveling to the co-terminal airport, which is likely to be the choice of many passengers, and the option of receiving a refund.

With respect to a change of a connecting airport, the Department is defining such a change to be a ''significant change of flight itinerary'' only for consumers who are persons with a disability. The Department continues to believe that a change in a connecting airport would not impact most passengers because travelers' goal is to get to the destination, and they generally care less about the connecting airport. The Department is also not convinced that imposing a refund mandate is necessary for passengers who specifically arranged to have an extended layover at a connecting airport for other business or leisure purposes. Consumer comments were generally silent on this issue, and IATA has stated that airlines generally make such an accommodation on their own when requested.

The Department has decided to require a refund to a passenger with a disability [35] and other passengers on the same reservation who choose not to fly when the person with a disability does not accept a change in the origination, destination, and connection airport. The Department appreciates PVA and United Spinal Association sharing their view that not defining a change to the origination, connection, and destination airport as a ''significant change of flight itinerary'' would negatively impact persons with disabilities. The Department accepts that a change of the origination, connection, or destination airport may represent a significant change to a person with a disability as the layout, design, and the availability of accessibility features of these airports are a major consideration for persons with disabilities when they select travel itineraries. A change of any of these airports could cause great harm to passengers with disabilities if the new airports are not as accessible as the original airports. This change could affect, for example, a passenger traveling with a service animal who carefully selected an airport with a service animal relief area located near the passenger's connecting gate to accommodate a tight connection timeframe, or a passenger with visual impairment who chose a connection, origination, or destination airport that provides wayfinding/mapping technologies through a mobile app. Further, the Department is of the view that a change of airports, at a minimum, adds uncertainties to the person with a disability regarding the accessibility of the airport and that the passenger with a disability is in the best position to conduct a risk assessment and determine whether he or she still wants to travel from, to, or through a particular airport.

(iii) Increase in the Number of Connection Points

The NPRM: The NPRM proposed that adding to the number of connection points in an itinerary qualifies as significant change that entitles a consumer to a refund if the consumer no longer wishes to travel. The Department explained that the number of connection points in an itinerary would significantly affect the value of a ticket because the more connection points, the more likely passengers will experience flight irregularities, complications, and disruptions, as well as mishandled checked baggage. As evidence, the Department pointed out that airfares are generally higher for an itinerary with fewer connection points than an itinerary with more connection points.

Comments Received: Airline commenters unanimously opposed considering adding connection points as a ''significant change.'' Large U.S. airlines argued that connections are a fundamental part of carriers' network structure and carriers should be allowed the ability to consider all available options to reroute passengers, including through additional connecting points. ULCCs argued that because of their small networks and the lack of interline partners, they may have to rebook passengers with more connections, and this would penalize ULCCs and other small carriers despite their best effort to reaccommodate passengers. Carriers also argued that adding connections does not necessarily mean consumer inconveniences and, in some cases, passengers may even arrive earlier than the original schedule. These carriers asserted that additional connections without adding more travel time or significant delay should not be considered a ''significant change.'' IATA commented that this proposal directly conflicts with the APPR, the Canadian regulation protecting air travelers, which includes obligation to reroute passengers on a reasonable route, including connections.

U.S. Chamber of Commerce also opposed the proposal, stating that in cases of severe weather or major disruptions at a hub airport, it is necessary to rebook passengers on itineraries with more connections to ensure that they get to their destinations as swiftly as possible.

Unlike airlines, National Consumers League and FlyersRights supported the Department's proposal to define significant change to include additions in the number of connection points on a flight itinerary. PVA and United Spinal Association also expressed their support for the proposal, stating that adding connections is a significant change to passengers with disabilities because additional connections mean additional inconveniences, increased chance of passenger injury during transfer, boarding, deplaning, and increased chance of damage to assistive devices such as wheelchairs, which may further lead to passengers being forced to use loaner chairs while waiting for their wheelchairs to be repaired, causing other health and safety concerns. These disability organizations also commented that more harm may occur from extended overall travel time to passengers forced to dehydrate themselves during travel because they cannot use the lavatories, or passengers who need to minimize the time spent in an airport wheelchair. In this regard, PVA suggested that extending the layover time by more than one hour is a significant change.

DOT Responses: The Department has decided to include an increase in the number of connections in a flight itinerary in the definition of ''significant change of flight itinerary.'' The Department finds the comments by PVA and United Spinal Association about the substantial inconveniences, and in some

[35] A passenger with a disability means an individual with a disability who, as a passenger

(1) With respect to obtaining a ticket for air transportation on a carrier, offers, or makes a good faith attempt to offer, to purchase or otherwise validly to obtain such a ticket;

(2) With respect to obtaining air transportation, or other services or accommodations required by this Part,

(i) Buys or otherwise validly obtains, or makes a good faith effort to obtain, a ticket for air transportation on a carrier and presents himself or herself at the airport for the purpose of traveling on the flight to which the ticket pertains; and

(ii) Meets reasonable, nondiscriminatory contract of carriage requirements applicable to all passengers. *See* 14 CFR 382.3.

cases, potential harm and injury to passengers with disabilities from additional connections to be compelling. The Department further views that adding connections may also negatively affect passengers who do not have a disability in many ways. It is a common sense that when a non-stop itinerary becomes a one-stop itinerary, or a one-stop itinerary becomes two-stop itinerary, each added stop indicates increased chance of irregularities, including the potential of missed flights and/or delayed baggage due to short connecting times, flight delays due to weather or air traffic control issues at the additional connecting airport, and additional complications related to traveling with young children or the elderly.

The Department disagrees with IATA's comment that considering an additional connection as a ''significant change'' under which a refund is due conflicts with APPR. Under APPR, carriers are obligated to provide passengers the option of rerouting or refunds.[36] APPR does not prohibit carriers from providing a refund if a consumer does not wish to be rerouted or does not accept the rerouting offered by carriers. Also, this final rule does not require carriers to provide a refund if the passenger prefers a rerouting even if that rerouting includes additional connections. The Department believes that the APPR and this final rule, when working together, increase choices provided to consumers affected by cancellations and significant changes and empower consumers to choose the best options for themselves, either rerouting or receiving a refund.

The Department is also not convinced that allowing additional connections to be a basis for a refund would impede carriers' ability to offer alternative itineraries including itineraries with additional connections. As stated throughout this document, the goal of defining ''significant flight itinerary'' is to set a baseline for consumers' rights to refunds when they are affected by a qualified change by providing them an opportunity to evaluate any alternative transportation offered by carriers against the option of obtaining a refund. The fact that a consumer is eligible for a refund because of a significant change does not mean airlines cannot or should not offer alternative transportation. In addition, there is nothing in the Department's regulation that prevents carriers from fully utilizing their networks and offering options with different connecting points to passengers. For example, if a passenger's non-stop flight is cancelled and the carrier determines that traveling on a set of connecting flights would get the passenger to the destination sooner than waiting on the next non-stop flight, the carrier is free to make the offer, and the passenger will likely accept the offer if the additional connection is acceptable and arriving at the destination sooner is more important to that passenger than a non-stop flight.

(iv) Change of Aircraft Resulting in Significant Downgrade of Available Amenities and Travel Experiences

The NPRM: While acknowledging that substitution of aircraft is often required for operational reasons, and that most substitutions do not substantially affect consumers' travel experience, the Department proposed that a change of aircraft would be considered a significant change entitling the affected passengers to a refund only if it results in ''a significant downgrade of the available amenities and travel experiences.'' The NPRM recognized that aircraft substitution may impact passengers differently, noting that an aircraft change may impact a passenger traveling with a wheelchair when the wheelchair no longer fits in the cargo compartment of the new aircraft, but it may not impact another passenger, even one with a disability. The NPRM proposed that the lack of certain disability accommodation features as the result of aircraft change, such as onboard wheelchair storage spaces and moveable armrests, which negatively impacts the travel experiences of persons with a disability and their access to services onboard, would be considered a ''significant change'' that entitles the passenger to a refund upon request. The Department solicited comments on how to determine whether an aircraft downgrade is a significant change, whether it should be a case-by-case analysis, and whether there are certain types of changes in amenities or air travel experiences that should automatically be considered significant irrespective of the affected person.

Comments Received: Airlines and their representatives expressed strong concerns about the proposal and argued that the term ''significant downgrade of available amenities and travel experiences'' is too broad, vague, and subjective. U.S. Chamber of Commerce supported the airlines' argument that the proposal is too vague and broad. A4A suggested that in the absence of clear guidance on this term, passengers could assert seat configuration changes, the lack of Wi-Fi, a decrease in the number of available movies, and a reduction of seat reclining degrees as a significant downgrade. A4A commented that if the Department finalizes this category as a significant change, it should allow airlines to establish and publish their own criteria and adhere to the standard. IATA and Air Canada argued that this proposal would significantly impact carriers operating multiple types of aircraft, or airlines that are experiencing significant flight disruptions and needing the flexibility to fully utilize all available aircraft to mitigate total passenger inconveniences across the network. IATA pointed out that the proposal does not consider the situations where a substitute aircraft provides downgrades to certain amenities and upgrades to other amenities. Airline commenters agreed that a change of aircraft that impacts a carrier's ability to accommodate mobility aids should be considered a significant change.

National Consumers League and FlyersRights expressed their support of the Department's proposal to consider a significant downgrade of available amenities and travel experiences to be a significant change that would entitle consumers to a refund. FlyersRights added that changes in aircraft size, stowage space, or seat size that no longer allow passengers with disabilities to travel safely should be considered a significant change. Several individual consumer commenters also supported this proposal.

Among ticket agent representatives, USTOA opposed the proposal, asserting that it is too subjective and thus unworkable. It further commented that a change from a twin-aisle aircraft to a single-aisle aircraft, the loss of Wi-Fi, or a change to an older version of business class may have little impact on some consumers but more impact on others. It opined that to determine whether a passenger is eligible for a refund under the proposal may cause extensive and time-consuming disputes between consumers and airlines and it is counter to the Department's goal of achieving consistency across the industry. Global Business Travel Association agreed that aircraft change causing a lack of disability accommodation should be considered as a significant change. It further stated that a service downgrade such as the lack of Wi-Fi would materially impact the value of a flight to business travelers.

Disability rights advocacy groups voiced their strong opinion that aircraft changes affecting disability accommodations should be viewed as significant changes for passengers with

[36] *See* Air Passenger Protection Regulation (SOR/2019–150) (APPR), Sections 17–18. *https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-150/index.html.*

disabilities. PVA commented that if a substitute aircraft cannot accommodate a passenger's assistive device, carriers should accommodate the affected passenger and any caregivers, family members, and other companions on another flight of that carrier or other carriers, or other mode of transportation without additional cost. All Wheels Up commented that the Department should specify that refunds for the affected passenger and others in the travel party are required when the substitute aircraft cannot accommodate wheelchairs in the cargo compartment. United Spinal Association also supported the position that a significant change includes downgrade or change of aircraft without equal accessibility features. It urged the Department to require carriers to find accessible alternative transportation. PVA and United Spinal Association also commented on additional accessibility-related issues beyond the substitution of aircraft, which will be discussed in detail in the next section.

Public Hearing: In addition to considering the public comments filed in the rulemaking docket, at the request of A4A and IATA, the Department also conducted a public hearing pursuant to the Department's procedural regulation on rulemakings relating to unfair and deceptive practices at 14 CFR 399.75. Such hearings are intended to afford stakeholders an opportunity to present factual issues that they believe are pertinent to the Department's decision on the rulemaking. One of the subjects stakeholders raised during the hearing is how to determine whether a downgrade of amenities or travel experiences qualifies as a ''significant change of flight itinerary.'' In the Notice [37] announcing the hearing, the Department requested interested parties to provide information on whether there are certain types of amenity changes that should be considered ''significant'' changes that would entitle a consumer to a refund and if so, whether the determination should be made categorically or by airlines on a case-by-case basis. The Department also requested information on how different airline operational and pricing models affect onboard amenities and travel experiences, and subsequently affect consumer expectations.

During the public hearing, airline representatives reiterated the view they expressed in the written comments to the NPRM that the proposal undercuts the Department's goal of achieving consistency and predictability to consumers who are affected by itinerary changes. They pointed out that the proposal relies heavily on the subjective expectations of travelers and the vague concept of ''significant downgrade of available amenities and travel experiences'' creates problems for all parties involved, leading to time-consuming and unsatisfactory case-by-case adjudications by the airlines and the Department. They suggested that if the Department proceeds to finalize this proposal, it should explicitly limit qualifying downgrades to those identified in the airlines' customer service plans. They further indicated that airlines would support the concept of considering the inability to accommodate a passenger's mobility device to be a significant change. Representatives from FlyersRights and National Consumers League both expressed their support of the proposal to consider a change of aircraft that results in ''a significant downgrade of the available amenities and travel experiences'' to be a significant change that entitles consumers to a refund if they choose not to travel. The representative from FlyersRights commented that the guiding principle in determining what downgrades are significant should be whether a typical passenger would have booked the flight knowing that they would receive a downgrade of amenities or travel experiences. That representative further commented that allowing airlines the sole discretion to make the determination will lead to ever shifting standards. The representative from National Consumers League commented that if airlines were allowed to determine what downgrades are significant, it is highly likely that airlines would define it so narrowly as to make the consumers' rights under DOT regulation unusable by most consumers. He suggested that the Department should adopt a definition that covers as many services as possible to give consumers the flexibility to determine what is and is not a significant downgrade for them.

A representative from PVA spoke at the hearing regarding the broad impact of flight itinerary changes on passengers with disabilities. In addition to the impact of aircraft substitution on the transportation of passengers' mobility aids, she also commented on changes of other accessibility features that may lead to significant disruption to passengers' travel, such as the lack of accessible lavatories. She emphasized that passengers with disabilities should not be forced to accept flights that cause unnecessary inconveniences or undesirable circumstances because the negative impact of air travel extends not only to the passengers but also to those who assist them during the journey or at the destination. Therefore, she commented that any determinations regarding significant changes should be made categorically, considering the challenges faced by these passengers.

Representatives from Travel Tech and Travel Management Coalition spoke on behalf of ticket agents. While supporting the Department's proposal in principle, they emphasized the importance of designating airlines with the responsibility to determine whether a change of available amenities or travel experiences caused by aircraft substitution is a significant change. They commented that ticket agents rely on clear guidance from both the regulatory bodies and airlines to make these determinations.

A public participant provided her opinions as an expert on consumer law on this issue by suggesting that the Department should adopt a ''reasonable consumer'' standard. She commented that the determination should be a case-by-case analysis and encouraged the Department to provide guidance but not adopt a rigid definition.

Following the hearing, A4A, IATA, Spirit, USTOA, and PVA filed supplemental written comments on this issue. A4A and IATA's joint comment emphasizes their position to support a rule requiring refunds when aircraft downgrade prevents the transportation of a passenger's mobility aid, when an accessible lavatory is no longer available on the flight, when an on-board wheelchair requested by a passenger is no longer available, or when moveable armrests are not available on the aircraft. Spirit commented that a rule consistent with the Department's oversales regulation should be adopted to require a refund for the amenity not provided, but not a refund for the full fare. USTOA comments that, in addition to its written comment on the NPRM, it continues to strongly oppose the proposal as it believes that consistency and predictability are necessary and crucial elements in a final rule which would be lacking if the Department adopts the proposed standard. USTOA adds that public interest will not be served by adopting the proposal that introduces further confusion into the ticket refund process and leaves sellers of travel to grapple with case-by-case determinations. PVA's comment urges the Department to establish a clear definition to include downgrades of amenities and travel experiences for passengers using mobility devices. PVA further provided examples of downgrades that affect these passengers, including circumstances in which the

[37] 88 FR 13387, Mar. 3, 2023.

mobility aids will not fit in the cargo compartment or in-cabin stowage, loss of lavatory access and/or on-board wheelchair, and loss of movable armrests.

DOT Responses: After carefully considering all the comments, the Department has determined that adopting the proposal to include in the definition for ''significant change of flight itinerary'' any aircraft change that leads to ''significant downgrade of available amenities or travel experiences'' applicable to *all passengers* is not practical and workable, and as a result, we are modifying the proposal to cover specific passengers who are categorically protected and would be affected by this ''significant change.'' The Department recognizes the ambiguity and subjectivity of the proposed term ''significant downgrade of available amenities and travel experience'' and has determined that adopting this term and requiring airlines and ticket agents to conduct a case-by-case analysis will lead to tremendous confusion among consumers, airlines, and ticket agents, who would incur significant administrative costs when disputes arise. The Department also believes that outside of accessibility features, most discomfort and inconvenience caused by aircraft substitution-related changes can be addressed between airlines or ticket agents and their customers without a regulatory mandate on ticket refunds. In another part of this final rule, the Department is adopting the proposal to require airlines to provide refunds for any ancillary service fees when the services that consumers paid for are not provided. The Department believes that this strikes a good balance between ensuring that consumers receive a refund of the ancillary service fees for services that they did not receive, including due to aircraft substitution, and avoiding the major administrative complication related to determining what amenities or ancillary services are so significant to a passenger that their loss warrants a refund of the entire ticket.

On the other hand, the Department strongly agrees with the disability rights organizations that any change of aircraft that leads to the unavailability of an accessible feature needed by a passenger with a disability is a significant change and should entitle the passenger to a refund. We recognize that for persons with disabilities, a downgrade of onboard amenities or travel experiences from aircraft substitution may have serious negative implications on the passengers' health and safety and may fundamentally change these passengers' decision about travel. As such, the Department determines that aircraft substitution leading to an accessibility feature being unavailable to a passenger with a disability who needs the feature is categorically a ''significant change'' for that passenger. The Department notes that comments from airlines focus on a change involving the inability to transport a wheelchair in the cargo compartment, which is an example provided in the NPRM. The Department's final rule, however, is broader than that example. Under this final rule, airlines and ticket agents are required to refund to a passenger with a disability who no longer wishes to travel if an aircraft change leads to the loss of one or more accessibility feature needed by that passenger. Such features would include, but are not limited to, in-cabin stowage of assistive devices, a movable armrest, accessible lavatories, on-board wheelchairs, and cargo stowage of mobility aids. The Department is also requiring airlines and ticket agents to provide refunds to other individuals traveling with the passenger with a disability in the same reservation, if the passenger with a disability no longer wishes to travel due to a significant change impacting accessibility. Details of this requirement will be discussed in Section B below.

The Department also notes that although the rule does not specifically require airlines to provide refunds to passengers who are affected by aircraft substitution outside of the disability accommodation grounds, we expect that airlines will continue to assess the impact of aircraft substitution on each passenger based on the passenger's situation and consider providing refunds when appropriate.

(v) Downgrade in the Class of Service

The NPRM: The NPRM proposed that a carrier-initiated downgrade in the class of service is a ''significant change of flight itinerary'' and would entitle a passenger to a refund if the passenger decides not to continue travel. The NPRM noted that under the Department's oversales regulation, when a passenger on an oversold flight is offered accommodation or is seated in a section of the aircraft for which a lower fare is charged, the passenger is not entitled to be denied boarding compensation but is entitled to an appropriate refund for the fare difference, assuming the passenger traveled on the flight in the downgraded class of service.[38] Here, the NPRM proposed that when a passenger is downgraded to a lower class of service, either on the originally booked flight or on an alternative flight offered by the carrier, and the passenger declines to take the downgraded flight, a refund of the entire unused portion of the ticket must be offered. The NPRM explained that the Department views a downgrade in the class of service as significantly changing the passenger's ticket value and travel experience and entitling the consumer to a refund of the ticket price and any unused ancillary services if the consumer does not travel. The NPRM further clarified that the proposal is not limited to situations where the entire flight or the class of service the passenger was initially booked on was oversold. Downgrade of a passenger's class of service could occur for other reasons such as weight and balance or change of aircraft. The NPRM asked whether the Department should require airlines to provide a refund of only the ticket price difference, and not mandate a full refund if the passenger does not accept the downgrade, similar to the existing oversales regulation.

Comments Received: Airline representatives opposed the Department's proposal of considering a downgrade of the class of service a significant change, arguing that it would disincentivize carriers from rebooking affected passengers on the same aircraft but in a lower class of service. They expressed their belief that a downgrade to a lower class of service should only result in a refund of the fare differences because the passenger would be provided with the flight as scheduled. IATA stated that if this proposal is adopted, minors and companions traveling with the downgraded passenger should not be eligible for a refund if they were not downgraded as well. This position was supported by Qatar Airways. IATA further requested that the Department define a change in ''class of service'' as a change of cabin to avoid any confusion. Air Canada suggested that the proposal, if adopted, would conflict with certain provisions of EC 261/2004, which requires compensation as opposed to refunds for certain downgrades. SATA suggested that the Department should adopt a similar requirement as EC 261/2004 that requires a percentage of refund according to the amount of fare paid and the flight distance.

DOT Responses: The Department has carefully considered this issue and determined that although not all passengers view a downgrade to a lower class of service so significantly that they would prefer to not travel on the flight, there are a substantial number of passengers who would be impacted significantly by a downgrade and would

[38] *See* 14 CFR 250.6(c).

prefer a refund. The Department believes that affected passengers should be given the choice of either accepting the change and continuing to travel or receiving a refund. The Department notes that many passengers with disabilities select a certain class of service when booking tickets for reasons related to their disabilities. For example, a higher class of service may provide extra legroom needed by passengers with a mobility impairment or traveling with service animals. Besides passengers with disabilities, other passengers may find a downgrade not acceptable because it substantially affects their travel experiences. For instance, a passenger of size being downgraded to a lower class of service may no longer wish to travel because of the discomfort associated with the reduced seat pitch and width, and this is particularly a concern for these passengers on long flights.

The Department is not convinced that this requirement would disincentivize airlines and ticket agents from offering to rebook passengers in a lower class of service, either on the original flight or another flight. As in all the other scenarios involving significant changes, carriers and ticket agents are free to offer a variety of other options to affected consumers so long as they are informed about their right to a refund. Consumers can choose the option that best meets their needs, including traveling in a lower class of service. Carriers and ticket agents are incentivized to make these offers to passengers to fill vacant seats on aircraft.

The Department clarifies that this final rule requiring carriers and ticket agents to provide a refund to passengers who choose to not travel when being downgraded to a lower class of service does not negate carriers' and ticket agents' obligation to refund the fare differences when passengers choose to travel in a lower class of service. This will continue to be the requirement regardless of whether the downgrade was due to an oversales situation or any other situation.

The Department does not believe that requiring airlines and ticket agents to provide a refund to passengers who are downgraded to a lower class of service conflicts with the laws of other jurisdictions, including EC261. Like the Department's oversales rule that requires carriers to refund the fare differences to passengers who are continuing to travel on a lower class of service, EC261 requires that carriers refund between 30% to 75% of the ticket price, depending on the distance of the flight, to a downgraded passenger who is continuing the flight. In contrast, this final rule simply addresses the situation in which the passenger chooses not to travel on the original or rebooked flight in a lower class of service, a situation that is not directly addressed in EC261.

As suggested by IATA, the Department is also adopting a definition of class of service in the final rule to avoid any confusion. A class of service is defined as seating in the same cabin class such as First, Business, Premium Economy, or Economy class, based on seat location in the aircraft and seat characteristics such as width, seat recline angles, or pitch (including the amount of legroom). Premium Economy would be considered a different class of service from standard Economy, while Basic Economy would not. Basic Economy seats do not differ in pitch size or legroom from standard Economy.

In situations where a group of passengers are traveling under the same reservation, the Department generally is not requiring airlines to offer refunds to all passengers in the group if not all passengers are affected by a downgrade of class of service, except when the affected passenger is a qualified individual with a disability *and* the downgrade of class of service affects an accessibility feature needed by that passenger, in which case refunds must be offered to all passengers in the group upon notification by the passenger with a disability or someone authorized to act on behalf of the passenger with a disability that the person with a disability does not intend to continue travel on that flight.

B. Individuals Entitled to Refunds When a Significant Change Impacts Accessibility

The Department agrees with comments received from disability rights organizations and is requiring a refund to a passenger with a disability and other passengers on the same reservation who choose not to fly because the person with a disability does not accept a significant change of flight itinerary resulting from a change in aircraft or class of service that results in the unavailability of one or more accessibility features needed by the person with a disability. The Department is also requiring a refund to person with a disability and others on the same reservation who do not wish to continue to travel because the person with a disability does not accept a significant change in flight itinerary resulting from a change in connecting airport. The Department believes that a change in the flight itinerary that reduces the accessibility of the air travel to a person with a disability must entitle not only that individual to a refund but also all other individuals on the same reservation.

The Department notes that being a qualified individual with a disability alone may not necessarily entitle travel companions to refunds. This final rule requires carriers to provide passengers with a disability affected by a change in aircraft or downgrade of a class of service a refund if they do not continue travel. That refund is limited to the individual being downgraded, however, unless the downgrade results in the unavailability of one or more accessibility features needed by the person with a disability. In that case, individuals who are not directly affected by the downgrade of class of service are also entitled to a refund. For example, if a passenger with a hearing impairment was downgraded to a lower class of service and it is determined that the downgrade does not impact any accessibility feature needed by that passenger, that passenger is entitled to a refund if he or she does not accept the downgrade, but airlines and ticket agents are not required to extend the refund offer to other persons in the same reservation who are not downgraded. Conversely, if a passenger needing extra legroom to accommodate a disability was downgraded and the extra legroom is no longer available as a result, that passenger is entitled to a refund and so are any other persons in the same reservation. For an aircraft change to entitle travel companions of a person with a disability to a refund, the aircraft change must result in the unavailability of one or more accessibility features needed by the person with a disability and that person with a disability must reject the significant change.

The Department believes that extending refund eligibility to travel companions of passengers with disabilities whose ability to travel comfortably or safely is significantly impacted by a flight itinerary change that affects accessibility is appropriate because family members or other individuals with whom the person with a disability is traveling may not wish to continue travel without that person. Also, the person with a disability may be traveling with a personal care assistant. The requirement that refunds must be offered to all passengers in the same reservation is intended to provide flexibility for passengers to determine whether the group wants to travel together, decline travel and receive refunds together, or split up with some continuing to travel and some (including the passenger with a disability) canceling travel and receiving refunds. Airlines and ticket

agents may not mandate that all members of the group make the same decision about refunds but may refuse refunds if the only passengers requesting refunds are those who would not have qualified for a refund but for traveling with the passenger with a disability.

The Table below summarizes the rights to a refund by individuals with disabilities and their travel companions on the same reservations under certain significant changes that may impact accessibility.

TABLE 1—RIGHTS TO A REFUND BY INDIVIDUALS WITH DISABILITIES AND TRAVEL COMPANIONS

Significant change	Is an individual with a disability entitled to a refund?	Are travel companions on the same reservation entitled to a refund if an individual with a disability rejects change?
Aircraft Substitution:		
Impacts an accessibility feature needed by a passenger with a disability.	Yes	Yes.
Does NOT impact an accessibility feature needed by a passenger with a disability.	No	No.
Downgrade in Class of Service:		
Impacts an accessibility feature needed by a passenger with a disability.	Yes	Yes.
Does NOT impact an accessibility feature needed by a passenger with a disability.	Yes (NOTE: any passenger downgraded is entitled to refund irrespective of disability).	No. (NOTE: if travel companion is downgraded then that individual would be entitled to refund).
Change of Connecting Airport:		
Does not require analysis of impact on accessibility	Yes	Yes.

The Department acknowledges that the disability organizations also requested that the rule impose a requirement on airlines and ticket agents to rebook passengers with disabilities and their travel companions on another flight or ground transportation that would accommodate the disability without additional cost. The Department is examining the issue further in its rulemaking on Ensuring Safe Accommodations for Air Travelers with Disabilities Using Wheelchairs.[39] The Department is committed to continuing its efforts to protect the rights of air travelers with disabilities and is further exploring how to accommodate their needs during flight disruptions in this separate rulemaking.

The Department recognizes that the special considerations given to passengers with disabilities and their travel companions due to a significant change of flight itinerary impacting disability accommodations may lead to some passengers falsely claiming that they have a disability that was impacted by a change of connecting airport or an aircraft substitution, as well as to an entire travel group requesting refunds based on a false claim that one passenger in the group has a disability the accommodation of which was affected by a significant flight itinerary change. Consistent with the Department's Air Carrier Access Act regulation, when conducting inquiries regarding how a passenger's disability accommodation needs are impacted by a significant change, carriers should never ask about the nature or the extent of a passenger's disability. Carriers can ask questions about an individual's ability to perform specific air travel-related functions that may be impacted by the change. For example, carriers should not ask ''what is your disability?'' but may ask ''what is the accessibility feature that is needed that is no longer available because of the aircraft substitution or change in class of service?'' Also, the Department notes that an advance request for disability accommodation recorded in the passenger's reservation before the significant change occurred can serve as evidence that the passenger is a qualified individual with a disability and the significant change indeed impacts the accommodation for that disability. However, some individuals with disabilities may not request assistance in advance, but a significant change of flight itinerary may nonetheless impact an accessibility feature that they need, resulting in them no longer wishing to travel. As such, the Department cautions that lack of such a notation is not sufficient on its own as proof that the individual is not a person with a disability.

5. Entities Responsible for Refunds

The NPRM: The NPRM described the significant volume of refund complaints against ticket agents received by the Department during the COVID–19 pandemic and states that this is an indicator that strengthening protections for consumers purchasing air transportation from ticket agents is needed. These complaints also illustrated the difficulty that consumers sometimes encounter in obtaining a refund for a ticket purchased through a ticket agent when consumers do not have the means to determine whether the airline or ticket agent needs to take action to process the refunds and which entity is in possession of the consumers' money. To address this difficulty, the NPRM proposed that ticket agents who ''sold'' the tickets would be responsible for issuing refunds when they are due. It further explained that a ticket agent would be considered to have ''sold'' the ticket at issue if the ticket agent is the entity shown in the consumer's financial charge statements such as debit or credit card charge statements (commonly known as the ''merchant of record''). Under the proposal, a ticket agent obligated to provide a refund under this standard would be required to issue refunds promptly irrespective of which entity has possession of the funds. In the NPRM, the Department shared that it considered placing the obligation of providing the refund on the entity that is in the possession of the funds but did not propose this approach because which entity is in possession of the funds would not necessarily be clear to the consumer because multiple entities may be involved in the transaction process.

With respect to airlines' obligations to provide refunds in codeshare and interline situations, the NPRM proposed that the marketing carrier of an itinerary involving codeshare or interline flights

[39] *See* 89 FR 17766 (Mar. 12, 2024).

would be responsible for providing the refund, regardless of whether the marketing carrier is also the operating carrier of the flight(s) affected by a cancellation or a significant change or whether the marketing carrier is the carrier that cancelled or made a significant change to the flight itinerary. The NPRM explained that this approach benefits consumers by streamlining the process to obtain refunds and expects that carriers will be able to develop a system with their codeshare and interline partners to ensure that refunds are provided in a timely manner. The NPRM sought comments on the costs associated with establishing such a system for interline and codeshare partners to process refunds according to this proposal and whether there are technical obstacles that should be considered.

Comments Received: Airline commenters agreed that the refund requirement should apply to ticket agents when they are the merchants of record for the ticket sales or have otherwise paid for the ticket on behalf of the passenger. In supporting this position, airlines argued that they are incapable of issuing refunds for tickets purchased through ticket agents or other third parties because airlines may not be in possession of the passenger's payment information and/or personal contact information and airlines often do not have full visibility of the prices paid by consumers, especially in situations where ticket agents purchase bulk fares from airlines to resell to consumers. IATA commented that when consumer funds collected by ticket agents are processed through IATA's settlement system, the Billing and Settlement Plan (BSP), ticket agents are responsible for filing for reimbursement from airlines via the settlement system, and the airlines determine refund eligibility. A4A supported the proposed standard to hold ticket agents responsible for refunds when the ticket agents are the merchants of record, or the consumer has paid by cash or check to the ticket agent. A4A stated that it is the standard practice today and should be codified in the Department's regulation. Both A4A and IATA as well as several airline commenters supported applying the refund requirement to ticket agents globally who sell tickets for covered flights. Several consumer commenters expressed their support to hold ticket agents responsible for refunds, describing their frustrations in chasing refunds between the airline and the ticket agent.

Ticket agents and their trade representatives voiced strong opposition to the proposal that requires ticket agents who are the merchants of record to provide refunds irrespective of whether they are in possession of consumer funds. Many ticket agent commenters acknowledged that in the vast majority of transactions involving ticket agents, airlines are the merchants of record.[40] They argued, however, that although ticket agents have the technical ability to issue refunds when they are the merchants of record, they should not be required to do so because the consumer's funds were often remitted to airlines through the settlement systems immediately or shortly after ticket booking, and requiring ticket agents to refund before they receive the funds back from airlines would significantly impact the cashflow of ticket agents, especially ticket agents that qualify as small businesses.[41] Many commenters opined that such a requirement is fundamentally unfair because ticket agents have no control over airlines' cancellation or change of flights, nor do they have any control over the determination on whether a consumer is eligible for a refund. Ticket agents also argued that the process of returning funds from airlines to ticket agents through intermediary settlement systems such as the Airline Reporting Corporation (ARC) system typically takes much longer than seven days. Hundreds of small business ticket agent commenters further argue that the impact of such a requirement on ticket agents is so profound that many of them would consider stopping offering airline tickets booking services, which has the potential consequence of disrupting a major airline tickets distribution channel and causing consumers to lose the valuable travel advisory services offered by ticket agents.

Additionally, several ticket agents trade associations contended that ticket agents lack information regarding consumers' refund eligibility and any alternative transportation or compensation offered by airlines and accepted by consumers. They argued that airlines should have the sole responsibility to determine refund eligibility and timely communicate such information to ticket agents. Further, ASTA stated that to process a refund through settlement systems such as ARC, ticket agents must first receive an Electronic Authorization Code directly from airlines, confirming the flight coupon has been changed to a refund status, which minimizes duplicate refunds and prevents fraud. Ticket agent commenters suggested that the Department should revise its proposal and require ticket agents who are the merchants of record to issue refunds only when they receive confirmation of refund eligibility and funds from the airlines, and that the Department should not impose refund deadlines on ticket agents until all these conditions are met.

ASTA also expressed concerns about how to determine which entity is the merchant of record, commenting that consumers may not know which entity is the merchant of record by looking at the credit card statement. ASTA stated that some credit card issuers would identify both the airline and the ticket agent on the consumers' credit card statements to reduce the likelihood that consumers mistakenly dispute the charges because they did not recognize the transactions. ASTA also asked the Department to clarify that when a ticket agent appears on a consumer's credit card statement as the merchant of record for charging a service fee, it would not trigger the ticket refund requirement. ASTA further stated that more clarity is needed on how to determine which entity is the merchant of record when tickets are not paid by credit cards or debit cards.

The ACPAC also discussed the issue of ticket agents' responsibility to refund and heard from numerous ticket agent representatives about the potential impact on their businesses should the Department adopt the proposal. The ACPAC recommended that the Department adopt the proposed standard to hold ticket agents responsible for refunds when they ''sold'' the tickets. Further, in recognition of the potential financial impact on small businesses, the ACPAC recommended that the Department revise the proposal to provide some relief for ticket agents.[42] Specifically, the ACPAC recommended that the Department impose a requirement on airlines to return the consumer funds to ticket agents within seven days of receiving the refund requests, and that ticket agents that qualify as ''small businesses'' under the standard set forth

[40] For example, according to American Society of Travel Advisors (ASTA), it estimates that between five and eight percent of all airline ticket transactions by credit cards facilitated by its members have the ticket agents appear as the merchants of record, with the majority of which involving group bookings, air-inclusive tour packages, or resale of consolidated fares.

[41] ASTA states that its data indicates that 98% of travel agencies qualify as ''small businesses'' under the Small Business Administration (SBA) size standards.

[42] Among the four members of ACPAC, three members voted in support of this recommendation and the member representing airlines abstained, expressing concerns about whether the recommendation regarding refund timeline is consistent with other Federal regulations, *i.e.,* Regulation Z.

by the Small Business Administration (SBA) be given up to 14 days, instead of seven days, to issue refunds.

On entities responsible for refunds for codeshare or interline itineraries, IATA indicated that it supports the proposal to require the marketing carriers be responsible for issuing refunds for codeshare flights. IATA further commented that the Department should require the operating carriers to refund any portion of the fare or fees paid by the marketing carrier in the event a refund is due to passengers.

DOT Response: Sales by ticket agents constitute a major airline ticket distribution channel. According to anecdotal data from the Airline Reporting Corporation published in 2019, travel agencies generated 44% of air segment sales.[43] During the COVID–19 pandemic, the unprecedented number of consumer complaints on refunds included a significant number of complaints against ticket agents and tour operators. In those complaints, consumers expressed frustration at being sent back and forth between the ticket agent and the airline when trying to obtain their refunds. As many commenters from the industry have illustrated, in a typical airline ticket transaction involving ticket agents as the merchant of record, the consumer funds are transferred through various entities including intermediary settlement systems. It is the Department's understanding that for those ticket sales, the refund process reverses the flow of money among the entities involved. Thus, focusing on which entity is in possession of the funds when assigning a refund obligation is impractical and unworkable from a consumer's perspective because consumers do not know which entity is in possession of the funds at any given time. The Department continues to view such uncertainty as a main driving force leading to additional costs, delay, and confusion to consumers. Given this concern, the Department declines to adopt the suggestion to assign refund obligation based on which entity is in possession of consumer funds, and instead, adopts the proposed standard to hold retail ticket agents responsible for refunds when they ''sold'' the tickets to consumers as the merchants of record. This requirement would cover retail ticket agents of all sizes that conduct business online or via brick-and-mortar stores that *transact directly* with consumers. The Department believes that this bright line standard is the most effective way to address the potential consumer confusion and frustration when there is more than one entity involved in the selling of airline tickets. The Department also agrees with airline commenters that holding ticket agents who sold the tickets responsible for refunds addresses the issues that arise when airlines do not have the consumers' payment and/or contact information, or visibility of how much consumers paid for the tickets when tickets are sold as consolidated fare or bulk fare, all of which are necessary for processing refunds promptly and accurately.

The refund requirements for ticket agents apply to airfare or airfare-inclusive travel package transactions in which the ticket agents are the merchants of record for the transactions irrespective of whether the ticket agent is in possession of the consumer funds at the time when the refund is due. The Department defines ''merchant of record'' as an entity that processes consumer payments for airfare or airline ancillary service fees and whose name appears on the consumer's bank or similar transaction statement. Regarding ASTA's comment that some credit card statements will list both the airline and the ticket agent for the transaction, the Department understands that this is done by credit card issuers with the intention to ensure that consumers recognize the charges. As there is always one merchant processing the card payment, consumers can contact their credit card issuers and ask which entity is the merchant of record who imposed the charge. For transactions paid by a payment other than credit cards or debit cards, the transaction receipt provided to consumers should list the entity that is responsible. In that regard, if the consumer purchased the ticket with cash or check, the entity that issued the receipt should be responsible for refunds.

The Department appreciates the information from the industry regarding the flow of funds in ticket agent-involved airline ticket transactions. It is the Department's understanding that ticket agents' main concern is not about taking on the obligation to refund when they are the merchants of record. It seems that their concern, instead, is the obligation to refund according to the refund timelines even when the funds have not been returned to them by the airlines. Ticket agents emphasized that imposing this obligation regardless of whether they have possession of the funds will place a significant burden on their cashflow, particularly on ticket agents that are small businesses. Accordingly, many commenters asked that, should the Department adopt the merchant of record standard to hold ticket agents responsible for refunds, ticket agents should be required to provide refunds only when they receive the funds returned by airlines.

The Department disagrees with the approach proposed by ticket agents that they would not be required to refund consumers until they receive the funds from airlines because it would harm consumers should airlines, who are not directly responsible for refunds, not timely return the funds to ticket agents. The result of the ticket agents' proposed approach is that consumers would have no meaningful timeline within which they can expect to receive refunds. The Department has considered the ACPAC's recommendation that there be an affirmative obligation on airlines to return consumer funds back to ticket agents within seven days of receiving a refund request from a ticket agent when the airlines are not the merchants of record for the ticket sales. While the Department agrees that airlines should return consumer funds to ticket agents promptly in these situations, it is not persuaded that DOT intervention into airlines' and ticket agents' business and contractual arrangements is necessary at this time. The Department's authority to prohibit unfair or deceptive practices in 49 U.S.C. 41712 is intended to protect consumers. The Department expects that airlines and ticket agents both have the interest to negotiate, form, and adhere to a standard procedure in handling consumer funds to ensure that ticket transactions and refunds are processed smoothly to the benefit of consumers, as well as the businesses involved.

Although the Department does not believe that ticket agents' obligation to refund should be dependent upon receiving the return of the funds from airlines, we acknowledge that before issuing the refund, the ticket agent may need further information to verify whether a refund is due under the Department's regulation. The NPRM states that in most situations involving cancellations or significant changes, there would be sufficient information (*e.g.,* airlines' publications on cancellations or flight itinerary change notifications sent to consumers) to confirm refund eligibility without contacting airlines; however, after reviewing comments, we realize that even in those situations, ticket agents may need airlines' confirmation that the affected consumers did not accept alternative transportation or other compensation in lieu of refunds.

[43] *Phocuswright White Paper—Air Sales and the Travel Agency Distribution Channel,* Airline Reporting Corporation, April 2019. *https://www.phocuswright.com/Free-Travel-Research/Air-Sales-and-the-Travel-Agency-Distribution-Channel.*

Comments submitted by ticket agents also state that airline ticket settlement systems often incorporate a process under which airlines need to issue refund authorization codes to prevent duplicate refunds and fraud. To ensure that refunds to consumers are not unreasonably delayed because ticket agents are waiting on airlines' confirmation of refund eligibility, we are requiring airlines to determine whether consumers are eligible for refunds and if so, inform ticket agents of the refund eligibility without delay upon receiving the refund request from the ticket agent. The Department's Office of Aviation Consumer Protection will determine the timeliness of airlines' response based on the totality of the circumstances, including how quickly the airline took steps upon receiving the ticket agent's refund request to determine refund eligibility and whether the airline informed the ticket agent of the refund eligibility as soon as it has confirmed it. The Department expects airlines and ticket agents to work together to develop and enhance channels of communication to ensure that information regarding passengers' refund requests and eligibility are transmitted in an effective, accurate, and efficient manner.

This final rule makes it an unfair practice for airlines to fail to timely confirm refund eligibility and communicate that eligibility to ticket agents. Airlines not confirming refund eligibility in a timely manner slow the refund process and cause substantial harm to consumers. This harm is not reasonably avoidable by consumers, as they have no control over how soon airlines inform ticket agents that a refund is due so the ticket agents can begin to process the refund. The Department also sees no benefits to consumers and competition from this conduct. On the contrary, the Department views that not imposing this requirement on airlines would allow airlines or ticket agents to keep money that is due to consumers indefinitely, which in turn harms consumers and competition by penalizing good customer service and rewarding dilatory behavior.

For codeshare or interline itineraries sold by a carrier, the Department is requiring the carrier that ''sold'' the airline ticket (*i.e.,* the merchant of record for the ticket transaction) to provide the refunds, as this is the most straightforward standard from consumers' perspective. Consistent with the rationale for the ''merchant of record'' approach that we adopted in determining ticket agents' refund obligation, we believe the carriers who are the merchants of record for the ticket transactions are in the best position to process and issue refunds as they have direct visibility of the passengers' payment instruments information and the total amounts paid for the itineraries. The Department further notes that in most codeshare or interline itineraries, the marketing carriers are the merchants of record. The Department's focus is on making consumers whole when their flights are cancelled or significantly changed, and we decline to regulate how airlines manage the transfer and the return of funds among themselves in the event of ticket refunds, as we expect that airlines engaging in codeshare or interline arrangements will work together on contractual agreements to ensure that account settlements are conducted through the normal course of business dealing following refunds provided to consumers.

6. Timing of Refunds

The NPRM: As explained in the NPRM, the Department's current refund timeframes are based on the form of payment used for the ticket purchase, *i.e.,* seven days for credit card purchases and 20 days for cash and other forms of payment. 14 CFR part 374 is the Department's regulation implementing the Consumer Credit Protection Act and its regulations, including Regulation Z of the Consumer Financial Protection Bureau (CFPB) regulation, 12 CFR part 1026 (Regulation Z), with respect to airlines issuing refunds for credit card purchases. Regulation Z, in relevant provision under 12 CFR 1026.12(e)(1) provides that ''when a creditor other than the card issuer accepts the return of property or forgives a debt for services that is to be reflected as a credit to the consumers' credit card account, that creditor shall, *within 7 business days* [emphasis added] from accepting the return or forgiving the debt, transmit a credit statement to the card issuer through the card issuers' normal channels for credit statements.'' The Department's own regulation in 14 CFR 259.5(b)(5) imposes a refund timeline of 20 days on airlines for purchases made by cash or check. It also specifies that the refund timeline starts after airlines receive the complete refund request. With respect to ticket agents, the Department's regulation in 14 CFR 399.80 requires that they make ''proper refund promptly'' when services cannot be performed as contracted. Because Regulation Z impacts all consumer credit, ticket agents are also subject to the refund requirement of Regulation Z (12 CFR 1026.12(e)(1)) with respect to refunds of credit card purchases. Under its authority against unfair or deceptive practices, 49 U.S.C. 41712, the Department also requires that ticket agents provide refunds for purchases by payments other than credit cards within a reasonable time.

The NPRM's proposal on ''prompt'' refunds when they are due requires airlines to issue refunds ''within 7 days of a refund request as required by 14 CFR 374.3 for credit card purchases, and within 20 days after receiving a refund request for cash or check or other forms of purchases.'' [44] Similarly, the proposed rule on ticket agents defines ''a prompt refund'' as ''one that is made within 7 days of receiving a refund request as required by 12 CFR part 1026 for credit cards purchases, and within 20 days after receiving a refund request for cash or check or other forms of purchases.'' [45] The NPRM sought comments on whether these timeframes are appropriate when a carrier has cancelled or made a significant change to a scheduled flight to, from, or within the United States and consumers found the alternative transportation offered to be unacceptable.

Comments Received: IATA supported the 7/20-day refund timelines under normal circumstances but argued that during public health emergencies, airlines should have at least 30 days to process a refund request. IATA stated that due to spikes of refund requests, some airlines facing financial difficulties had to choose between delaying refunds or going out of business. Air Canada argued that carriers should have no less than 30 days to issue refunds in the original form of payment, and the refund timeline should be suspended during major crises. Air Canada stated that the proposed timelines are disconnected from the actual time needed for refund processing by various parties involved, and the situation can be more complex when the original ticket was sold through a ticket agent. Air Canada further argued that the refund timelines should consider situations that trigger the need for more time, such as the original form of payment no longer being valid, and the time needed to calculate the refund amount when the ticket is partially used. A4A commented that the Department should ensure that the 7/20-day refund timelines are consistent with longstanding DOT enforcement precedent and Regulation Z by clarifying that they are in reference to business days and not calendar days.

[44] See proposed rule text for 14 CFR 259.5(b)(5), 87 FR 51550, 51576.

[45] See proposed rule text for 14 CFR 399.80(l), 87 FR 51550, 51579.

USTOA representing tour operators commented that the 7/20-day timelines are reasonable so long as the sellers are in possession of the funds. It further elaborated that for ticket agents, counting of the timelines should not begin until the ticket agents are in possession of the funds and have received refund eligibility confirmation from airlines.

Ticket agent representatives also provided comments during the ACPAC meetings regarding the financial difficulties they face if they are required to issue refunds before receiving the funds back from airlines. In recognition of the potential financial impact on small businesses, the ACPAC recommended that the Department revise the proposal to provide some relief for ticket agents. Specifically, the ACPAC recommended that the Department impose a requirement on airlines to return the consumer funds to ticket agents within seven days of receiving the refund requests, and that ticket agents that qualify as ''small businesses'' under the standard set forth by the Small Business Administration (SBA) be given up to 14 days, instead of seven days, to issue refunds to consumers. [46] In a joint comment filed by A4A and IATA, the carrier representatives stated that this ACPAC recommendation conflicts with Federal Reserve regulation (12 CFR 1026.11) and the Department's rule (14 CFR 374.3). They further commented that the NPRM did not propose to change the Department's refund regulations or discuss a different refund standard and therefore adopting a different refund standard in a final rule would violate the notice and comment requirements of the Administrative Procedure Act.

Furthermore, airline commenters expressed concerns about passengers not informing carriers of their decisions to reject the alternative transportation offered until close to the flight's departure, therefore depriving airlines the opportunity to resell those seats. IATA and Air Canada argued that passengers should have the obligation to take positive steps to inform airlines within a reasonable time after the passenger is notified of a significant change and offered alternative transportation. During an ACPAC meeting, the member representing airlines also expressed similar concerns.

Some consumer commenters urged the Department to require airlines to issue ''automatic'' refunds. They argued that airlines have the incentive to adopt complex refund processes that make requesting refunds cumbersome and difficult for consumers, engineered to dissuade consumers from receiving their due compensation. Some commenters provided examples of inefficient and complex refund request procedures currently adopted by airlines, including hidden refund request links on their websites, excessive data input requirements from consumers, lengthy and confusing refund request forms, and excessive hold time for requesting refunds over the telephone. In addition, PVA and United Spinal Associates commented that when alternative transportation does not provide the same or similar accessibility features or seating arrangements, this deficiency should prompt an automatic refund offer.

DOT Responses: Based on the comments received, the Department is addressing—(i) the meaning of prompt refunds, including during public health emergencies; (ii) automatic refunds as a way to reduce cumbersome refund request processes for consumers and ensure consumers' rejection of the alternative transportation offered do not deprive airlines of the opportunity to resell those seats; (iii) commencement of refund deadlines; and (iv) the meaning of business day for purpose of providing refunds.

(i) Prompt Refunds

In this final rule, we are requiring that airlines and ticket agents provide prompt refunds when due. Prompt is defined to mean within 7 business days of refunds becoming due for credit card purchases, and within 20 calendar days of refunds becoming due for purchases by cash, check, or other forms of payment. To the extent the purchase is made by a debit card, the Department has reviewed the relevant definitions in CFPB's regulations, including Regulation Z, and has determined that a typical debit card does not fall under the 7-day refund timeline that only applies to ''credit card'' and therefore would be subject to the 20-day timeline.[47]

The Department has considered airlines' suggestion of additional time to provide refunds including one airline's request for no less than 30 days to issue refunds and to suspend the refund deadlines during major crisis. The Department believes that maintaining the 7/20-day refund timeline is reasonable as airlines and ticket agents have been required to comply with these timeframes for decades. The Department is also not convinced that extending or suspending the 7-day timeline for credit card purchases during large-scale air travel disruptions is either permissible under Regulation Z or warranted. Taking the COVID–19 pandemic as an example, although the Department recognizes the challenges airlines and ticket agents faced when dealing with a significant increase of refund requests, the Department also recognizes the financial difficulties average consumers faced during the pandemic, including the impact of not receiving timely refunds of airline tickets they paid for when the service is cancelled or significantly changed. During such an event, the Department considers consumers to be in need of the regulatory protection afforded by the prompt refund requirements specified in this final rule. As discussed earlier, the Department is adopting the proposal to hold ticket agents responsible for refunds when they are the merchants of record for the ticket transactions. We have considered comments by numerous small ticket agents and the ACPAC's recommendation to provide small ticket agents additional times to issue refunds by credit cards. After a careful review of Regulation Z and relevant interpretations by CFPB, we have determined that the Department does not have the discretion to *extend* the 7-day refund timeline for credit card purchases, which would contradict Regulation Z. The Department acknowledges the concerns of small ticket agents regarding the financial burden to issue refunds before receiving the funds back from airlines. We note that, as several ticket agent commenters point out, that less than 10% of ticket transactions involving air travel have ticket agents as the merchants of record, for which they will be obligated to issue refunds. The Department expects that outside of a massive disruption to air transportation on a national or global scale, ticket refund requests made to small ticket agents due to airline cancellation or significant change should be rare. In addition, the Department is mandating that airlines confirm refund eligibility before a

[46] Among the four members of ACPAC, three members voted in support of this recommendation and the member representing airlines abstained, stating that he is unclear about whether this recommendation is consistent with other Federal regulations, *i.e.,* Regulation Z.

[47] The CFPB regulation defines a ''credit card'' as any card, plate, or other single credit device that may be used from time to time to obtain credit. See 12 CFR 1026.2(a)(15)(i). The term ''credit'' is defined as the right to defer payment of debt or to incur debt and defer its payment. See 12 CFR 1026.2(a)(14). In contrast, ''debit card'' is defined as any card, plate, or other single device that may be used from time to time to access an asset account other than a prepaid account. See 12 CFR 1026.2(a)(15)(iv).

refund is due by ticket agents.[48] We expect that this requirement, along with the tolling of the refund timeline discussed below, will alleviate the financial burden on small ticket agents.

(ii) Automatic Refunds

The NPRM proposed that the 7/20-day refund timelines start upon airlines or ticket agents ''receiving a complete refund request'' from consumers. After considering the comments from consumers and the industry, the Department has determined that under certain circumstances where consumers' rights to refunds and their intention to receive a refund are unequivocal, using consumers' explicit refund requests as the starting point for computing the refund timelines is an approach that imposes an unnecessary burden on consumers. Consumers in comments expressed their frustrations about the cumbersome process to request and receive a refund following a flight cancellation or significant change, at times waiting for hours on the phone, digging through cumbersome airline websites to find a link for requesting a refund, or having to navigate through extra ''digital paperwork'' to complete a refund request form. The Department is persuaded by consumers that in these circumstances automatic refunds are warranted. For example, if a flight is cancelled and no alternative transportation or compensation is offered to the passenger in lieu of a refund, the carrier must refund the consumer because the contracted service was not provided. Similarly, if a flight is significantly changed and the consumer rejects the significantly changed flight and no alternative transportation or compensation is offered to the passenger in lieu of a refund, the carrier must refund the consumer because the contracted service was not provided. It is inefficient and unreasonable for the carrier to wait to receive an explicit refund request from the consumer in such situations. Also, if alternative transportation or a travel credit, voucher, or other compensation is offered to a consumer for a canceled flight or a significantly changed flight and the consumer rejects the alternative transportation or compensation offered, then the carrier should refund the consumer without further delay because the contracted service was not provided and the consumer rejected the alternative offered. It should not be necessary for the consumer to separately request a refund because the rejection of the alternatives offered is tantamount to a request for a refund.

The Department acknowledges airlines' concerns about consumers not rejecting a significantly changed flight or a booked alternative flight itinerary after being notified of such an offer until closer to flight operation, thus depriving airlines the opportunity to sell the seats for revenue. Under this final rule, airlines may set a deadline that provides reasonable time for a consumer to decide whether to accept the existing itinerary with a significant change or an airline's offer of alternative transportation in lieu of a refund. To determine whether a carrier provided consumers reasonable time to consider the options and make a decision, the Department will look primarily at when the cancellation or significant change occurred, how soon after the carrier became aware of the flight cancellation or significant change that the carrier notified affected consumers of this event and made an offer of alternative transportation, and how close the consumer notification is to the scheduled departure date of the significantly changed flight or the alternative transportation offered.

The Department recognizes that some consumers may not respond to a carrier's offer of a significantly changed flight or an alternative flight by the deadline. To ensure that consumers understand the potential consequences of not responding by the deadline, the Department is also requiring airlines when notifying affected consumers of a significantly changed flight or offering alternative flight to inform consumers whether the carrier will treat the lack of response by the deadline as a rejection (*i.e.,* prompt refund to be provided but reservation is no longer held for passenger) or an acceptance (*i.e.,* reservation held for passenger but passenger forfeits right to a refund) of the offer. A carrier may determine whether it will treat the lack of response by the deadline as a rejection or an acceptance of the offers, but such determination must be adopted as a customer service policy applicable universally to all passengers of the carrier. Any change to the policy applies only to passengers who booked their tickets after the effective date of the change. If a carrier chooses not to set a deadline for the consumer to respond to the offer, the carrier is essentially giving the consumer the option to decide until the date of the significantly changed flight or the alternative flight as to whether to accept or decline the offer. Under these circumstances, the consumer taking the significantly changed flight or the alternative flight is an acceptance of the offer and the consumer not taking the flight is a rejection of the offer. Again, if the consumer has rejected an offer of alternative transportation (informed airline of rejection of alternative transportation, failed to respond within the timeframe provided by the carrier after carrier notified passenger that lack of a response to offer of alternative transportation would be deemed a rejection, or did not take the flight when the carrier did not set a deadline for a response to an offer of alternative transportation), there is no need for the consumer to send a separate request for a refund.

To ensure consumers have reasonable time to consider and respond to the options offered by a carrier, the Department is requiring carriers to notify consumers of the options available to them in a timely manner. It is an unfair practice for airlines to not timely notify consumers of their options yet impose a short deadline to respond. Such a practice harms consumers by depriving them of a reasonable time to consider their options. The failure to fully inform consumers of the consequence of not responding by the deadline (*i.e.,* losing their money paid for the ticket or losing their seats on the booked flights) is also an unfair practice. Such a practice harms consumers by omitting a material matter in the notification, and the omission would negatively affect consumers' conduct. Both harms are not reasonably avoidable by consumers because consumers would not have known about material matters unless they were informed. These practices do not benefit consumers or competition—rather these practices would hinder transparency and causes inefficiency in airlines' inventory management. As such, the Department is requiring carriers to provide timely notification to affected consumers about the options available to consumers when a flight is canceled or significantly changed, any responsive deadline, and the consequence of not responding by the deadline. For carriers that have in

[48] In an enforcement notice issued by the Department's Office of Aviation Consumer Protection (OACP) on March 12, 2020, the Department states that it interprets the requirement for ticket agents to provide refunds to include providing refunds in any instance when the following three conditions are met: (1) an airline cancels or significantly changes a flight, (2) an airline acknowledges that a consumer is entitled to a refund, and (3) passenger funds are possessed by a ticket agent. See, *https://www.transportation.gov/airconsumer/FAQ_refunds_may_12_2020.* The Department has reconsidered this issue and determined that the final rule appropriately ensures that consumers receive prompt refunds as required by the rule and are not caught in the middle between airlines and ticket agents, but also provides safeguards for ticket agents in the requirement for airlines to verify refund eligibility before the refund timeline starts.

place notification subscription services, this notification must be provided through media that the carriers offer and the subscribers choose, including emails, text messages, and push notices from mobile apps. As the content of the notification may be over the size limits of text messages or mobile app push notices, carriers may include in a text message or push notice a link to the consumer's reservation page on its website, where the full content of the notification is displayed.

In addition to notifying affected consumers, this final rule requires that carriers provide clear, conspicuous, and accurate information in their customer service plan regarding the carriers' policies and procedures on refunds and rebooking including when consumers are non-responsive to carriers' offers of significantly changed or alternative flights. More specifically, the Department is amending 14 CFR 259.5 to require carriers to incorporate into their Customer Service Plans a commitment to disclose relevant refund and cancellation policies as provided in 14 CFR part 260, including policies related to consumers' right to a refund due to airline-initiated cancellations or significant changes, consumers' right to ''automatic refunds'' under certain circumstances, consumers' right to refunds and rebooking when consumers are non-responsive to carriers' offers of significantly changed or alternative transportation. This information is intended to better inform consumers about their rights before purchasing tickets and whenever questions arise later. The Department considers any misrepresentation or omission of material matters regarding a consumer's rights when airlines and ticket agents publish their refund polices or notify consumers affected by a canceled or significantly changed flight to constitute an unfair practice in violation of 49 U.S.C. 41712. Consumers who are not provided complete and accurate information about their rights are not likely to choose the options that best suit their needs. For example, consumers who are offered alternative transportation but not notified of the need to respond before an airline-imposed deadline may lose their rights to a refund or lose the flight reservations that they intend to keep. This is a substantial harm that cannot be reasonably avoided by consumers because consumers have no way to fully understand their rights without being notified by airlines or ticket agents. Airlines or ticket agents not providing clear, accurate, and complete notifications to consumers harms competition because it hinders the development of open and fair competition that maximizes consumer choices based on information transparency. The Department further views such misrepresentation or omission as a deceptive practice because misrepresenting or omitting a material fact relating to a consumer's right to a refund or other options available in lieu of a refund in the carrier's customer service plan is likely to deprive that consumer of important information that could impact which carrier the consumer selects for the air transportation and similar misrepresentation or omission in notifications provided to consumers affected by significant change and cancellation could impact the choice that the consumer makes between a refund and another option.

(iii) Commencement of Refund Timelines

The Department's existing refund regulation requires that a refund must be provided within the required timelines after receiving a ''complete refund request.'' The Department did not use this language in the proposed rule but ''acknowledge[d] that for transactions in which a ticket agent would be responsible for issuing a refund if due, before issuing the refund, the ticket agent may need further information to verify whether a refund is due under the Department's regulation.'' [49] After carefully reviewing the comments received, the Department is of the view that the obligation of a ticket agent to provide refunds should begin when the ticket agent receives confirmation about the passengers' refund eligibility from airlines. Under this final rule, the 7/20-day refund timelines start at the time the ticket agent receives the eligibility confirmation from the airline. For example, if an airline confirms that the passenger is eligible for a refund on day 3, the 7 or 20-day refund timeline for the ticket agent starts on day 3. Airlines and ticket agents are encouraged to establish effective communication channels and airlines are expected to work expeditiously to confirm refund eligibility. The Department does not view tolling the refund timelines for lack of essential information needed for refunds to be contradictory to Regulation Z, as Regulations Z's 7-day refund timeline starts from the time a ''*creditor other than the card issuer*'' ''*accepting the return [of property] or forgiving the debt.*'' In the Department's view, an airline or ticket agent should not be expected to accept the return of property or forgive the debt until it can be confirmed that the consumer is eligible.

(iv) Business Days

In this final rule, the Department is requiring refunds be provided within seven business days of when it is due for credit card purchases and within 20 calendar days of when it is due for cash and other forms of payment. The Department agrees with A4A's comment that the 7-day refund timeline should be consistent with CFPB's Regulation Z. The CFPB regulation defines ''business days'' as a day on which *the creditor's offices are open to the public for carrying on substantially all of its business functions.*[50] CFPB's Official Interpretation of its definition explains that ''*[a]ctivities that indicate that the creditor is not open for substantially all of its business functions include a retailer's merely accepting credit cards for purchases. . . .*'' [51] CFPB also explains that ''*activities that indicate that the creditor is open for substantially all of its business functions include the availability of personnel to make loan disbursements, to open new accounts, and to handle credit transaction inquiries.*'' [52]

Based on CFPB's Official Interpretation of its definition, the Department has decided not to use the days that airlines and ticket agents accept credit cards for purchases of airline tickets and related services to determine business day. Instead, the Department is focusing on the days on which the offices of airlines and ticket agents are typically open to process refund requests and defining business day to be Monday through Friday, excluding Federal holidays in the United States. By defining business day in this simplified manner, the Department is providing regulatory clarity to airlines and ticket agents regarding their obligations to provide prompt refunds. Importantly, consumers can also easily understand their rights and advocate for themselves when regulations are defied or disregarded. The Department expects that this clarification regarding refund timeline for credit card payment refunds will enhance transparency and consistency in the airline ticket refund process but will revisit this issue in the future should it be necessary.

The Department notes that the CFPB regulation is not applicable to the DOT

[49] 87 FR 51550, 51563.

[50] 12 CFR 1026.2(a)(6).

[51] *https://www.consumerfinance.gov/rules-policy/regulations/1026/interp-2/#2-a-4-Interp-3.*

[52] *Id.*

requirement concerning providing refunds within 20 days for purchases paid by a payment other than a credit card. As is the case currently, the Department is continuing to require airlines and ticket agents to provide refunds for non-credit card purchases within 20 calendar days. The Department has amended the regulation text accordingly.

7. Amount and Form of Refunds

The NPRM: Under the NPRM, when ticket refunds are due because of a significantly changed or canceled flight, a passenger would be entitled to receive a full refund equal to the ticket purchase price including government-imposed taxes and fees and carrier-imposed fees and surcharges (such as fuel surcharges), minus the value of any air transportation that is already used by the passenger. To calculate the value of any used portion of the air transportation when determining the amount of refunds, the Department suggested that airlines rely on established industry practices and guidelines.

On the form of refunds, the NPRM explained that the Department intends to explore ways to provide consumers, carriers, and ticket agents more flexibility in issuing and receiving refunds. As such, the NPRM proposed to allow airlines and ticket agents to choose whether to refund passengers by returning the money in the original form of payment or by providing the refund in cash or a form of cash equivalent, including prepaid cards, electronic fund transfers to passengers' bank accounts, or digital payment methods such as PayPal or Venmo. The NPRM stated that a carrier- or ticket agent-issued travel credit or voucher or a store gift card is not considered a cash equivalent form of payment because these forms of compensation are not widely accepted in commerce. Further, the Department considered that when a carrier or ticket agent issues a prepaid card, any maintenance or usage related fees should be prepaid into the card by the issuer in addition to the full amount of refund that is due. The NPRM asked whether this proposal would be beneficial to consumers, carriers, and ticket agents as intended and whether there are any unintended negative impacts.

Comments Received: Airlines generally did not object to the proposal to require a refund of the full ticket price including taxes and fees. However, A4A and IATA commented that the refund amount should exclude any government taxes and fees that are non-refundable. This position was supported by the U.S. Chamber of Commerce.

FlyersRights argues that amount of refunds for cancelled or significantly changed flights should include a premium if the cancellation or significant change occurs close to the scheduled departure date as consumers will likely have to pay a much higher price for another ticket. Also, hundreds of consumer commenters stated that a refund of the ticket is inadequate to address the costs and inconvenience to passengers when a flight cancellation or significant change occurs mid-journey. PVA stated that a refund by itself is useless when a passenger with a disability is stranded.

On the form of refunds, most airlines commenters supported the proposal to allow carriers and ticket agents to choose between the original form of ticket payment and another form that is cash-equivalent, stating that this would provide flexibility to carriers, ticket agents, and consumers. Spirit Airlines argued that refunds should be in the original form of payment, expressing concerns about the privacy of cash equivalent payments that potentially expose consumers to scam and confusion. Qatar Airways also supported the position that the default refund form should be in the original form of payment and stated that only when the original form of payment service declines the refund should another form of payment be used. Travel Management Coalition also favored the refund being issued in the original form of payment and added that if the Department directs another form of refund, the refund timeframe should be extended. Global Business Travel Association commented that refunds should be directed back through the original form of payment for business travelers to ensure that the business, not the traveler, is refunded.

DOT Response: After carefully considering the comments, the Department is finalizing the proposal to require airlines and ticket agents to provide full refunds to eligible passengers of the ticket purchase price, minus the value of any portion of transportation already used. The refunds must include all government-imposed taxes and fees and airline-imposed fees, regardless of whether the taxes or fees are refundable to airlines. The Department disagrees with the airlines' position that consumers should bear the burden of any non-refundable government taxes and fees when consumers have not initiated, caused, or contributed to the cancellation or significant changes to their flight itineraries.

Regarding how best to calculate the value of any portion of transportation already used, the Department emphasizes that carriers are expected to adhere to established industry practice and treat consumers fairly. The Department will view any arbitrary deviation from industry practice in calculating the value of the unused portion to the detriment of the consumer to be indicative of an unfair practice. Further, any assigned value to a used or unused segment that is significantly disproportionate to the distance covered by that segment (*e.g.,* assigning 10% of the total ticket value to the unused segment that covers 50% of the total travel distance) will be viewed as a *prima facie* unfair practice unless carriers can justify the assignment with established and verifiable industry practice.

Although the final rule requires carriers to refund only unused portion of the ticket price if a passenger has used a part of the ticket, the Department acknowledges the comment from a consumer organization regarding consumers having to pay a premium to purchase a new ticket when their flights are cancelled or significantly changed close to the scheduled departure date, as well as comments that flight cancellations or significant changes impact consumers more significantly when they have already traveled a portion of the itineraries, particularly persons with disabilities. Consumers stranded at a connecting airport by a cancellation or significant change face not only the challenge of limited choices for continuing travel or returning to their origination airport, but also increased cost of food, lodging and other expenses. These comments reflect consumers' concern that simply refunding the ticket price may not adequately compensate the actual cost to consumers from airline cancellations or significant changes. The Department's rulemaking on Rights of Airline Passengers When There Are Controllable Flight Delays or Cancellations [53] intends to examine how best to ensure passengers' needs are addressed beyond refunds including essential services such as meals, rebooking, and hotel as well as compensation to mitigate passenger inconveniences when there is a controllable cancellation or delay.

To reduce the likelihood of consumers embarking on a journey without knowledge of a downstream cancellation or significant change, the Department reminds carriers of their obligation under 14 CFR 259.8 to

[53] *See* fn. 29, *supra.*

promptly provide to passengers who are ticketed or hold reservations, and to the public, information about a change in the status of the flight within 30 minutes after the carrier becomes aware of a change in the status of a flight. These notifications are important to ensure that consumers are aware of any known flight itinerary or schedule changes and cancellation that would affect their travel downstream before they begin the journey to avoid being stranded mid-travel and facing difficult choices. Also, the Department reminds carriers of their obligation under 14 CFR 259.8 to identify and adhere to the services that it promises to provide consumers in their customer service plan to mitigate passenger inconveniences resulting from flight disruptions. Beginning in September 2022, the large U.S. carriers have made significant changes to their customer service plans to improve services provided to passengers when their flights are canceled or delayed because of an airline issue (*i.e.,* controllable cancelations and delays). As a result, many U.S. customers impacted by controllable cancellations and delays are entitled today to receive reimbursements for expenses such as meals, hotels, and ground transportation.[54] On the form of refunds, the Department is convinced by commenters that the best approach is to require that refunds be in the original form of ticket purchase, and allow airlines and ticket agents to offer, in addition to the original form of payment, other cash-equivalent payments. The Department views that making the original form of payment the default refund form has several benefits. First, it ensures that all passengers, as a minimum, can receive their money back in the same way they paid for the tickets, therefore avoiding the situations where consumers are forced to accept an alternative payment form through which they have no way to access cash directly. Second, it expedites and streamlines the process of refunds in most situations by simply reversing the ticket purchasing process using the payment information already available to airlines or ticket agents. Thirdly, it avoids complications in business travel by ensuring that businesses, as opposed to travelers, receive the refunds. The Department notes that under this final rule, all airlines and ticket agents are required to provide refunds in the original form of payment, unless the passenger has agreed to a different form of payment. Airlines and ticket agents are permitted, but not required, to offer other forms of refunds that are equivalent to cash, but only if it is made clear to the customer that they have the right to receive a refund in the original form of payment. Having received no comments on the proposed definition for ''cash equivalent,'' the Department is adopting the definition as proposed, including the prohibition on requiring consumers to bear the burden for maintenance fees, usage fees, or transaction fees related to a cash equivalent payment method.

8. Offers of Travel Vouchers, Credits and Other Compensation and Notification to Consumers of Their Right to a Refund

The NPRM: The Department proposed to allow airlines and ticket agents to offer but not require other compensation choices such as travel credits or vouchers and store gift cards in lieu of refunds. The NPRM recognized that while a refund in the original form of payment or cash or a cash equivalent form of payment would be preferred by many passengers, some passengers may prefer receiving travel credits or vouchers or store gift cards. The proposal would allow airlines and ticket agents the flexibility, at their discretion, to work with passengers by offering more choices of compensation for interrupted travel plans.

To ensure consumers know their right to a refund, the Department also proposed to require carriers and ticket agents inform consumers that they are entitled to a refund if that is the case before making an offer for travel credits, vouchers, or other compensation in lieu of refunds. Further, under the Department's proposal, the option for carriers and ticket agents to offer compensation other than refund of cash or cash equivalent when a carrier cancels or makes a significant change to a flight itinerary must not be misleading with respect to the passengers' rights to receive a refund. Under the proposal, airlines and ticket agents must clearly disclose any material restrictions, conditions, and limitations on the compensation they offer, so consumers can make informed choices about which types of compensation and refunds would best suit their needs.

Comments Received: FlyersRights and several consumer commenters expressed their support for the proposal to require airlines to notify consumers of their rights to a refund before offering other compensation. Some commenters also stated that such disclosure should be in clear language, using terms that ordinary individuals would understand. All airline commenters who commented on non-cash equivalent compensation supported the proposal to allow airlines and ticket agents to offer these types of compensation to consumers who are eligible for refunds. IATA and SATA also commented that the Department should allow carriers to offer refunds when travel credits or vouchers are required by the regulation. National Consumers League supported the proposal to allow airlines and ticket agents to offer non-cash equivalent compensation but argues that any travel credits or vouchers offered should never expire.

DOT Response: This final rule is requiring airlines and ticket agents to inform passengers entitled to receive a refund of their right to a refund before making an offer for travel credits, vouchers, or other compensation in lieu of refunds. The Department is persuaded by comments of the importance of disclosing to consumers their rights to a refund up front in plain language. Passengers lacking this information may not be able to make an informed decision as to whether to obtain a refund or accept other compensation. For similar reasons, the Department is also requiring airlines and ticket agents to inform passengers of their rights to a refund, if this is the case, when offering a significantly changed flight or alternative transportation for a significantly changed or cancelled flight.

To provide more flexibilities and choices to consumers, the Department is allowing airlines and ticket agents to offer, in addition to refunds, other compensation to eligible consumers. The Department emphasizes the importance of carriers and ticket agents providing clear, prominent, and accurate disclosures to consumers of their rights to refunds when offering these options, and of any material restrictions, limitations, and conditions on any compensation offered as an alternative to refunds. The Department views any misrepresentation or omission of these matters to be unfair and deceptive practices in violation of 49 U.S.C. 41712. A consumer's entitlement to a refund and restrictions, limitations, and conditions on alternatives offered such as travel credits and vouchers in lieu of a refund are material matters that are likely to affect consumers' decisions with respect to whether they accept the offered voucher or credit. The Department views misrepresenting or omitting the consumer's right to a refund or the restrictions, limitations, and conditions that apply on the compensation offered

[54] See *https://www.transportation.gov/airconsumer/airline-customer-service-dashboard,* an easy-to-use dashboard that displays airlines' commitments.

as an alternative to refunds to be a deceptive practice because it deprives that consumer of important information that could impact the choice that the consumer makes between a refund and another option. During the COVID–19 pandemic, the Department became aware of many consumers who accepted travel credits and vouchers from airlines for canceled or significantly changed flights because they were not aware of their right to a refund or because they were not aware of the restrictions that applied on their travel credits and vouchers. This conduct is also an unfair practice because it causes substantial consumer harm by depriving consumers of the knowledge that they are entitled to a refund, which is not reasonably avoidable by consumers as they are unable to obtain this knowledge unless they are informed by the airlines or ticket agents. This conduct also harms competition because, by avoiding issuing refunds to consumer, entities engaging in this conduct gain unfair advantages over entities providing full disclosure to consumers about their right to a refund.

9. Service Charges

The NPRM: The NPRM proposed that airlines may not charge a fee when issuing a refund following a carrier-initiated cancellation or significant change and that the terms or conditions in airline contracts of carriage should be consistent with the proposed regulation. With respect to refunds issued by ticket agents, the NPRM proposed that ticket agents are permitted to retain the service fee they charged for ticket issuance at the time of purchase in recognition that ticket agents are providing a service apart from airfare purchase and that service has been completed regardless of whether the passenger took the flight. The NPRM further proposed that ticket agents may also charge a fee for issuing refunds, reasoning that, unlike airlines, ticket agents do not initiate the cancellation or significant changes that result in a refund being due, nor do the ticket agents have any control over the cancellation or significant changes to a flight itinerary. The NPRM emphasized that the amount of the ticket issuance service fee or refund processing fee that ticket agents may retain must be on a per-passenger basis and the existence of the fee must be clearly and prominently disclosed to consumers at the time they purchased the airfare.

Comments Received: The Department received comments from consumers, ticket agents, and airlines regarding service fees. Several consumers opposed allowing refund processing fees charged by airlines. One commenter noted that if airlines are allowed to charge such a fee, there is nothing to prevent them from charging $100 or more. The same commenter added that processing refunds is computerized and can be done with a few keystrokes. Qatar Airways asserted that airlines should be permitted to collect service fees, including fees for processing refunds. Ticket agent representatives supported the proposal to allow ticket agents to retain the ticket issuance service charge and refund service fee, agreeing with the Department's rationale that issuing tickets and processing refunds are separate services provided by ticket agents independent of the value of the ticket. Travel Management Coalition commented that when additional paperwork is involved to verify refund eligibility, ticket agents should be allowed to charge a service fee and it would be disclosed in a client agreement.

DOT Response: The Department reaffirms its belief that ticket agents offer valuable services to the traveling public apart from booking airfare, such as providing specialized knowledge of suitable travel options in accordance with consumers' wants and capabilities, offering access to limited availability fares or tools to comparison shop across various airlines to find the best value for consumers, and researching and booking activities at consumers' destinations (*e.g.,* sightseeing tours, events). The Department is of the view that, even in situations where the consumer did not travel because of a canceled or significantly changed flight, it is reasonable for ticket agents to retain service charges related to issuing the original tickets to the extent the service charge is not simply for processing payment for a flight that the consumer found. The Department views this service as being independent of the value of the ticket. Also, regardless of whether the passenger travels, the fee represents the cost of service already provided by ticket agents. Under this final rule, ticket agents may retain this type of service charge even if the passenger did not travel due to an airline cancellation or significant change so long as the nature and amount of these fees are clearly and prominently disclosed to consumers when they purchase the tickets, and they are assessed on a per-passenger basis.

The Department's Office of Aviation Consumer Protection would consider undisclosed fees to be a deceptive practice in violation of 49 U.S.C. 41712. Pursuant to 14 CFR 399.79, a practice is ''deceptive,'' within the meaning of 49 U.S.C. 41712, to consumers if it is likely to mislead a consumer, acting reasonably under the circumstances, with respect to a material matter. A matter is material if it is likely to have affected the consumer's conduct or decision with respect to a product or service. A ticket agent's failure to disclose that the service fee charged at the time of reservation is nonrefundable should a ticket refund be due would likely mislead a consumer to reasonably conclude that the entire amount paid for the ticket is refundable when a ticket refund is due. Similarly, a ticket agent's failure to disclose the existence and the amount of a fee for issuing a refund is likely to mislead a consumer to reasonably believe that no such fee would apply when a ticket refund is due. Failing to provide either disclosure would be an omission of material information that may affect the consumer's purchase decision because a consumer might choose not to purchase the ticket if the consumer was aware that if a refund is due the amount of the refund would be for less than the purchase price.

The Department does not address in this final rule whether a ticket agent can retain a booking fee (*i.e.,* a fee for processing payment for a flight that the consumer found) when processing a refund for an airline ticket because the passenger's flight was canceled or significantly changed and the passenger no longer wishes to travel. The Department notes that it is addressing the issue of whether carriers can charge a booking fee separately from the ticket price as part of another rulemaking.[55] While that rulemaking is pending, the Department's Office of Aviation Consumer Protection will focus on whether the nature and amount of the booking fee was clearly and prominently disclosed to a consumer at time of ticket purchase in determining if an airline or ticket agent engaged in an unfair or deceptive practice in violation of 49 U.S.C. 41712.[56]

Regarding the issue of whether airlines or ticket agents can retain a fee for processing refunds, the Department remains of the view that airlines must refund the entire ticket price and not be permitted to retain a fee for processing

[55] In that rulemaking, the Department is examining whether fees for basic airline services such as booking a ticket should be included in the advertised fare and prohibited as a separate charge. See *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=2105-AF15.*

[56] The Department's full-fare advertising rule requires all mandatory fees to be paid by the customer to the carrier, or agent, for air transportation to be included in the advertised fare. See 14 CFR 399.84. To the extent that a booking fee is not avoidable and is a mandatory fee, it must be included in the advertised fare.

refunds when airlines cancel or significantly change a flight and the passenger no longer wishes to travel. The Department received consumer comments objecting to refund processing fees by airlines for flights that the airlines cancel or significantly change, and limited industry comment in support of allowing such fees. In the Department's view, airlines charging a service fee for processing refunds caused by an airline-initiated cancellation or significant change is an unfair practice in violation of section 41712. Consumers are substantially harmed by having to pay a fee to receive their money back after services they paid for were not provided. This harm is not reasonably avoidable by consumers because consumers have no control over the cancellation, significant change, or the issuance of the refund, with or without a fee. The Department further views that allowing airlines to charge a refund processing fee harms competition and consumers because it reduces the incentives for airlines to minimize cancellations and significant changes, based on which refunds are due to consumers.

As for ticket agents, the Department is concerned that permitting a ticket agent to charge a fee for processing refunds may be unfair to consumers. While the Department recognizes that ticket agents do not initiate the cancellation or significant changes that result in a refund being due, neither does a consumer. The Department plans to explore this issue further at a later time, including through its rulemaking [57] pursuant to a requirement by 49 U.S.C. 42301 note prec. to issue a rule requiring ticket agents with an annual revenue of at least $100 million to adopt minimum customer service standards. In the meantime, the Department's Office of Aviation Consumer Protection will focus on whether the nature and amount of the refund processing fee was clearly and prominently disclosed to a consumer in determining whether, when a refund is due, a ticket agent engaged in an unfair or deceptive practice by charging a refund processing fee that was not properly disclosed at the time of ticket purchase. Also, if the Department determines that ticket agents' processing fees appear to circumvent the intent behind the requirement for consumers to receive a meaningful refund, the Department will consider whether further action is appropriate.

The Table below summarizes whether airlines or ticket agents can retain certain fees when processing refunds.

TABLE 2—FEES CHARGED BY AIRLINES AND TICKET AGENTS WHEN PROCESSING REFUNDS

Types of service fees	Are airlines allowed to retain fee when processing refunds?	Are ticket agents allowed to retain fee when processing refunds?
Booking Fee (for processing payment for flight that the consumer found).	No	N/A (DOT is not aware of ticket agents that charge this type of booking fees).
Service Fee Related to Issuing Original Ticket (for services provided beyond processing payment for flight that the consumer found).	N/A (DOT is not aware of airlines that charge these types of service fees).	Yes, subject to required disclosures.
Processing Fee for Required Refunds	No	No determination in this final rule—DOT will continue to examine issue.

II. Refunding Fees for Significantly Delayed Bags

1. Covered Entities and Flights

The NPRM: In the NPRM, the Department proposed to mandate U.S. and foreign air carriers provide refunds to consumers for the fees charged to transport checked bags on scheduled flights to, from, or within the United States using aircraft of any size if the bags are significantly delayed. The Department explained that the proposed requirement is based on a mandate in 49 U.S.C. 41704 note for the Department to promulgate a regulation requiring U.S. and foreign air carriers refund bag fees to consumers when carriers fail to deliver checked bags to them within a specified time of their arrival on a domestic or international flight. In the NPRM, the Department acknowledged that the proposed requirement would apply to some small carriers but explained that it does not expect it to have a significant economic impact on a substantial number of small entities because many small carriers operate flights under codeshare arrangements with larger carriers, with the larger carriers responsible for collecting and refunding baggage fees.

With respect to ticket agents, the Department did not propose to apply the baggage refund requirements to ticket agents. The Department stated in the NPRM that the Department has independent authority under 49 U.S.C. 41712, which prohibits ticket agents from engaging in unfair or deceptive practices in air transportation, to include ticket agents in the regulation if deemed appropriate. The Department stated, however, that it is required by 49 U.S.C. 42301 note prec. to issue a rule requiring ticket agents with an annual revenue of at least $100 million to adopt minimum customer service standards, and the Department intends to address this requirement through that separate rulemaking. In addition, the Department noted that a ticket agent's failure or refusal to make proper refunds promptly when service cannot be performed as contracted or a ticket agent's representation that such refunds are obtainable only at some other point violates 14 CFR 399.80(l) and constitutes an unfair or deceptive practice. This requirement does not, however, directly address whether ticket agents that collect baggage fees from passengers must provide refunds of the fees when checked bags are significantly delayed. DOT sought comments on whether the proposed refund requirement for delayed checked bags should apply to ticket agents who engage in the transaction of baggage fees.

Comments Received: The Department received no comments regarding the proposed scope of carriers that would be required to refund fees to consumers for significantly delayed bags on their domestic or international flights. The Department did receive comments on whether, as a policy matter, the Department should require ticket agents to refund baggage fees that they collected when the bags were significantly delayed. A4A, IATA, RAA, and Qatar Airways all supported holding ticket agents responsible for

[57] Information on the rulemaking titled ''Air Transportation Consumer Protection Requirements for Ticket Agents'' (RIN 2015–AE57) is available in the Fall 2023 Unified Agenda of Regulatory and Deregulatory Action at *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=2105-AE57.*

refunds if they collected the baggage fees. Spirit also commented that ticket agents should be required to refund baggage fees, arguing that the Department has existing regulation requiring ticket agents to make ''proper'' ticket refunds when contracted services are not provided, and it is arbitrary, inconsistent, and unfair to not require ticket agents to refund baggage fees.

Travelers United commented that whether the ticket was purchased from airlines or ticket agents, airlines should ultimately be responsible for refunds of baggage fees and other ancillary fees. Similarly, ASTA and Travel Tech both argued that ticket agents should not be required to refund baggage fees. They pointed out that the statute directs the Department to issue a rule specifically requiring airlines to refund baggage fees. They argued that where ticket agents collect the fees, they are authorized by airlines to do so as agents of airlines. They noted that depending on the payment settlement system used, ticket agents can facilitate the issuance of baggage fee refunds, but each airline determines whether it would allow ticket agents to issue refunds. They further commented that any fees collected by ticket agents under airlines' authorization are promptly remitted to airlines.

DOT Response: In this final rule, the Department requires U.S. and foreign carriers that operate scheduled passenger service to, within, and from the U.S. to provide a refund to passengers of fees charged for transporting a significantly delayed checked bag. The Department is applying this requirement to carriers regardless of the aircraft size that the carriers operate. DOT continues to believe that it is important to not exclude aircraft designed to have a maximum passenger capacity of 60 seats or fewer, which are considered small aircraft,[58] because a significant number of passengers travel on such aircraft.[59]

With regard to applying the proposed baggage refund requirements to ticket agents, the Department does not adopt in this final rule a specific requirement for ticket agents to provide refunds of baggage fees for significantly delayed bags even if ticket agents collect the bag fees. The NPRM sought information on ticket agents' involvement in collecting baggage fees from passengers, either as a carrier's agent or as a principal. It is the Department's understanding, based on comments from both ASTA and Travel Tech, that ticket agents' involvement in collecting baggage fees is minimal and the collections are generally authorized by airlines as their agents. Also, the Department believes that tracing mishandled baggage and ensuring delivery as soon as possible is best handled by carriers through direct communication with passengers. The Department is concerned that placing the obligation to refund baggage fees for delayed bags on ticket agents may cause unnecessary delays by removing some of the incentives for airlines to recover the bags as quickly as possible. It would also necessarily require that ticket agents determine whether refunds for significantly delayed bags are due, which the ticket agents cannot determine on their own. Further, 49 U.S.C. 41704 note directs the Department to promulgate a regulation requiring *airlines* to provide refunds for baggage fees. For all these reasons, the Department is not requiring ticket agents to provide refunds of baggage fees for significantly delayed bags in this final rule. The Department will continue to monitor the transactions of baggage fees and other ancillary service fees conducted by ticket agents and intends to revisit the issue in its rulemaking requiring ticket agents with an annual revenue of at least $100 million to adopt minimum customer service standards, as required by 49 U.S.C. 42301 note prec.[60]

2. Length of Delay Triggering Baggage Fee Refund Requirement

The NPRM: The Department proposed to require an airline refund the fee paid by a passenger for a checked bag if the airline fails to deliver the bag to the passenger within 12 hours of arrival for domestic flights and within 25 hours of arrival for international flights. 49 U.S.C. 41704 note prescribes the minimum lengths of baggage delivery delay that would trigger the refund requirement as not later than 12 hours after arrival for domestic flights and not later than 15 hours after arrival for international flights. It also provides the Department the flexibility to modify these timeframes to up to 18 hours for domestic flights and up to 30 hours for international flights if the Department determines that the 12-hour or 15-hour standards are infeasible and would ''adversely affect consumers in certain cases.'' The Department explained that it proposed 12 hours for domestic flights because airlines have tracking systems in place to identify the location of bags and airlines should be able to place delayed bags on the next available flight, often resulting in bags being delivered within 12 hours for domestic flights. With respect to international flights, the Department proposed to allow carriers up to 25 hours (an extension of the statutory default standard of 15 hours) to deliver checked bags without having to issue a refund, reasoning that many international long-haul flights are scheduled once a day which makes recovery and delivery of a delayed checked bag within the minimum length delay of 15 hours prescribed in the statute extremely challenging for carriers. The Department stated that consumers may be negatively impacted if the Department were to impose a 15-hour deadline because carriers may have less incentive to deliver the delayed bag on the next flight when flights are scheduled once a day. The NPRM solicited comment on whether it has adequately considered the impact on consumers and airlines of the proposed 25-hour deadline for international flights and whether the proposed 12-hour deadline for domestic flights is reasonable, particularly for ULCCs that may operate scheduled flights in a lower frequency and lack interline agreements with other carriers.

Additionally, the NPRM discussed a tiered standard where the maximum number of delay hours that would trigger a refund would vary based on domestic versus international flights, the length or frequency of the flights, or other variables. The Department tentatively determined to not propose a tiered standard based on flights' frequency or length because carriers would have to implement a costly system of sorting and prioritizing delivery of delayed bags based on the length or frequency of each individual flight. It proposed instead a tiered standard based on domestic and international flights because it would be easier for carriers to implement and for consumers to understand. For international itineraries that include domestic segments, the NPRM proposed that the international standard for bag delay would apply.

Comments Received: Most airline commenters generally supported adopting the maximum length of timeframes permitted by the statute, *i.e.,* 18-hour delay for domestic itineraries

[58] An air carrier is a small business if it provides air transportation only with small aircraft (*i.e.,* aircraft with up to 60 seats/18,000-pound payload capacity). See 14 CFR 399.73.

[59] According to data from the Department's Bureau of Transportation Statistics (BTS), a total of 760,159,634 domestic passengers were transported in 2022. While most of these passengers (734,090,772 passengers or 96.6%) were on flights using aircraft of more than 60 seats, a significant number (26,068,862 passengers or 3.4%) were on flights using aircraft with 60 seats or fewer. See Bureau of Transportation Statistics ''T–100 Domestic Segment Data (World Area Code)'', *https://www.bts.gov/browse-statistical-products-and-data/bts-publications/data-bank-28ds-t-100-domestic-segment-data.*

[60] See fn. 55, *supra.*

and 30-hour delay for international itineraries, while AAPA opposed a blanket timeframe by regulation and Kuwait Airways suggested a 72-hour timeframe. A4A stated that carriers cannot meet the proposed 12 hours for domestic and 25 hours for international standards under certain circumstances, including itineraries involving routes for which airlines do not operate daily flights, passengers traveling on the last flight of the day out of a remotely located airport, and passengers continuing travel on cruise or ground transportation preventing timely delivery of bags. A4A, IATA, and multiple international carriers also commented that special considerations should be given to international operation complexities such as airport congestion preventing offloading bags, weather impact on ground operations, the impact of a positive bag match requirement, and customs and security inspections. RAA urged the Department to consider that many carriers serving remote markets under the Essential Air Service program or serving international markets may only operate one flight a day and not every day. NACA, Allegiant, and Spirit commented that from the ULCC perspective, operating low frequency and the lack of interline partners makes it difficult to meet the proposed timeframes. Some of these commenters believed that adopting the 18/30-hour maximum standards would at least incentivize ULCCs to seek other means (*e.g.,* overnight couriers) when transporting the bag on the next available flight would not meet the deadlines. Air New Zealand, Emirates, Kuwait Airways, and Qatar Airways indicated that the Department should give special consideration to ultra-long-haul international operations, arguing that the length of flight operations and the low frequency would prohibit their ability to meet the 25-hour deadline. Airline commenters supported the proposal to apply the international delay standard to domestic segments of international itineraries.

Among consumer rights advocacy groups, Travelers United, Business Travel Coalition *et al.,*[61] and FlyersRights commented that checked bags should be deemed late when they are not on the same flight as passengers. Business Travel Coalition *et al.* argued that the Department has its own authority under 49 U.S.C. 41712 to impose such a requirement without contradicting 49 U.S.C. 41704, note. Travelers United argued that refunds of bag fees should be issued automatically if the bags do not arrive within 60 minutes of the passengers' arrival. Business Travel Coalition *et al.* argued that the Department should require airlines to enter into interline agreements for baggage delivery. FlyersRights commented that by proposing a 25-hour standard for international flights, the Department has considered that international long-haul operations that operate one daily flight can still meet the deadline by placing the bag on the next flight. In that regard, FlyersRights questioned why the Department does not simply require that the bag be transported on the next flight. FlyersRights also stated that the 25-hour deadline would harm consumers on international flights that are operated more than once a day because bags that could have been transported within a shorter time now can be delayed for up to 25 hours.

ASTA, representing ticket agents, commented that the Department should adopt the 12/15-hour minimum standards set by the statute. It argued that while the proposed 25-hour standard acknowledges long-haul flights operated once a day, it does not recognize many international flights that are short in duration and operated multiple times a day. ASTA further stated that it disagrees with the Department's belief that imposing the 15-hour deadline for international flights would result in carriers having less incentive to recover the bags because the deadline has already passed. It argued that keeping the bag fees is not the airlines' sole or primary purpose when considering recovering delayed bags.

The Colorado Attorney General (Colorado AG) also provided comments in support of the Department's tentative decision to not adopt a tiered standard for the length of a delay triggering a refund based on flights' frequency, length, or other variables. The Colorado AG stated that a simplified system is certainly more accessible to all parties and is an example of the type of regulatory clarity that, in effect, protects consumers by enabling them to understand their own rights and advocate for themselves when regulations are defied or disregarded.

DOT Responses: After fully considering the comments, the Department is requiring carriers to refund the bag fee if a checked bag is delayed the minimum statutory standard of 12-hours for domestic flights as proposed, the minimum statutory standard of 15-hours for an international flight that is 12 hours or less, and the maximum statutory standard of 30-hours for an international flight that is more than 12 hours. The Department appreciates consumer rights advocacy groups' comments that urge the Department to adopt a ''zero hour'' standard for delayed bags. While we agree that the Department has broad authority under 49 U.S.C. 41712 to define unfair or deceptive practices, 49 U.S.C. 41704 note imposes a specific requirement on the Department with regard to airlines' refund of delayed baggage fees. Specifically, the Department is directed to require U.S. and foreign carriers to provide a refund for any fees paid by a passenger for checked baggage if the carriers fail to deliver the bag to passengers within 12 to 18 hours of their arrival from domestic flights and within 15 to 30 hours of their arrival from international flights. Although adopting a ''zero hour'' standard as suggested by a consumer organization would result in consumers receiving a refund of baggage fees in all instances where the bags did not arrive with the consumers, the Department is of the view that imposing a strict liability on airlines would not result in the maximum consumer benefit because this approach reduces the incentive for carriers to recover and return the delayed bags to consumers as soon as possible. As such, we are not setting a ''zero hour'' standard for delayed bags that would necessitate a refund of the bag fee.

The Department has carefully considered the comments received and is adopting the proposed 12-hour standard for domestic itineraries. Airline commenters did not provide convincing evidence demonstrating that the 12-hour standard for domestic itineraries is not feasible and would ''adversely affect consumers in certain cases,'' as set forth by the statute. Further, although the Department acknowledges the differences between the legacy carriers and ULCCs in terms of flight frequencies and the scope of networks, we continue to believe that these differences do not warrant adopting a standard for ULCCs different from that of the other carriers. Specifically, the Department notes that all carriers have the option to transport the delayed bags through overnight couriers and still meet the delay deadline, instead of waiting for the next available flight. Also, although compared to the legacy carriers, it is likely that ULCCs may have to use courier services more frequently to recover the delayed bags, this

[61] The joint comments by Business Travel Coalition *et al.* were signed by Business Travel Coalition, Consumer Action, the Consumer Federation of America, Consumer Reports, Ed Perkins of EdOnTravel.com, FlyersRights.org, National Consumers League, Travel Fairness Now, and U.S. PIRG.

disadvantage for the ULCCs is countered by the reduced likelihood of ULCCs having delayed bags compared to legacy carriers because of their point-to-point operations. Legacy carriers' hub-and-spoke networks means that many of the bags they transport will be traveling through connecting itineraries that statistically have a higher possibility of being delayed, in comparison to the ULCCs' point-to-point operations. According to a Société Internationale de Télécommunications Aéronautiques (SITA) Baggage IT Insights report,[62] transfer mishandling historically remains by far the leading cause of bag delays, which accounted for 42% of total bag delays in 2022.[63]

With respect to international itineraries, the Department has decided that a ''one-size-fit-all'' standard may not be in the best interest of consumers. We agree with comments suggesting that the proposed 25-hour standard to return a bag before the carrier has to refund the bag fee may be too long when consumers are traveling on international routes with shorter durations and/or more frequencies. At the same time, we agree with comments asserting that, in many cases, it may not be feasible for carriers to return bags within the proposed 25-hour standard for consumers traveling on ultra long-haul flights operated under low frequencies. This is not only because the carrier's next available flight could be 24 hours or more later, but also because there could be very limited choices to transport the bags on rerouted itineraries, on another carrier's flight, or through courier services. The flight segment duration data on major U.S. carriers collected by the Bureau of Transportation Statistics (BTS) shows that in 2022, the majority of non-stop flight segments operated by U.S. carriers to and from the U.S. have a flight duration of 12 hours or less, including all flights between the United States and Canada, Central/South America, and Europe, 65% of flights between the United States and Africa, 46% of the flights between the United States and Far East, 73% of flights between the United States and Middle East, and 14% of the flights between United States and Australia/Oceania.[64] The Department assumes the duration of flights operated by foreign carriers is similar, but BTS does not collect this data from foreign air carriers. For these reasons, the Department is adopting two standards for international itineraries. For international itineraries with a non-stop flight segment to or from the United States that is 12 hours or less, we are adopting the minimum statutory standard of 15 hours. For international itineraries with a non-stop flight segment to or from the United States that is more than 12 hours, we are allowing carriers to recover the delayed bags within 30 hours to avoid refunding the bag fees.

The Department notes that to qualify for the 30-hour standard, the itinerary must include an international segment (*i.e.* a flight segment between the United States and a foreign point) that is more than 12 hours in duration. If the itinerary includes a segment between two foreign points that is more than 12 hours and the segment between the United States and a foreign point is 12-hour or less in duration, the 15-hour delay standard would apply.

The Department disagrees with some commenters' suggestion that the rule should explicitly require that the delayed bags be transported on the next available flight. We intend to provide carriers the maximum flexibility to recover the delayed bags to the benefit of passengers, including transporting the bags on partner airlines' flights, on cargo flights, or through commercial couriers. In addition, the Department agrees with ASTA's comment that it is inappropriate to assume that retaining the baggage fees is carriers' sole or primary goal and that once the deadline has passed for delivering delayed bags, carriers will not have the incentive to recover the bag as quickly as possible. As ASTA pointed out in its comment, delivering a delayed bag as soon as possible is a way to gain custom satisfaction and goodwill, regardless of whether carriers must refund the bag fee. Further, carriers are under the obligation to compensate consumers for incidental expenses related to delayed bags, subject to maximum liability limits under 14 CFR 257 for domestic travel and under international treaties for international travel. The longer the bag is delayed, the more potential liability for incidental expenses carriers will face. The Department believes that all these factors provide incentives to carriers to recover the bags regardless of whether the refund deadline has passed.

Regarding international itineraries that include a domestic segment, we are adopting the proposal to apply the international deadline to such itineraries. The Department holds the view expressed in the NPRM that mishandled bag incidents occur more frequently on the international segments. This is also confirmed by the aforementioned SITA Baggage IT Insight report, which states that globally, mishandling rates on international routes is 19.3 per thousand passengers, compared to 2.4 for domestic routes.[65] The Department also received no objection to this proposal and believes that applying the international deadlines to such itineraries avoids consumer confusion and appropriately takes into account that many delayed bags traveling on an international itinerary were likely delayed on the international portion of the trip.

Also, the Department notes that it is making an editorial change to the rule text in 14 CFR 259.5(b)(3). The existing rule requires carriers to make every reasonable effort to return mishandled baggage within twenty-four hours. The Department is removing the reference to ''twenty-four hours'' and, instead, requiring carriers to make every reasonable effort to return mishandled baggage within the timeframes set forth in this final rule for purpose of avoiding refunding baggage fees.

3. Measuring the Length of Delay in Delivering a Checked Bag

The NPRM: To calculate the length of the delay for a carrier to deliver a checked bag, it is necessary to specify the start and end of the delay. The provision at 49 U.S.C. 41704 note states that the baggage delay clock starts at ''the arrival'' of a flight and ends when the carrier ''[delivers] the checked baggage to the passenger.'' However, that provision does not specify what it meant by the arrival of a flight or delivery of the checked baggage.

The Department proposed the start of the delay to be when the passenger arrives at his or her destination and is given the opportunity to deplane from the last flight segment. The Department reasoned that airlines already track this information for the purpose of ensuring compliance with the Department's tarmac delay rule in 14 CFR part 259. Another measure considered in the NPRM for the start of the delay is the published scheduled arrival time of a flight or the ''block-in time,'' *i.e.,* the time when a flight has parked at the arrival gate or another disembarkation location and blocks were placed in front of its wheels.

As to when a bag is considered to be delivered to the passenger for the

[62] *https://www.sita.aero/resources/surveys-reports/baggage-it-insights-2023/.*

[63] As noted in the NPRM, the SITA Baggage IT Insights report for 2019 states that transfer mishandling account for 46% of total bag delays in 2018. *https://www.sita.aero/resources/surveys-reports/baggage-it-insights-2019/.*

[64] Data is derived from the T–100 Segment report as filed monthly by major U.S. carriers with BTS. Flight duration is calculated by dividing minutes airborne with performed departures.

[65] The Report also noted that in 2022, there was a considerable surge in the international mishandling rate, which was at 8.7 during the previous year.

purpose of ending the delay in receiving a checked bag, the Department proposed that, at the carrier's discretion, the end of the delay is: (1) when the bag is transported to a location agreed to by the passenger and the carrier, regardless of whether the passenger is present to take possession of the bag; (2) when the bag has arrived at the destination airport, is available for pickup, and the carrier has provided notice to the passenger of the location and availability of the bag for pick-up; or (3) if the carrier offers delivery service and the passenger accepts such service, when the bag has arrived at the destination airport, and the carrier has provided notice to the passenger that the bag has arrived and will be delivered to the passenger. The Department shared in the NPRM that the three options to determine the end of the delay are intended to allow airlines, with less financial risk, to work with the passengers to transport the bags to the most convenient location in the most efficient manner to the passenger. The NPRM sought comment on whether this analysis accurately captures carriers' incentives to work with passengers and provide baggage delivery or if there are other factors that could cause carriers to engage in different behaviors in response to the proposed options. In addition, the NPRM sought comment on whether allowing carriers to choose among these three options is reasonable and effective to achieve the goal of providing carriers and passengers the maximum level of flexibility, promoting efficiency in delayed baggage recovery, and ensuring passengers are treated fairly when their bags are delayed in air transportation.

The Department also solicited specific comment on the second option, which stops the delay clock when the bag has arrived at the destination airport, is available for pickup, and the carrier has provided notice to the passenger of the location and availability of the bag for pick-up. The NPRM noted that carriers have the burden of proving that notices have been provided to passengers prior to the applicable deadline, invited comment on sufficient forms of notifications, and asked what evidence should a carrier be required to provide if notification is through a voice call or message and there is a dispute between a carrier and a passenger about whether such a notification was provided.

Comments Received: Regarding the start of baggage delivery delay, all airline commenters who commented on this issue suggested that the delay clock should start at the time a passenger files a Mishandled Baggage Report (MBR). They argue that airlines do not always know that a bag is delayed until a passenger notifies the carrier by filing an MBR. They further commented that this notification would allow carriers to collect necessary information for searching and delivering the bag, such as the passenger's contact information, the bag's tag number, and the bag's description. Qatar Airway asked if the Department would consider passengers using carriers' online reporting system to have started the clock.

An individual consumer objected to the airlines' approach and argued that airlines determine how and when an MBR may be filed and there is obvious conflict of interest on airlines' part. This commenter suggested that a passenger arriving at 10 p.m. may not file an MBR until 9 a.m. the next day. This commenter further indicated that airlines' rejections of MBRs would increase DOT complaint volume.

Regarding the end of the delay, airline commenters supported the Department's proposal to allow airlines to choose one of the three options, arguing that this approach would allow carriers the flexibility to recover bags and work with passengers for tailored solutions. A4A commented that for option 2 (bag has arrived at the destination airport, is available for pickup, and the carrier has provided notice to the passenger of the location and availability of the bag for pick-up), it is unreasonable to require carriers' baggage office to open 24/7 so the clock should stop at the time of notification even if the carrier's baggage office is closed. A4A, IATA, Spirit, and Virgin Atlantic further indicated that the Department should adopt a performance-based standard for notifications, taking into account any future innovations, and the notification requirement should focus on timeliness and not the form. A4A and IATA also stated that the Department should not prescribe how carriers keep records of the notifications as carriers use different systems to record communications with passengers. A4A further commented that recording the time of a voice call should be sufficient as evidence that a notification by phone call has been provided.

Travelers United and Business Travel Coalition *et al.* opposed the proposal. Business Travel Coalition *et al.* argue that allowing the three options would result in airlines selecting the option that is most likely to relieve them from the obligation of refund baggage fee (*i.e.,* option 2) and doing no more than the minimum necessary to avoid having to refund. One individual consumer expressed support for the proposal of three options and commented that the flexibility allows carriers to provide the service in reasonable time and cost effectively. Another consumer commented that the regulation should not indicate that carriers may use app push notices to provide notification because many passengers do not want to or have mobile apps for various reasons, including the lack of memory to download the app, the lack of cellular data, unwillingness to share location, or concerns about viruses. The commenter suggested that consumers should have the right to receive notifications through privacy-friendly means such as email or text message.

ASTA commented that the clock should stop when the bag is physically in the passenger's possession because passengers continuously experience inconveniences until reunited with the bags. ASTA further stated, however, that it recognizes that it is inequitable to keep the clock running when a passenger delays the reclaim of a bag, and as such, it suggests that the clock should stop when the bag is delivered to a location designated by the passenger and the passenger is notified.

DOT Responses: After carefully considering the comments provided, the Department is requiring that the length of the delay for a carrier to deliver a checked bag be calculated based on when the passenger arrives at his or her destination and is given the opportunity to deplane from the last flight segment (start of the delay) and when the carrier delivers the bag to a mutually agreed upon location such as a hotel or the passenger's home or when the passenger (or someone authorized to act on behalf of the passenger) picks up the bag at the airport (end of the delay). In determining the start of the delay, the Department focused on the fact that the delay started when the bag did not arrive with the passenger. In determining the end of the delay, the Department focused on when the carrier relinquishes its custody of the bag to the passenger, which is consistent with the Department's position on U.S. airlines reporting of mishandled baggage.[66]

Based on carriers' comments that in many circumstances carriers may not know when a bag is delayed until the passenger files an MBR, and consistent with the requirement of section 41704 note that passengers must notify carriers of the baggage delay, the Department is specifying that filing an MBR is

[66] The Technical Directive issued by the Department's Bureau of Transportation Statistics requires that reporting carriers must report the number of mishandled bags, as reported by or on behalf of passengers, that were mishandled *while in its custody. https://www.bts.gov/topics/airlines-and-airports/number-30a-technical-directive-mishandled-baggage-amended-effective-jan.*

necessary to obtain a refund of the fee for a significantly delayed checked bag. Typically, airlines obtain, through the filing of an MBR, information such as the passenger's contact information, the bag's tag number, and the bag's description which helps them search for and deliver a bag. The provision in this final rule that a refund of the bag fee for a significantly delayed checked bag is not due until the passenger files an MBR with the last operating carrier is consistent with the statute in 49 U.S.C. 41704 note that provides a refund shall be provided if a carrier fails to meet the baggage delivery deadline ''and . . . the passenger has notified the [carrier] of the lost or delayed checked baggage.'' The Department considers that a consumer filing an MBR to be notification to the carrier of the lost or delayed checked bag.

Regarding the end of the delay for a carrier to deliver a checked bag, the Department had proposed in the NPRM to allow carriers to consider as end of the delay, among other things, instances where the carrier offers delivery service of the bag and the passenger accepts such service and the carrier has provided notice to the passenger that the bag has arrived and will be delivered to the passenger. The Department has determined that this is not an appropriate end of the delay because the bag remains under the carrier's custody and the passenger is not reunited with the bag when the carrier provides notice to the passenger that the bag has arrived and ''will be'' delivered. 49 U.S.C. 41704 note states that the baggage delay clock ends when the carrier ''[delivers] the checked baggage to the passenger.'' Notifying passengers that the bag will be delivered is not a form of ''delivery.'' [67]

Similarly, the Department has determined that its proposal that the end of the delay includes instances when the bag arrives at the destination airport, is available for pickup, and the carrier has provided notice to the passenger is inconsistent with 49 U.S.C. 41704 note. Again, notifying the passenger that the bag is available for pickup is not a form of delivery. Further, the Department agrees with consumer representatives that this option provides the easiest option for airlines to stop the clock and may incentivize carriers to do the bare minimum to assist passengers in reuniting with their bags. The Department is also of the view that requiring passengers to return to the airport to pick up their delayed bags, after they have already experienced the inconvenience of leaving the airport without their checked bags upon arrival, adds a potentially significant burden to passengers in terms of their time, effort, and cost. As such, the Department is revising this option in the final rule so the delay clock stops at the time the passenger or someone authorized to act on behalf of the passenger are timely notified of the arrival of the bag and *actually picks* up the bag at the airport instead of when the carrier has provided notice to the passenger of the location and availability of the bag for pick-up.

The Department is adopting its proposal that the end of the delay include instances when the bag is transported to a location (*e.g.,* passenger's home, hotel) agreed to by the passenger and the carrier, regardless of whether the passenger is present to take possession of the bag. The Department agrees with comments that the clock should stop when the carrier delivers the bag to a location designated by the passenger and the passenger is notified. At this point, the bag is effectively no longer under the custody of the airline because the passenger agreed to delivery of the bag to the specified location. In this final rule, airlines have the option to choose as the end of the delay either (1) when the carrier delivers the bag to a mutually agreed upon location; or (2) when the passenger picks up the bag at the airport. The Department believes that these two options provide flexibility for airlines to work with passengers in finding the best solution to reunite them with their bags. If airlines determine that passengers could or are purposefully delaying arriving picking up their bags to receive a refund, carriers are free to choose option (1).

4. Entities Responsive for Refunds in Multiple Carrier Itineraries

The NPRM: The Department proposed that, in a multiple carrier itinerary where a carrier collected the bag fee, the carrier that collected the baggage fee be the entity responsible for refunding the fee to a passenger should the checked bag be significantly delayed. The Department tentatively rejected an ''at fault'' approach that assigns the refund obligation to the carrier that causes the baggage delay, reasoning that expecting consumers to track down which airline caused the bag to be delayed would be an unreasonable burden on consumers. The Department also noted that it would be costly for carriers to determine which carrier is at fault for causing each bag delay.

With respect to multiple-carrier itineraries for which a ticket agent collected the bag fee, the NPRM proposed to hold the carrier that operated the last flight segment, rather than the ticket agent, responsible for issuing the refund when a checked bag is significantly delayed. There was discussion in the NPRM of ticket agents being authorized by carriers to collect bag fees on the carriers' behalf. Also, while the Department acknowledged that the carrier that operates the last flight segment may be a fee-for-service carrier that normally does not handle baggage fee refunds since these carriers generally do not sell tickets or ancillary services, the Department added that carriers can prorate the cost of refunds among themselves. The Department solicited comment on whether, rather than requiring the carrier that operated the last flight segment to provide the refund, the Department should require the carrier that marketed the last flight segment to issue the refund when a ticket agent collects the bag fee.

Comments Received: Most airline commenters supported requiring the carrier that collected the baggage fees to provide refunds for delayed bags in multiple carrier itineraries. Emirates agreed that the collecting carrier should refund but notes that the collecting carrier may not be the marketing/ticketing carrier. Virgin Atlantic commented that the marketing carrier has the payment information but may not have the information on the status of the bag, and the last operating carrier has the status of the bag but may not have the payment information. It suggested that carriers need to investigate together, and that additional time is needed. RAA commented that fee-for-service carriers that operate the last segments do not conduct transactions with passengers and are unable to process refunds. NACA stated that ULCCs that operate non-scheduled services often operate on behalf of other ULCCs for scheduled services. It contended that these non-scheduled operating carriers do not collect baggage fees or take control of bags when passengers check in, and they should not be responsible for refunds. A4A suggested that the ticket agents collecting baggage fees for multiple carrier itineraries should refund and the passenger should be required to notify the last operating carrier about the bag delay. ASTA supported not requiring the carrier at fault of mishandling baggage to refund when multiple carriers are involved. It argued that this approach would result in passengers being sent back and forth among

[67] The Merriam-Webster Dictionary defines ''deliver'' to mean ''to take and hand over to or leave for another.''

carriers. ASTA also supported requiring the carrier collecting the fee be responsible for refunds.

DOT Responses: The Department is requiring that, in a multiple carrier itinerary, the carrier that collected the baggage fee is the entity responsible for refunding the fee to a passenger should the checked bag be significantly delayed. Based on the comments received, it appears that the carrier that markets the itinerary may not always be the carrier that collects the baggage fee. Regardless of which carrier is marketing the flight or which carrier is at fault for the mishandling, the Department concludes that the most simplified and straightforward approach, from the passengers' perspective, is to hold the carrier that collected the baggage fee responsible for the refund because the collecting carrier already has the passenger's payment information for the baggage fee. The Department considers the carrier whose name is shown in the consumer's financial statements for the baggage fee transaction such as the debit or credit card charge statements (commonly known as the merchant of record) to be the carrier that collected the bag fee. As pointed out by commenters, the Department recognizes that the carrier that collected payment may not have information on the status of the bag. The Department agrees with Virgin Atlantic's suggestion that those carriers need to work together. In situations where the carrier that collected the bag fee and the carrier operating the last flight segment are different entities, the Department is requiring that the last operating carrier, which is the carrier that accepts MBRs, to determine whether a bag was significantly delayed and if so, provide the baggage delay information to the collecting carrier without delay. The Department's Office of Aviation Consumer Protection will determine the timeliness of the information provided by the last operating carrier to the collecting carrier based on the totality of the circumstances, including the operating carrier's process and procedures for determining whether the checked bag is significantly delayed and whether the last operating carrier informed the collecting carrier of the refund eligibility soon after it determined the bag was significantly delayed. The collecting carrier remains responsible for providing the refund. Under this final rule, the 7/20-day refund timelines start at the time the collecting carrier receives information from the last operating carrier that the passenger's bag has been significantly delayed and the passenger has filed an MBR.

This final rule makes it an unfair practice for the last operating carrier to fail to timely determine if a bag has been significantly delayed and communicate that information to the collecting carrier. Airlines not providing such information in a timely manner pause the refund process and cause substantial harm to consumers by extending the timeline for consumers to receive the money to which they are entitled. This harm is not reasonably avoidable by consumers as they have no control over the airlines' actions. The Department also sees no benefits to consumers and competition from this conduct. Without this requirement, the money that is due to consumers could take however long an airline chooses, which in turn harms consumers and competition by penalizing good customer service and rewarding dilatory behavior. Regarding multiple-carrier itineraries for which a ticket agent collected the bag fee (*i.e.,* the ticket agent's name is in the consumer's financial statement), the Department is adopting the NPRM proposal to require the operating carrier for the last flight segment to refund the baggage fee to the passenger when a checked bag is significantly delayed. In these situations, neither the marketing nor the operating carrier may have the payment information because the ticket agent collected the fees, but the operating carrier for the last flight segment will have information about the status of the bag. By taking this approach in the final rule, the Department is recognizing that when no carrier has collected the baggage fee, requiring the last operating carrier to refund makes sense because the operating carrier is the one that accepts and handles the MBRs and has information about the status of the bag. In these situations, the operating carrier may decide to request that the consumer completing the MBR form identify the ticket agent that collected the bag fee and the consumer's payment information in case a refund of the baggage fee should be necessary. Also, based on comments from both ASTA and Travel Tech, it is the Department's understanding that these types of situations will be infrequent because ticket agents' involvement in collecting baggage fees is minimal.

With regard to RAA's comment that fee-for-service carriers do not transact with consumers and are unable to issue refunds, the Department's understanding of the industry practice is that the marketing carriers that contract and codeshare with fee-for-service carriers are usually the entities that handle most aspects of customer services for these flights, including accepting MBRs and compensating passengers for expenses that they may incur while their bags are delayed. Under this final rule, although a fee-for-service carrier operating the last flight segment is ultimately responsible for issuing refunds of baggage fees for ticket agent-transacted multi-carrier itineraries, it is permissible for the carrier to rely on other entities, such as their marketing codeshare partner, to process MBRs and issue refunds to consumers on its behalf.

5. Refund Mechanism and Passengers' Responsibility To Notify Carriers About Bag Delay

The NPRM: The Department proposed to require that airlines provide refunds for delayed bags within seven business days of a refund being due for credit cards and within 20 days of a refund being due for payments using cash, check, vouchers, frequent flyer miles, or other form of payment. Under the NPRM, for the refund process to start, passengers would need to notify the airline that collected the bag fee about the delay in receiving the bag. The Department proposed that, in situations in which the carrier accepting and handling an MBR from the passenger is the same carrier that collected the baggage fee, the filing of an MBR would constitute notification from the passenger to the carrier that the baggage was delayed for the purpose of receiving a checked baggage fee refund.

As proposed, if the carrier that received an MBR about a delayed bag and the carrier that charged the baggage fee are different entities, the Department proposed to require the passenger inform the carrier that collected the baggage fee of the lost or delayed bag. This would mean that the passenger would need to file an MBR with one carrier and then contact another carrier to state that his/her bag was lost or delayed. In situations in which a ticket agent collected the bag fee, the Department proposed that passengers would need to notify the carrier that operated the last flight segment about the delay in receiving the bag. The NPRM solicited comments on whether, instead of requiring passengers to notify the carrier that operated the last flight segment about the bag delays, the Department should require passengers to notify the carrier that marketed the last flight segment.

The NPRM proposed that baggage fee refunds would be issued in the same form of payment as the original baggage fee payment. Under this proposal, in addition to credit card, cash, and check

payments being refunded in their respective original forms of payment, baggage fees paid by airline credit/voucher or frequent flyer miles would be refunded in their original forms of payment as well.

Comments Received: Airlines were generally in support of requiring passengers to notify the last operating carrier and, if the last operating carrier is not the entity that collected the bag fee, also notify the entity (carrier or ticket agent) that collected the bag fee. They reasoned that notifying the last operating carrier is necessary to establish MBRs and provide the passenger's contact information, and that notifying the collecting entity is needed to more effectively determine liability among various entities. Contrary to this general position, COPA commented that notifying the last operating carrier alone is sufficient and the last operating carrier should be responsible for the refunds. Several airline commenters suggested that the Department should allow additional time (*e.g.,* 30 days) to issue refunds, especially when multiple parties are involved. A4A stated that the Department should allow carriers the maximum flexibility to provide refunds, with passengers' consent, in alternative electronic forms.

Although consumers and their advocacy groups did not specifically comment on this subject, ASTA disagreed with the Department's proposal that passengers should separately notify the collecting carrier if the last operating carrier is not the collecting carrier. ASTA commented that filing an MBR with the last operating carrier should be sufficient and requiring passengers to provide two notifications is unduly burdensome and may confuse passengers.

ASTA agreed with the proposed timelines to require the collecting carrier to issue refunds.

DOT Responses: After carefully considering the comments received, the Department has decided that in all situations, including when the carrier that received an MBR about a delayed bag and the carrier or ticket agent that collected the baggage fee are different entities, the filing of an MBR constitutes adequate notification from the passenger that the baggage was delayed for the purpose of receiving a checked baggage fee refund. The Department agrees with ASTA that requiring passengers to provide separate notifications to two entities to obtain a baggage fee refund is unduly burdensome and may confuse passengers. Further, 49 U.S.C. 41704 note requires carriers to provide ''prompt'' and ''automated'' baggage fee refund when the baggage delivery delay has exceeded the specified delivery deadline. In this final rule, the Department is defining an ''automated'' refund of the bag fee to mean a refund provided to a consumer for a checked bag that has been significantly delayed (*i.e.,* delayed 12 hours or more for domestic flights, delayed 15 hours or more for international flight that is 12 hours or less in duration, delayed 30 hours or more for an international flight that is more than 12 hours in duration) without action by the passenger beyond the filing of an MBR.

In situations where the carrier accepting and handling an MBR from the passenger is the same carrier that collected the baggage fee, it should be simple for the carrier to provide passengers automated refunds if the checked bag is significantly delayed because that carrier has the passenger's payment information and knows whether the checked bag has been significantly delayed. In situations where a carrier collected the baggage fee and a different carrier accepted the MBR, both carriers are expected to work together to ensure that a refund is issued promptly when due, with the carrier accepting the MBR timely notifying the collecting carrier of the baggage delay status and any other information collected from the passenger necessary for processing the refund, and the collecting carrier promptly issuing the automatic refund when it is notified that the delay has exceeded the deadline. As stated earlier, both carriers will be held responsible when a refund is not issued promptly. In situations where a ticket agent collected the bag fee, under this final rule, the carrier that operated the last flight segment is both the carrier accepting and handling an MBR and the carrier required to provide an automated refund. As the carrier accepting and handling the MBR, the carrier knows whether the consumer's checked bag has been significantly delayed entitling the consumer to a refund of the bag fee. While that carrier may not know the identity of the ticket agent that collected the bag fee or have the consumer's payment information should a refund be necessary, the carrier can obtain such information from the consumer as part of the MBR form that the consumer completes. The carrier may also choose to use the information that the consumer provided about the ticket agent that collected the bag fee to seek reimbursement.

In all the situations described above, the Department is requiring that the refund of the bag fee for a significantly delayed checked bag be prompt. The Department is defining a ''prompt'' refund of bag fees to mean a refund issued within 7 business days of the expiration of the baggage delivery deadline for tickets purchased with credit cards or 20 calendar days of the expiration of the baggage delivery deadline for tickets purchased with other payments, unless the consumer did not file an MBR before the expiration of the baggage delivery deadline, in which case the refund is due within 7 or 20 days of the date when the MBR was filed. The Department notes that its requirement for carriers to refund baggage fees within 7 business days for credit card purchases and 20 calendar days for purchases with other payments is consistent with the Department's existing refund regulation in 14 CFR 259.5 and 14 CFR part 374. The requirement in part 374, which implements Regulation Z's 7-day refund timeline for credit card payments applies to all airline transactions for which refunds are due, not just ticket refunds. The Department disagrees with airline commenters that investigations of refund eligibility involving multiple carriers warrant additional time beyond the 7- or 20-day timeframes. As stated in the NPRM, our understanding is that the vast majority of travel itineraries marketed to consumers in the United States are either itineraries involving only one carrier or itineraries involving fee-for-service codeshare operations for which the operating fee-for-service carrier works closely with the marketing carrier on baggage handling and resolving MBRs. For delayed baggage claims in those itineraries, investigations should be a straightforward process. In other cases, the Department expects that carriers engaging in marketing codeshare or interline arrangements will continue to improve inter-airline communication channels to increase the efficiency of information exchange relating to customer service, including delivering delayed bags to passengers as soon as possible and providing refunds for baggage fees when appropriate.

6. Other Issues

The NPRM: The NPRM raised a number of miscellaneous issues relating to refunding fees for significantly delayed bags and asked for public comments. These issues concern: (1) what types of bags are subject to the refund requirement, including whether fees for oversized/overweight bags should be exempt from refund requirement; (2) how to determine the amount of refund if a fee was charged for multiple bags under an escalated fee scale and one or some of multiple

checked bags are delayed, or if a passenger paid a fixed fee for a baggage fee subscription program that covers the passenger's checked bag fees for a specified period; (3) whether there are particular circumstances in which airlines should not be required to issue a refund for a significantly delayed bag; (4) whether a carrier can require waiver of fees and liability if a passenger voluntarily agrees to travel without the checked bag on the same flight; and (5) how the baggage fee refund requirement should apply when airlines arrange alternative transportation or when passengers choose not to travel on the scheduled or substituted flight.

With regard to the types of checked bags subject to the refund requirement, the Department noted that the statute requires the rule to cover ''checked baggage'' and the Department interpreted this to include not only bags checked with carriers at the ticket counters but also gate-checked bags and valet bags. The Department added that the statute makes no distinction or exception for special items that are transported as checked bags and interpreted the statute to also cover oversized and overweight bags.

As for the amount of baggage fee refund to be provided if a passenger paid a lump sum fee for multiple bags under an escalated fee scale and one or some of multiple checked bags are delayed, the Department indicated its intention to require a carrier to refund the highest baggage fee per bag if there is not a unique identifier for each checked bag that correlates to the fee. The Department stated that it would permit the specific fee paid for the significantly delayed bag to be refunded if a carrier can identify the specific fee paid for that delayed bag. For passengers who paid for a baggage fee subscription program, the Department stated that it would require airlines to provide refunds and solicited comment on how to determine the amount of refund to which these passengers should be entitled. The Department reasoned that a refund is appropriate because the subscribers are paying a fee to transport their bags even if it is not on a per bag basis.

Another issue that the Department examined in the NPRM is whether the mandate for baggage fee refunds should exempt certain situations. The Department provided examples of two instances in which a delay of a bag may be a result of passenger inaction. The first example was of a passenger who fails to comply with the requirement of U.S. Customs and Border Protection to pick up a checked bag at the first point of entry into the United States and recheck the bag, causing baggage delay. The second example was of a passenger who is traveling with two separate tickets and the passenger fails to collect the checked bag at the end of the first itinerary and check it with the carrier on the second itinerary. The Department also asked whether, instead of specifying particular circumstances in which airlines are not required to issue a refund for a lengthy delay in delivering the bag, a general exception for checked baggage delays that were a result of a passenger's negligence is preferable. The Department sought comment on what level of proof, if any, carriers should be required to provide to show that a bag delay was caused by the passenger's negligent action or inaction.

In addition, the Department analyzed and solicited comment on whether a carrier should be allowed to require a waiver of fee refunds for significantly delayed checked bags and a waiver of incidental expenses associated with the delay from a passenger who voluntarily agrees to be separated from his or her checked bags, usually due to late check-in or traveling as a standby passenger. The Department also asked whether it should require airlines to retain records of waivers for a specified time period if it were to allow such waivers. A related issue addressed in the NPRM was whether a baggage fee refund requirement should apply when passengers choose not to travel on the scheduled or substituted flight. In the NPRM, the Department noted that it has tentatively determined that when passengers *voluntarily* choose not to travel on the scheduled flight or a substitute flight offered by the carrier, either by taking ground transportation that the passengers arrange on their own, or by purchasing tickets on flights of another carrier, the baggage fee refund requirement should not apply. The Department stated, however, if it is the carrier that arranges the alternative transportation, the bag fee refund requirement would apply, and the baggage delay clock would start when the passenger arrives at his or her destination in the alternative transportation provided.

Lastly, the Department stated that baggage fees included in airfares, or baggage services provided as a complementary service due to frequent flyer status or credit card benefits should not be included in the refund requirement.

Comments Received: A4A and AAPA stated that the refund requirement should not cover oversized/overweight bags and other specialty checked bags such as pets. A4A asserted that transporting these bags involves additional special care and costs, higher injury risks to employees, and increased chance of delay due to weight and balance limits. Both commenters argued that requiring carriers to refund fees for these bags would disincentivize carriers from accepting them for transportation or cause carriers to increase the price for transporting these bags. IATA commented that it supports the proposal that airlines should assign a specific fee to each bag if using an escalated fee scale and the proposal that when no such assignment was made airlines should refund the highest fee per bag.

A4A commented that passenger negligence or failure to meet the conditions set forth by the carrier's contract of carriage that causes bags to be delayed should exempt carriers from the refund obligation. It specifically listed situations that it believes should qualify for exemptions, including when: passengers fail to pick up and recheck bags at the international entry points, passengers travel to ''hidden cities'' (*i.e.,* passengers book a through fare with intention to disembark mid-travel but the bags are checked all the way through to the final destination), passengers purchase two separate tickets and then fail to collect the bag and recheck with the second carrier, passengers do not meet the check-in and other contract of carriage requirements, or passengers pack prohibited items in bags. A4A also stated that the exemption should apply when passengers take an earlier flight as standby or arrange their own alternative transportation, in which case carriers should be allowed to request passengers sign a waiver. A4A further contended that third-party actions that cause the bag delay should also exempt carriers from refund liability and these situations include bags being mistakenly claimed by another passenger, bag delays due to government actions such as bags being held by customs or airport security, bag delays due to airport-operated system failure, negligence by third-party delivery services that is beyond carriers' control, or bag delays due to carriers' compliance with positive bag match requirements.

IATA, AAPA, Qatar Airways, and Spirit supported the proposal that carriers may request a waiver from passengers when passengers arrange their own alternative transportation or when passengers choose to voluntarily separate from their bags. IATA further supported the proposal that the refund requirement would apply when carriers arrange the alternative transportation but suggests that the clock should start at the time of MBR filing, as opposed to the arrival of the alternative transportation as proposed in the

NPRM. Spirit and Qatar Airways supported the proposal that carriers are not responsible for refunds when consumers arrange for alternative ground transportation or travel on anther carrier's flight.

On baggage subscription programs, A4A, IATA, and AAPA argued that baggage transportation services that are purchased as part of a baggage fee subscription service should not be subject to the refund requirement proposed in the NPRM. A4A argued that carriers should be exempted from the refund requirement because carriers cannot accurately calculate the cost of the bag transportation and the amount of refund due. It further argued that passengers purchasing the subscription program are receiving a bargain on baggage transportation and they understand the risk of not receiving a refund when a bag is delayed. A4A commented that not providing an exemption to the program will stifle innovation on dynamic pricing and comparison marketplaces.

A4A, IATA, and AAPA argued that baggage transportation services included as part of the fare or provided free of charge due to the passenger's frequent flyer status or because the passenger holds a branded credit card from the airline should not be subject to the refund requirement. Spirit, on the other hand, stated that carriers that do not separately charge a bag fee should be required to provide partial ticket refunds when bags are delayed because these carriers have incorporated the baggage fee into ticket prices.

Travelers United supported the proposal to treat oversized/overweight bags the same as regular checked bags for the purpose of baggage fee refunds. It also supported the rule covering gate-checked and valet bags to the extent that baggage fees are charged. Travelers United commented that if fees for all bags are paid in the same transaction, when one of the bags are delayed, carriers should refund the highest per bag fee. On carrier-arranged alternative transportation, Traveler United expressed its belief that passengers should be protected by the same rule regarding baggage fee refunds. It further emphasizes that when passengers waive their rights to baggage fee refunds, they are not waiving their rights to compensation related to lost or damaged baggage. One individual consumer expressed disagreement with airlines' suggestion that the rule should exempt oversized or overweight bags. The consumer commented that the suggestion introduces incentives for airlines to give these bags the lowest priority.

The Colorado AG suggested that instead of adopting a general category of ''passenger negligence'' that exempts carriers from the refund obligation, the Department should specify the particular circumstances in which carriers are exempted. The comment further contended that a vague concept of ''passenger negligence'' would likely post challenges to consumers, carriers, and the enforcement process, and it would also invite carriers to deny refunds more readily and place consumers in a challenging position. The comment recommended that the structure of the rule place the burden on the airline to establish any exception.

DOT Responses: After careful consideration of the comments, the Department is: (1) defining checked bags subject to the refund requirement to include gate-checked bags, valet bags, checked bags that exceed carriers' normal allowance, oversized/overweight checked bags, and specialty checked bags such as sporting equipment and pets; (2) requiring the highest amount per bag fee on an escalated fee scale be refunded if one or some of multiple checked bags are significantly delayed without a unique identifier for each checked bag that correlates to the fee; and (3) requiring the lowest amount of baggage fee the carrier charges another passenger of similar status without the subscription be refunded to a passenger who paid a fixed price for a baggage fee subscription program and a checked bag is significantly delayed. The Department is also exempting from the requirement to refund a fee for significantly delayed checked bag instances where the delay is a result of: (1) passengers failing to comply with the requirement of U.S. Customs and Border Protection to pick up a checked bag at the first point of entry into the United States and recheck the bag; (2) passengers agreeing to travel without their checked bag on the same flight because they checked in late for the flight or are flying as stand-by passengers; (3) a third-party delivery service that is not a contactor or an agent of the carrier and, instead, is contracting directly with the passenger failing to deliver the bag promptly; and (4) passengers not being present to pick up a bag that arrived on time at the passenger's ticketed final destination.

(i) Types of Bags Covered by the Refund Requirement

The requirement adopted in this final rule for airlines to refund baggage fees when airlines significantly delay delivery of checked bags does not distinguish between different types of checked bags. The Department is defining checked bags to include gate-checked bags, valet bags, checked bags that exceed carriers' normal allowances, oversized/overweight checked bags, and specialty checked bags such as sporting equipment and pets. This interpretation is consistent with the language of section 41704 note, which refers only to ''checked baggage'' and does not distinguish between different types of checked bags.

The Department acknowledges the need for special handling for oversized or overweight bags but notes that carriers are not required to accept these bags for transportation and those carriers that do generally charge a higher fee. The Department is not persuaded by the airlines' argument that including oversized/overweight bags in the refund requirement will disincentivize carriers from accepting these bags. We view competition the main incentive for carriers to continue to accept these bags for transportation, with the prices of baggage fees determined by the free market, based on consumer demands, carriers' costs and risk, and the likelihood of timely delivery.

(ii) Amount of Refund When Multiple Checked Bags Are Transported Under Escalated Fee Scale or Passenger Paid for Baggage Subscription Programs

Having received no objections in the comments, we are adopting the proposal that when one of the multiple bags checked by a passenger was significantly delayed by a carrier that adopts an escalated baggage fee scale, and there is no specific fee assigned to the delayed bag, the highest per bag fee should be refunded.

Regarding what the amount of the refund should be if a passenger paid for a checked bag through a baggage subscription program and the checked bag is significantly delayed, the Department is requiring that airlines refund the passenger the amount that is equal to the lowest amount the carrier charges another passenger of similar frequent flyer status without the subscription. The Department is not convinced by airlines' argument that delayed bags paid through a baggage subscription program should be exempted from the refund requirement. In support of this argument, airlines comment that passengers purchasing the subscription are receiving a bargain on baggage transportation and they understand the risk of not receiving a refund when a bag is delayed. We disagree. Although passengers choosing to purchase the subscription program receive a discount on the total cost of baggage transportation over the subscription period based on their

anticipated travel frequencies, they still paid a fee to airlines to transport their checked bags. The Department believes that these passengers should receive a refund if the bag delay exceeds the applicable timeline. Because it is difficult and impractical to determine the amount of refund due based on the actual per bag fee charged for the delayed bag, the Department is requiring a refund in the amount that is equal to the lowest amount the carrier charges another passenger of similar frequent flyer status without the subscription.

(iii) Exemptions From the Refund Requirement

The Department generally agrees with commenters that when passengers' own negligence is the cause of baggage delivery delay, carriers should be exempted from the refund requirement. The Department also shares the Colorado Attorney General's concerns that adopting a general category of ''passenger negligence'' that exempts carriers from the refund obligation may pose challenges to both consumers and carriers. As a result, the Department specifies in this final rule the particular circumstances in which carriers are exempted.

In the NPRM, the Department described situations where the baggage delivery delay was due to a passenger's failure to comply with the requirement of U.S. Customs and Border Protection to pick up a checked bag at the first point of entry into the United States and recheck the bag and a passenger failure to pick up the bag at the transition point and recheck the bag with the second carrier when traveling with two separate tickets.[68] Many other situations were also cited by the airline commenters as potentially qualifying for exemptions because the passengers' own action of negligence caused the baggage delivery delay. Of the various examples suggested by commenters as potentially qualifying for an exemption, the Department agrees that situations where passengers fail to pick up and recheck bags at international entry points into the United States qualify for an exemption from the refund bag fee requirement. The Department is also persuaded that an exemption is appropriate when passengers are not present to pick up a bag that arrived on time at the passenger's ticketed final destination whether that is because the passenger traveled to a ''hidden city,'' the passenger failed to pick up the bag before taking a flight on a separate ticket, or any other reason that is due to the fault of the passenger if documented by the carrier.

For different reasons, the Department has concluded that the other situations described do not qualify for an exemption. For example, carriers suggest that the Department should exempt carriers from the refund obligation when the baggage delay was because passengers packed prohibited items in their checked bags. However, based on the Department's understanding of the procedures of the Transportation Security Administration (TSA), in the vast majority of these cases, the prohibited items would be removed from the bags during the screening process, and the bags would be allowed to continue their travel. Based on this understanding, the Department does not believe it is appropriate to categorically exempt bags that are temporarily held by TSA due to prohibited items being found in the bags. In addition, a bag is not late when passengers purchase two separate tickets and fail to collect the bag and recheck the bag with the second carrier. The second carrier could not transport the bag on the same flight as the passenger when the bag was never checked by the passenger, and the first carrier is exempted for the delay because the passenger failed to pick up the bag that arrived on time at the passenger's ticketed final destination. Similarly, a bag is not late when a third-party that contracted directly with the passenger picks it up from the carrier before 12 hours for domestic flights, 15 hours for international flights of 12 hours or less in duration, and 30 hours for international flights of over 12 hours in duration. If the third-party then caused a delay in the bag reaching the passenger, the carrier does not owe a refund of the bag fee to the passenger.

As for the comment that the Department should exempt carriers from refund liability when the baggage delay was a result of third-party actions, the Department is of the view that an exemption is not appropriate when the third-party actions took place while the bag was in the custody of the airline before it has been delivered to the passenger. Airlines in their comments suggest that the Department should exempt a list of situations in which actions by a third-party cause the baggage deliver delay. The Department's view is that a third-party's action that directly causes significant bag delivery delays while the bag is under a carrier's custody should not be exempted from the requirement to refund the bag fee. Consistent with the Department's policy for reporting mishandled baggage by U.S. carriers, a bag is in the custody of a carrier beginning at the point in time which the passenger hands the bag to the carrier's representative or agent, or leaves the bag at a location as instructed by the carrier; a carrier's custody ends when the passenger, a party acting on the passenger's behalf, or another carrier takes possession of the bag.[69] Bag delays due to third-party actions (*e.g.,* security authority or Customs holding bags, airport baggage processing system failure, or recovery bag delays due to carriers' compliance with the positive passenger-bag match requirement) are not permissible grounds for exempting the carriers from the baggage fee refund obligation because the affected bags are under carriers' custody. Also, bag delays caused by another passenger picking up the bag by mistake before the passenger or a party acting on the passenger's behalf takes physical possession of the bag is not exempted because the passenger provided his or her bag to the carrier and the bag was not available to be picked up by that passenger at the passenger's final destination.[70]

Consistent with this approach, the Department considers baggage delays caused by a third-party delivery service to be a ground to exempt the carrier from refunding baggage fees only if the third-party is not a contactor or an agent of the carrier and, instead, is contracting directly with the passenger. For example, if a passenger arranges a third-party delivery service to pick up the bag at the passenger's final destination airport and transport it to a location designated by the passenger, the airline is exempted from refunding baggage fees if the baggage delivery is delayed by that third-party, who took possession of the bag from the carrier on behalf of the passenger.

(iv) Waiver of Fee Refunds and Incidental Expenses for Voluntary Separation

The Department is exempting airlines from the refund obligation when passengers voluntarily agree to travel without their checked bags on the same flight as a way to make the flight when they checked in late for the flight or are flying as stand-by passengers. We agree with commenters that carriers offering passengers different travel options that meet their needs, including the option of traveling without their bags on the same flight, benefits consumers. In those situations where carriers are willing to accommodate passengers but may not have adequate time to load the

[68] 86 FR 38423 (July 21, 2021).

[69] See, *Technical Reporting Directive #30A—Mishandled Baggage and Wheelchairs and Scooters (Amended),* Dec. 21, 2018.

[70] *Id.*

passengers' bags onto the same flights, we believe it is fair to exempt carriers from the baggage fee refund obligation provided that carriers clearly disclose to the passenger that the checked bag may not arrive promptly. In those circumstances, carriers are permitted to require passengers sign a document waiving their right to a refund of the baggage fees if the bag delivery is delayed beyond the regulatory timelines. The waiver that carriers seek from passengers in these situations must be limited to passengers relinquishing their right to refund of bag fees if delayed beyond the regulatory timelines. The waiver should also include an estimated delivery time and a delivery location that the carrier and the passenger agreed upon. The waiver must not include language suggesting that the passengers are relinquishing their right to refund of bag fees if the bag is lost, their right to compensation for damaged, lost, or pilfered bags, or their right to incidental expenses arising from delayed bags beyond the agreed upon delivery date/time consistent with the Department's regulation in 14 CFR part 254 and applicable international treaties.

(v) Alternative Transportation

The Department has considered the comments regarding whether the baggage fee refund requirements should apply to significantly delayed bags when passengers arrange for alternative transportation. Passengers choosing to arrange their own alternative transportation even after already having handed over their checked bags to carriers' custody often do so because their flight has been canceled or significantly delayed. As explained later in this document, if a flight is canceled or significantly changed and the passenger chooses not to fly with the carrier, the passenger is entitled to receive a refund of the ancillary service fee, including baggage fee, for a service that they paid for and did not receive. Unless the carrier delivers the checked bag to the passenger at an agreed-upon location, the checked bag fee must be refunded.

The Department is also not persuaded that it should exempt from the requirement to refund fees for significantly delayed bags when the carrier arranges alternative air travel for its passengers because of a flight cancellation or significant change by the carrier. The requirement to refund fees for significantly delayed bags still applies when the alternative transportation that the carrier arranges is a later flight operated by that carrier or a flight by another carrier. In those situations, the start of the delay when measuring the length of the delay for a carrier to deliver a checked bag is when the passenger arrives at his or her destination on the alternative air transportation, consistent with the Department's position on start of the baggage delay when passengers fly on their original scheduled flight. Because the statute applies to delays in transporting bags on flights and not on ground transportation, however, this rule requiring carriers to refund fees for significantly delayed bags does not apply to the alternative ground transportation.

As a final matter, the Department is providing clarification that the refund requirement of 49 U.S.C. 41704 note covers ''any *ancillary fees* paid by the passenger for checked baggage'' (emphasis added). It is irrelevant whether the consumer uses a credit card, frequent flyer miles/points, travel vouchers, or something else to pay the fee for the checked bag. An ancillary fee is a fee for an optional service that is not included as part of the fare and includes baggage fees charged separately from the ticket price. To the extent that there was no separate bag fee paid by any form of payment (*e.g.,* credit card, airline miles) because the transport of baggage was included as part of the fare or the baggage fee was waived due to the passenger's airline loyalty program status or as a benefit of using an airline-associated credit card, carriers are not required to provide a refund as the passenger did not pay an ''ancillary fee'' for the checked bag.

III. Refunding Ancillary Service Fees for Services Not Provided

1. Covered Entities and Flights

The NPRM: The Department proposed to mandate U.S. and foreign air carriers provide refunds to consumers of the fees a passenger pays for an ancillary service related to air travel on a flight to, from, or within the United States that the passenger does not receive, including retaining the existing regulatory requirement for such refunds due to oversales and flight cancellations [71] and other situations when the ancillary service is not available to the passenger. The Department is required by 49 U.S.C. 42301 note prec. to cover U.S. and foreign air carriers that offer ancillary services for a fee on their domestic and international flights.[72] With respect to ticket agents, similar to the requirement on refunding baggage fees for significantly delayed bags, although the Department is not required by statute to cover them, the NPRM stated that the Department has independent authority under 49 U.S.C. 41712, which prohibits ticket agents from engaging in unfair or deceptive practices in air transportation, to include them in the regulation if deemed appropriate. As such, in the NPRM, the Department sought a general overview of ticket agents' role in the transaction and collection ancillary service fees and the process of how fees collected by ticket agents are transferred to carriers. The NPRM stated that this information would assist the Department in determining whether its regulation on ancillary fee refund should address ticket agents' role and the role of other non-carrier entities involved in the sale of ancillary fees.

Comments Received: The Department received no comments regarding the scope of covered flights and covered carriers. With respect to ticket agents, IATA indicated that the entity that collected the ancillary fee should be responsible for the refund. Spirit also supported a requirement for ticket agents to issue refunds if they collected the fees. Ticket agent representatives' position on whether they should be required to refund ancillary service fees when the services are not provided is similar to their view on refunding baggage fees for significantly delayed bags, which was summarized in that section. In short, ticket agent representatives believe that based on the statutory language of 49 U.S.C. 42301 note prec., which referred only to air carriers, the infrequency of ticket agent-transacted ancillary fees, and the role of ticket agents in those transactions (*i.e.,* acting as the agents of airlines), ticket agents should not be required to refund ancillary service fees.

DOT Responses: The Department is requiring U.S. and foreign carriers that operate scheduled passenger service to, within, and from the U.S. to provide a refund to passengers of fees charged for an ancillary service that is paid for but

[71] 14 CFR 259.5(b)(5) requires carriers to provide prompt refunds where due, including refunding fees charged to a passenger for optional services that the passenger was unable to use due to an oversale situation or flight cancellation.

[72] Section 421 of the FAA Reauthorization Act of 2018 (2018 FAA Act), which was codified under 49 U.S.C. 42301 note prec., directs the Department to promulgate regulations requiring ''each covered air carrier'' to provide refunds of ancillary service fees that a passenger paid for but did not receive. Section 401 of the 2018 FAA Act defines ''covered air carrier,'' as used in Section 421, to mean means an air carrier or a foreign air carrier as those terms are defined in section 40102 of title 49, United States Code. *https://www.congress.gov/bill/115th-congress/house-bill/302/text?q=%7B%22search%22%3A%5B%22FAA+Reauthorization%22%5D%7D.*

not provided. The Department is applying this requirement to carriers regardless of the aircraft size that the carriers operate. With regard to ticket agents, the Department is not adopting in this final rule a specific requirement for ticket agents to provide refunds of ancillary service fees even if ticket agents collect the fees. The Department believes that whether an ancillary service paid by a consumer was provided by an airline is a factual matter better handled directly by the airline through direct communication with passengers. The Department views that placing responsibility to provide such refunds on ticket agents may further complicate the matter and cause unnecessary delays for consumers to receive a refund. Further, 49 U.S.C. 42301 note prec. directs the Department to promulgate regulations requiring ''covered air carriers'' to provide refunds for ancillary service fees. For these reasons, in this final rule, the Department is placing the responsibility to provide refunds of ancillary service fees for services not provided on carriers rather than ticket agents. The Department will continue to monitor the transactions of ancillary service fees conducted by ticket agents and may revisit the issue in the future should it become necessary.

2. Need for Rulemaking

The NPRM: The Department proposed to require refunds of ancillary service fees for services paid for but not provided to implement a statutory provision of the FAA Reauthorization Act of 2018 (49 U.S.C. 42301 note prec.), and to codify the Department's longstanding enforcement practice of viewing any airline practice of not refunding fees for ancillary services that passengers paid for but are not provided as an unfair or deceptive practice in violation of 49 U.S.C. 41712. The statutory provision in 49 U.S.C. 42301 note prec., requires the Department to promulgate a rule that mandates that airlines promptly provide a refund to a passenger of any ancillary fees paid for services related to air travel that the passenger does not receive, including on the passenger's scheduled flight, on a subsequent replacement itinerary if there has been a rescheduling, or for a flight not taken by the passenger. Currently, the Department's regulation in 14 CFR part 259.5(b)(5) explicitly requires that airlines refund fees charged to a passenger for optional services that the passenger was unable to use due to an oversale situation or flight cancellation. Under the statutory authority of 49 U.S.C. 41712, which authorizes the Department to investigate and, if necessary, take action to address unfair or deceptive practices or unfair methods of competition by air carriers, foreign air carriers, or ticket agents, the Department has a longstanding enforcement policy that considers any airline practice of not refunding fees for ancillary services that passengers paid for but are not provided to be an unfair or deceptive practice in violation of 49 U.S.C. 41712, which goes beyond the situations related to oversales or flight cancellations. In the NPRM, DOT proposed to retain the existing regulatory requirement regarding ancillary fee refunds arising from flight oversales or cancellations, and to further clarify that the refund requirement would apply to any other situation in which an airline fails to provide passengers the ancillary services that passengers have paid for (*e.g.,* passengers paid for using the in-flight entertainment (IFE) system on a scheduled flight but the IFE system was broken and could not be used by the passengers). DOT stated that the inclusion of regulatory text requiring that airlines must refund ancillary fees for services related to air travel that passengers did not receive, as provided in 49 U.S.C. 42301 note prec., would not impose additional requirements on airlines as airlines are already providing refunds of ancillary fees when they fail to provide services that passengers paid for, consistent with the Department's interpretation of section 41712.

Comments Received: Virtually all consumers and consumer rights advocacy groups who submitted comments expressed their general support for this rulemaking. The majority of airlines and airline trade associations that commented on the NPRM also supported the Department's rulemaking to implement the Congressional mandate. Among airline commenters, however, AAPA argued that it is not necessary to promulgate a new rule because airlines generally are already providing refunds for services not rendered on their initiative. AAPA also noted that mandating prescriptive rules such as compulsory refunds for ancillary services would stifle innovation and restrict consumers' freedom of choice as it limits airlines' ability to offer other methods of compensation, such as vouchers or airline miles, which could be more attractive to the customer. Qatar Airways commented that it already offers refunds of ancillary service fees when there is a flight cancellation. Qatar also states that the majority of ancillary products are transferred to the new itinerary when a schedule change has occurred.

DOT Responses: The Department has concluded that the promulgation of this regulation not only fulfills a statutory mandate, but also is necessary to provide consistency and clarity to the regulated industry. Although many airlines are already providing refunds of fees for various ancillary services that they did not provide, this final rule defines the scope of ancillary services that are subject to this refund requirement and ensures that all carriers comply with the mandatory requirements following a unified standard with respect to the method and timeliness of refunds. The Department rejects AAPA's argument that having a compulsory refunds requirement would stifle innovation as under the mandatory refund requirement, airlines continue to have the option to offer other compensation such as vouchers or airline miles to consumers who did not receive the ancillary services they paid for, as long as carriers clearly inform consumers that they are entitled to a refund for the fees at the same time or before offering vouchers or other non-cash compensation.

3. Definition of Ancillary Services

The NPRM: The provision in 49 U.S.C. 42301 note prec. requires that airlines refund ancillary fees paid for services ''related to air travel.'' As stated in the NPRM, the Department has not defined ''ancillary services'' in its aviation economic regulations and proposes to adopt a definition that is substantially identical to the definition for ''optional services'' in 14 CFR 399.85(d) [73] which requires U.S. and foreign air carriers to prominently disclose on their websites marketing air transportation to U.S. consumers information on fees for all optional services available to a passenger purchasing air transportation. Specifically, DOT proposed to define ''ancillary service'' to mean any service related to air travel provided by a covered carrier, for a fee, beyond passenger air transportation. DOT specified that such service includes, but is not limited to, checked or carry-on baggage, advance seat selection, access to in-flight entertainment system, in-flight beverages, snacks and meals, pillows and blankets and seat upgrades. DOT noted that the definition in section

[73] ''Optional services'' is defined as any service the airline provides, for a fee, beyond passenger air transportation. Such fees include, but are not limited to, charges for checked or carry-on baggage, advance seat selection, inflight beverages, snacks and meals, pillows and blankets and seat upgrades. 14 CFR 399.85(d).

399.85(d) does not include fees charged for services to be provided by entities other than airlines, such as hotel accommodations or rental cars, which are commonly offered by some airlines as a package during the airfare reservation process. DOT sought comments on whether adopting a definition for ''ancillary service'' that is similar to the definition of ''optional service'' in section 399.85(d) is appropriate in the context of ancillary service fee refunds.

Comments Received: Airline and consumer commenters supported the proposed definition for ''ancillary service.'' Spirit stated that it supports the Department's efforts to harmonize the definition of ''ancillary services'' with that of ''optional services.'' AAPA commented that an alignment of definitions is crucial to avoid confusion for all stakeholders concerned, including passengers, airlines, and service providers. A4A noted that Department should clarify, in the definition, that ancillary service fees are not costs included in a fare or as a prerequisite; and that ''ancillary services'' do not include services provided pursuant to an agreement directly between the passenger and a third-party service provider. Among consumer commenters, Travelers United expressed its support for the Department's proposed definition of ''ancillary services.''

Panasonic Avionics, a manufacturer of in-flight entertainment (''IFE'') and in-flight connectivity (''IFC'') systems and a service provider, commented that the proposed refund requirement should apply only to covered carriers when they enter into a contract directly with a passenger for the provision of an ancillary service and process that passengers' payment for that ancillary service. It further stated that the rule should not be construed to obligate covered carriers to issue refunds when a passenger has contracted with a third-party service provider for an ancillary service and made payment to that third-party provider because in that case, the passengers' right to a refund will be governed by the terms and conditions of sale between the third-party provider and the passenger, with the third-party provider being governed by the consumer protection regulations of its applicable industry. Panasonic suggested that the Department's final rule should clarify in the applicability section that the regulation ''is not intended to address services provided by third-party service providers that entered into a service contract and/or terms and conditions directly with the passenger.'' Panasonic also suggested that the definition of ''ancillary service'' should clarify that it does not include services provided by third-party service providers that entered into a service contract directly with the passenger.

The Department also received a comment from the Colorado Attorney General, who, among other things, recommended that the Department's final rule ensure that consumers paying additional fees for add-on services truly receive items of tangible value.

DOT Response: With minor modifications, the Department is adopting the NPRM's proposed scope and definition for ''ancillary services'' in this final rule. The Department has considered A4A's comment that ancillary services subject to the refund requirement should not include services the costs of which are included in the airfare. We agree and have modified the definition of ancillary service by adding the word ''optional'' to reflect that the ancillary services covered under this rule are services that consumers can purchase at their discretion, and they do not include services mandatorily included in airfares or complimentary services provided to passengers without a separate fee.[74]

The Department has also considered Panasonic's and A4A's comments regarding the need to expressly clarify that ''ancillary services'' in this rule do not include services provided pursuant to an agreement directly between the passenger and a third-party service provider. The Department's authority to prohibit unfair or deceptive practices under 49 U.S.C. 41712 is limited to practices by U.S. carriers, foreign air carriers, and ticket agents in air transportation or the sale of air transportation. Also, the Department's authority to mandate prompt refund to a passenger of any ancillary fees paid for services related to air travel that the passenger did not receive pursuant to 49 U.S.C. 42301 note prec. is limited to carriers. The Department does not have the authority to regulate the practices of other entities under these statutory provisions. Accordingly, while not adopting the suggested rule text amendments by Panasonic, we are clarifying that services provided to passengers in relation to air travel pursuant to a contract between passengers and an independent third-party provider that does not act as an agent or contractor of an airline are not covered by this refund requirement. The Department understands that some independent third-party service providers may rely on airlines to refer interested customers to them for service purchases. In circumstances where an airline facilitates the purchase of an ancillary service but is not a direct party in the service contract, the Department expects the airline to provide clear disclaimer regarding the nature of the service contract and inform consumers that they should communicate directly with the service providers for any issues related to the service.

4. Refund Eligibility and Promptness of the Refund

The NPRM: The provision at 49 U.S.C. 42301 note prec. requires covered carriers to refund ancillary service fees for services that ''a passenger does not receive, including on the passenger's scheduled flight, on a subsequent replacement itinerary if there has been a rescheduling, or for a flight not taken by the passenger.'' The Department interpreted the statute to mean that a passenger would be eligible for a refund if he or she did not receive the ancillary service paid for because (1) the service was not made available to the passenger on the flight he or she took (either the original flights or an alternative flight due to cancellation or schedule changes made by the airlines or due to an oversales situation); or (2) if the passenger did not take any flight due to the airline canceling the flight or making a significant change to the flight. The proposal was focused on whether a carrier failed to fulfill its obligation to provide the service, as opposed to whether the service was utilized by the passenger. If the service was available but a passenger did not use the service, the passenger would not be entitled to a refund. Also under this proposal, if the ancillary service is not available because a flight schedule change affirmatively made by the passenger or due to passenger action, carriers are not required to refund the service fee.

Regarding ''prompt'' refunds, the Department proposed to apply the same standards to ancillary service fees when refunds are due that is currently applicable to airline ticket refunds. In both situations, prompt refund would mean refunds within seven days for credit card transactions and 20 days for transactions involving cash, checks, vouchers, or frequent flyer miles after the entity responsible for issuing a

[74] For passengers who did not receive an ancillary service because of an airline cancellation or a significant change of flight itinerary and the cost of the ancillary service is included in the airfare as a mandatory charge, carriers are required to refund the entire amount of airfare (all government taxes and fees and all mandatory carrier-imposed fees). See 14 CFR 260.6(a). To the extent that the cost of the ancillary service is not included in the airfare, carriers are required to refund the fee when the ancillary service was not provided because of a flight cancellation or significant change. See 14 CFR 260.4(a).

refund receives a request for a refund and the documentation necessary for processing the refund.

Comments Received: Virtually all airlines and airline trade organizations that provided comments supported the Department's proposal that a passenger would be entitled to a refund of the ancillary service fee if the passenger did not receive the ancillary service. Several airlines commented that the Department's rule should expressly state that a refund would not be required when the service was available but was not used by the passenger, when the passenger voluntarily changes or cancels their flight, or when the passenger violates the check-in requirements, the contract of carriage, or related policies. Spirit requested clarification on how to determine whether a service ''was not provided'' and whether a partial provision of the service would entitle a passenger to a refund. A4A stated that a refund should not be required for issues relating to partial provision of a service or the quality of the purchased ancillary service, as it would be impossible for a carrier to determine when refunds would be due or the proper amount of the refund. IATA and AAPA expressed their support for applying the same ''promptness'' standards to refunding ancillary service fees when refunds are due that is currently applicable to refunds for tickets, fees for optional services that could not be used due to an oversale or flight cancellation, and fees for lost bags.

A joint comment by Business Travel Coalition and multiple other consumer rights advocacy groups [75] stated that the Department should require carriers to automatically provide refunds for ancillary services not provided without consumers needing to complain. The consumer advocacy groups further stated that carriers should be required to proactively track when ancillary services paid for by passengers are not provided and to issue refunds automatically. They also expressed concerns that any regulation requiring passengers to seek out refunds will result in fewer refunds than consumers are entitled to receive. Travelers United stated its support of the Department's proposal and opines that passengers must request any refund of ancillary fees. Travelers United further suggested that the Department establish a form that can be used to notify both the airline and DOT at the same time regarding any refund request for ancillary service not provided.

In relation to its comments regarding the exclusion of third-party provided services from the definition of ''ancillary services,'' Panasonic stated that in the context of satellite services it provides, the discussion around refund eligibility must be left to the terms and conditions established between the customer and the service provider, not the covered carrier. However, Panasonic suggested that covered carriers be required to post information related to contacting the third-party service providers' support centers on carriers' websites or other locations.

DOT Response: After carefully considering the comments received, the Department has determined that, under certain circumstances where consumers' rights to refunds of ancillary services is undisputed, it is not necessary for carriers to wait to receive consumers' refund requests to provide refunds. More specifically, carriers are required to automatically refund fees for ancillary services in instances where the service was not available for any passenger who paid for the service, such as unavailable Wi-Fi for the entire flight. It should not be necessary for the consumer to separately request a refund under these circumstances because the carrier knows that no one on that flight received the service.

The Department does not believe an ''automatic'' refund approach in the same way is workable if the ancillary service is only unavailable to an individual passenger or passengers (*e.g.,* seatback entertainment equipment malfunction). In these situations, the operating carrier of the flight on which the paid ancillary service was not provided will need to be informed of the issue so they can conduct an investigation and verify refund eligibility. In our view, the affected consumer notifying the operating carrier when a paid-for service is not received is the most direct and efficient way to initiate the refund process. Notifying the operating carrier about the service not being provided is implicitly a request for refund by a consumer. The Department believes that notifying the operating carriers about the service issue should not be a significant burden to consumers. Carriers should make information available on their website on the different avenues available to customers to report such problems. Further, to the extent the operating carrier and the carrier that collected the ancillary service fee (merchant of record) are different carriers, the Department is requiring the operating carrier to, without delay, verify the passenger's claim about the ancillary service not being provided and notify the collecting carrier if this is the case as described more fully in the next section, so that the collecting carrier can provide an automatic refund. The collecting carrier is responsible for providing the refund. However, if a ticket agent collected the ancillary service fee, then the operating carrier that failed to provide the ancillary service is responsible for providing the automatic refund.

Regarding comments on how to determine whether a service ''was not provided'' and whether a partial provision of the service would entitle a passenger to a refund, the Department interprets the provision of section 42301 note prec. requiring refunds of fees for services that ''the passenger does not receive'' to mean a carrier has failed to fulfill its obligation to provide the service as opposed to the quality of the purchased ancillary service not being up to the expectation of the passengers. The Department does consider partial service such as providing Wi-Fi service for only a portion of the flight when a consumer paid for Wi-Fi service to entitle a consumer to a refund.

The Department generally agrees with airlines' comments that a refund should not be required when the service was available but was not used by the passenger. The Department further recognizes that actions by consumers may directly result in the pre-paid ancillary services not being available to passengers and in these situations, carriers are not required to provide refunds for the ancillary service fees. The actions by passengers that exempt carriers from the obligation to refund fees for ancillary services that a passenger does not receive include the passenger taking another flight due to non-compliance with minimum check-in time requirement or passengers being denied boarding on a flight due to non-compliance with carriers' contracts of carriage or governmental requirements. The Department notes that passenger-initiated cancellations or changes permitted by the terms of the tickets should not be a ground for carriers to refuse refunds of ancillary service fees that the passengers do not receive. For example, if a passenger holds a flexible ticket that allows the passenger to change flights without charge and the passenger changes to a new flight where the ancillary service that the passenger has paid for is not available, the passenger is entitled to a refund of the fee for that ancillary service.

With respect to Panasonic's comments on how to determine whether a refund

[75] Consumer Action, Consumer Federation of America, Consumer Reports, Edontravel.Com, Flyersrights.Org, National Consumers League, Travel Fairness Now, and U.S. PIRG.

is due for services provided by an independent third-party provider, as stated in the previous section, passengers not receiving a service they purchased directly from a third-party provider are not eligible to receive a refund under this rule as this rule applies to carriers and ticket agents. The passengers' refund eligibility will be governed by the terms and conditions of the service contract with the third-party provider and subject to applicable consumer protection laws. As suggested by Panasonic, the Department encourages carriers to provide consumers information on how to contact these third-party entities. The Department also reminds carriers that when promoting or facilitating the purchase of ancillary services or products provided by third-party entities, carriers may not provide information that is misleading to consumers as to which entity is responsible for providing the service or issuing refunds to dissatisfied consumers.

On the timeliness of refunds, the Department is adopting the same ''promptness'' standards for refunding ancillary service fees as proposed. A ''prompt'' refund of ancillary service fees means a refund issued within 7 business days for credit card payments or within 20 calendar days for non-credit card payments. For automatic refunds, the 7/20-day clock starts when a consumer's right to a refund of an ancillary service fee is clear. For circumstances where an ''automatic'' refund approach is not applicable, the 7/20-day clock starts when the passenger has notified the operating carrier about the unavailability of the service. The Department notes that adopting the 7- and 20-day refund timelines across the board on various refund issues provides consistency to consumers, carriers, and other stakeholder and streamlines carriers' customer service procedures, complaint resolutions, and training.

5. Entity Responsible for Refund

The NPRM: The Department recognized that for codeshare or interline itineraries or ticket agent-involved ancillary service fee transactions, the entity that collected the ancillary fee may not necessarily be the entity that is responsible for providing the ancillary service. Similar to the multiple-carrier scenario for refunding baggage fees for significantly delayed bags, the Department proposed to hold the carrier that collected the ancillary service fee responsible for issuing a refund when the ancillary service was not provided. When a ticket agent collected the ancillary service fee, the Department noted its understanding that the fee collected by a ticket agent is passed on to the carrier whose ticket stock is used for issuing the ticket and proposed to hold that carrier responsible for issuing the refund. The Department further noted that 49 U.S.C. 42301 note prec. requires airlines to refund ancillary fees paid for services related to air travel. For multiple-carrier itineraries for which a ticket agent collected the fee, the Department proposed that the last operating carrier issue the refunds, similar to the proposal for refunding baggage fees for delayed bags. The Department sought general information on ticket agents' role in the transaction and collection of ancillary service fees.

Comments Received: Comments on ticket agents' responsibility to refund were largely focused on refunding baggage fees for delayed bags. However, most comments also mentioned that their positions on ticket agents' responsibility to refund baggage fees should also apply to refunding ancillary fees for services not provided. In summary, airline commenters believed that ticket agents should be responsible for refunding ancillary service fees if they collected the fees, especially for multiple-carrier itineraries. One consumer rights advocacy group argued that airlines should ultimately be responsible for refunds, while two ticket agent representatives argued that airlines should be responsible. Details of these comments are provided in the comment summary section for refunding baggage fees for significantly delayed bags.

DOT Response: For multiple-carrier itineraries where one of the carriers collected the ancillary service fees, the Department is adopting the same approach as for refunding fees for delayed bags to require the carrier that collected the ancillary service fees (*i.e.,* merchant of record) to provide refunds when the services were not provided, regardless of whether the ancillary service at issue was not provided on a flight operated by the collecting carrier. In the Department's view, this approach is the most straightforward way to initiate and process a refund request from consumers' perspectives. The Department believes that the collecting carriers are in the best position to process and issue refunds as they have direct visibility of the passengers' selected ancillary services, the total amounts consumers were charged, and consumers' payment information. As noted in the prior section, automatic refunds are not required when the ancillary service is only unavailable to an individual passenger or passengers and under these circumstances passengers would need to notify the operating carrier that an ancillary service that they paid for was not available to them (*e.g.,* seat upgrade was not provided or seatback entertainment equipment malfunction), so carriers can conduct an investigation to verify refund eligibility.

In situations where the carrier that collected the ancillary service fee and the carrier(s) operating the flights are different entities, the Department is requiring the carrier(s) that failed to provide the passenger the ancillary service that the passenger paid for to provide that information to the collecting carrier without delay. Should the carrier that failed to provide the ancillary service not know which entity collected the ancillary service fee from the passenger, it can obtain that information from the passenger. The Department's Office of Aviation Consumer Protection will determine the timeliness of the information provided to the collecting carrier based on the totality of the circumstances, including how soon after becoming aware of the lack of service to the passenger did the carrier that failed to provide the ancillary service notify the collecting carrier.

The collecting carrier remains responsible for providing the refund. For example, a passenger purchased an itinerary that has two flight segments, with the first segment operated by Carrier A, and the second segment operated by Carrier B. Carrier A collected the ancillary service fee (merchant of record) for a seat upgrade on the second flight segment but the service was not provided. As this ancillary service was unavailable only to this passenger, automatic refund is not required. To obtain a refund, the passenger must inform Carrier B that the paid for seat upgrade was not provided on the second segment. Carrier A will be responsible for issuing the refund because it is the collecting carrier, and Carrier B is responsible for informing Carrier A that the paid for seat upgrade was not provided. The 7/20-day refund timeline starts for Carrier A at the time that it receives information from Carrier B that the paid for ancillary service was not provided.

For the same reasons articulated in the section on refunding baggage fees for significantly delayed bags, in cases where ancillary service fees are collected by a ticket agent for a single-carrier itinerary, the Department will hold that carrier responsible for issuing the refund. The Department notes that ticket agent representatives stated in

their comments that when ticket agents collect ancillary service fees including baggage fees, they do so primarily with the authorizations of airlines and act as airlines' agents. Airline commenters did not dispute this assertion. This approach is also consistent with 49 U.S.C. 42301 note prec., which requires ''each covered carrier'' to refund ancillary fees paid for services that are not provided. Ticket agents are encouraged to establish effective communication channels with airlines that authorize them to transact ancillary service fees and facilitate the refunds by providing necessary information to airlines.

Furthermore, when a ticket agent collects ancillary service fees for multiple-carrier itineraries, the Department is requiring the operating carrier of the flight on which the paid ancillary service was not provided to issue the refund. To the extent that the carrier that failed to provide the ancillary service does not know whether the entity that collected the ancillary service fee from the passenger is a ticket agent or a carrier, that information can be obtained from the consumer. The Department believes that when no carrier is the merchant of record, the operating carrier that failed to provide the service is in the best position to issue refunds to the affected consumers. That carrier would know if a service was not provided on the entire flight that it operated or if specific passengers on that flight did not receive the service. Because the operating carrier that failed to provide the service is the entity that knows or can verify whether the passenger received the ancillary service that the passenger paid for when the service was to be provided on its own flight, that carrier is the responsible party for providing a prompt refund when due. The Department notes that, to the extent that the carrier that failed to provide the ancillary service does not know whether the entity that collected the ancillary service fee from the passenger is a ticket agent or a carrier, that information can be obtained from the consumer. Although the operating carrier that failed to provide the passenger that ancillary service remains responsible for providing the refund when a ticket agent collected the fee, a fee-for-service carrier that fails to provide the ancillary service may choose to rely on other entities, such as their marketing codeshare partner, to issue refunds to consumers on its behalf. The Department expects the parties to work together and develop effective communication to ensure that information necessary to process passengers' refunds is transmitted in an accurate and efficient manner.

This final rule makes it an unfair practice for carriers that did not provide the paid for ancillary service to fail to timely inform the collecting carrier or, if a ticket agent collected the fee, the last operating carrier, that the service was not provided. The failure to provide in a timely manner information about ancillary services that have been paid for but not provided pauses the refund process and causes substantial harm to consumers by extending the timeline under which they are expected to receive the money they are entitled to. This harm is not reasonably avoidable by consumers as they have no control over how quickly this information is relayed which is what starts the refund process. The Department also sees no benefits to consumers and competition from this conduct. Without this requirement, money that is owed to consumers may be kept by others indefinitely, which in turn harms consumers and competition by penalizing good customer service and rewarding dilatory behavior.

IV. Providing Travel Vouchers or Credits to Passengers Due to Concerns Related to a Serious Communicable Disease

1. Statutory Authorities

The NPRM: The Department proposed this rulemaking pursuant to the authority set forth in 49 U.S.C. 41712 to take action to address unfair or deceptive practices or unfair methods of competition by air carriers, foreign air carriers, or ticket agents. The Department also relied on its authority in 49 U.S.C. 41702 to require air carriers to provide safe and adequate service in interstate air transportation. The Department noted that 49 U.S.C. 40101(a) directs the Department in carrying out aviation economic programs, including issuing regulations under 49 U.S.C. 41702 and 41712, to consider certain enumerated factors as being in the public interest and consistent with public convenience and necessity. These factors include ''the availability of a variety of adequate, economic, efficient, and low-priced services without unreasonable discrimination or unfair or deceptive practices'' and ''preventing unfair, deceptive, predatory, or anticompetitive practices in air transportation,'' as well as ''assigning and maintaining safety as the highest priority in air commerce.'' In issuing the NPRM, the Department also discussed the Airline Deregulation Act of 1978 (ADA) and noted that the ADA liberalized airlines' ability to freely price air travel products based on, among other things, consumer demand, and how airlines today offer a ''non-refundable'' ticket booking class that restricts passengers' ability to change or cancel the reserved flights in exchange for a lower price than tickets with more flexibilities for consumers.

Regarding the authority under 49 U.S.C. 41712, the Department stated its tentative position that it is an ''unfair practice'' [76] by an airline or a ticket agent to not provide non-expiring travel credits or vouchers to consumers who are restricted or prohibited from traveling by a governmental entity due to a serious communicable disease (*e.g.,* as a result of a stay at home order, entry restriction, or border closure) or are advised by a medical professional or determine consistent with public health guidance (*e.g.,* CDC guidance) not to travel to protect themselves or others from a serious communicable disease. The Department articulated that consumers are substantially harmed when they pay money for a service that they are unable to use because they were directed or advised by governmental entities or medical professionals or determine consistent with public health guidance not to travel to protect themselves or others from a serious communicable disease, and the airline or ticket agent does not provide a non-expiring credit or voucher or a refund. The Department pointed out that this substantial harm is not reasonably avoidable because the only way to avoid it is to disregard public health guidance or direction from governmental entities or medical professionals not to travel and risk inflicting serious health consequences on themselves or others. The Department added that the tangible and significant harm to consumers of losing the entire value of their ticket is not outweighed by potential benefits to consumers or competition. The Department expressed concern that, to avoid financial loss, consumers who have or may have contracted a serious communicable disease may choose to travel even when they have been advised not to travel, which is not in the public interest.

The Department further stated that aside from enhanced protection of consumers' financial interests, it believes that a regulation providing protection to non-refundable ticket holders who are unable to travel by air

[76] A practice is ''unfair'' to consumers if it causes or is likely to cause substantial injury, which is not reasonably avoidable, and the harm is not outweighed by benefits to consumers or competition. Proof of intent is not necessary to establish unfairness. 14 CFR 399.79.

due to reasonable concerns related to a serious communicable disease is needed to promote and maintain a safe and adequate aviation transportation system. Citing 49 U.S.C. 41702, which requires U.S. carriers to provide safe and adequate interstate air transportation, and 49 U.S.C. 40101(a), which directs the Department to consider certain enumerated factors including ''assigning and maintaining safety as the highest priority in air commerce'' in carrying out aviation economic programs, the Department asserted that the proposals would encourage certain consumers to postpone travel and avoid potential harm to themselves and others in the aviation system. The Department sought comments on whether requiring airlines and ticket agents to issue travel credits or vouchers to non-refundable ticket holders in these situations and refunds when entities receive government assistance is an appropriate way for the Department to promote safe and adequate air transportation.

Comments Received: Airline commenters stated that the NPRM failed to establish legal justification for the proposals relating to communicable diseases. A4A, RAA, IATA, AAPA, and Air Canada argued that the proposals interfere with airlines' tiered fare structure and threaten ''the availability of a variety of adequate, economic, efficient, and low-priced service'' and therefore, are inconsistent with the ADA and section 40101. They added that the proposals will result in a smaller pricing gap between refundable fares and non-refundable fares, with tickets priced closer to the higher fare group, decreasing load factors, and impacting the commercial viability of marginal routes and remote markets. A4A and IATA commented that it is important to maintain non-refundable fares because they increase access to air travel by providing the least expensive form of travel with a trade-off that consumers who choose this option may not be able to change or cancel the tickets. Air Canada commented that the proposals violate the pricing freedom principle set forth in the U.S.—Canada bilateral agreement.

A4A argued that any consumer harm stated in the Department's analysis for ''unfair'' practice can be mitigated by readily available market solutions such as travel insurance, refundable tickets, or airlines waiving change fees during a public health emergency. Similarly, two ticket agent representatives, ABTA and ASTA, commented that they oppose the proposal because the harm that the proposal is intending to address can be prevented by purchasing insurance or refundable tickets and is therefore reasonably avoidable by consumers. Furthermore, on the analysis for ''unfair'' practice, A4A contended that any harm to consumers during a public health emergency is not caused by a ''practice'' by a carrier or a ticket agent. A4A also commented that the asserted authorities under sections 41712 and 41702 contradict the conclusion included in the Regulatory Impact Analysis (RIA) for the NPRM that states the proposals would not decrease the spread of a serious communicable disease by a measurable amount. Lastly, A4A commented that the proposal on travel credits or vouchers is inconsistent with the Federal Trade Commission (FTC) and agency practices of other modes of transportation and other industries.

FlyersRights commented that the Department has the clear authority and responsibility to promulgate the pandemic related provisions to ensure airlines ''provide safe and adequate interstate air transportation.'' It stated that the proposals would ensure any passenger who has a serious communicable disease, who is complying with government orders pertaining to pandemics, or who is following the advice of governmental health and safety agencies, is able to cancel or change their flight reservations through non-expiring travel credits, releasing airlines from their obligation to transport the passengers during a pandemic or when the passengers are contagious. FlyersRights further argued that the Department also has the clear authority to determine it is an unfair or deceptive practice for airlines to deny refunds or non-expiring credits to passengers who have COVID–19 or COVID–19 symptoms, who have had immediate exposure to someone with COVID–19, or who have health conditions or fears that made it unsafe to fly on planes or congregate at airports.

Regarding airlines' argument that the proposal will circumvent the ''non-refundable'' feature of the ticket booking class and result in price increases, FlyersRights argued that in their view non-refundable tickets do not provide a cheaper alternative for passengers. Regarding airlines' rationale that enforcing the ''non-refundable'' feature provides needed certainty that confirmed passengers will actually take the flights and reduces the risk of airlines being unable to sell empty seats closer to flight departure, which in turn allows airlines to keep price low, FlyersRights commented that the same rationale can be applied to passengers when their flights are cancelled or changed by airlines closer to departure date, at which point passengers are likely to pay a premium for alternative transportation. According to FlyersRights, the airlines' rationale will result in the conclusion that passengers having their flights cancelled or significantly changed by airlines should receive a premium of the ticket price in addition to refunds.

U.S. Travel Association commented that the proposals relating to serious communicable disease are problematic because they are overly broad, ambiguous, subjective, and outside of DOT authority. USTOA also opposed the proposals and argued that the circumstances triggering the proposed requirements are beyond airlines' control and the Department fails to explain why not complying with the proposed requirements is an unfair or deceptive practice. It also supported the airlines' argument that there are other solutions for consumers such as travel insurance or higher-priced fares with more flexibility. It stated that the RIA acknowledges that the proposals would not be likely to reduce the spread of disease, therefore weakening the argument for authority under section 41702. U.S. Chamber of Commerce stated that the proposals are overly broad and subject to abuse and the Department should require vouchers or credits to be issued only when there is a public health emergency that inhibits travel.

DOT Responses: The Department has carefully considered the comments by stakeholders regarding the Department's stated authorities for imposing requirements to protect consumers whose air travel plans are affected by a serious communicable disease. We have reached the conclusion that such protections are consistent with the Department's authority to prohibit unfair or deceptive practices in air transportation and are necessary to ensure consumers are treated fairly when unexpected interruptions arising from a serious communicable disease result in them being unable to travel by air or hesitant to travel by air because traveling would pose potential harm to themselves or others. The Department has further concluded that such protections will contribute to the Department's mission in ensuring safe and adequate interstate air transportation through economic regulations and will not interfere with airlines' freedom of pricing as provided by the ADA and bilateral agreements between the United States and other jurisdictions.

A. Unfair Practice

Airline commenters do not dispute that consumers suffer a harm if they do not receive travel credits or vouchers when they are unable to travel due to a serious communicable disease. Instead, airline commenters contended that the Department failed to demonstrate that not providing travel credits or vouchers to consumers is an ''unfair practice'' pursuant to 49 U.S.C. 41712 because: (1) the consumer harm articulated in the NPRM is the result of a communicable disease outbreak and is not caused by the ''practices'' of carriers; (2) the harm is avoidable by consumers through the purchase of travel insurance or refundable tickets; and (3) the harm is outweighed by countervailing benefits to consumers or competition. For the reasons described below, the Department disagrees with these assertions.

In the 2020 final rule [77] that codifies the definition of ''unfair'' in 14 CFR 399.79, the Department also discussed the meaning of the term ''practice.'' While that rule did not adopt a definition for ''practice,'' it discussed how the Department would determine if an act or omission was a practice. To be a ''practice'' in the aviation consumer protection context, the conduct must generally be more than a single incident, however, ''even a single incident may be indicative of a practice if it reflects company policy, practice, training, or lack of training.'' [78] A carrier policy of not providing travel credits or vouchers when consumers are unable to travel due to a serious communicable disease is a practice. The fact that the outbreak of a serious communicable disease is not the fault of a carrier does not make carriers' policies of not providing travel credits or vouchers any less of a practice.

The Department is not persuaded by the argument by airlines and ticket agents that the proposed requirements ignore readily available market solutions that could prevent the consumer harm. While refundable tickets and travel insurance are intended to address uncertainty in travel, the Department believes that it is unreasonable to expect consumers to purchase travel insurance or refundable tickets to protect their money *just in case* a pandemic occurs, or *just in case* a government imposes a restriction or prohibition in relation to a serious communicable disease when a pandemic has not been declared. Also, some travel insurance policies do not provide protection against cancellations related to a pandemic. The Department agrees that persons who purchase airline tickets after a pandemic has been declared should know the potential risks of purchasing a non-refundable ticket without travel insurance. These consumers have the option to purchase refundable tickets or appropriate travel insurance to avoid financial loss should they not be able to travel due to a pandemic-related reason. For consumers who are advised not to travel to protect themselves during a public health emergency or consumers who are prohibited or required to be quarantined for a substantial portion of their trip by a governmental entity, the Department in this final rule requires airlines to provide travel credits and vouchers to individuals who purchased tickets prior to a public health emergency being declared or, if there is no declaration of a public health emergency, before the government prohibition or restriction for travel to that region. In addition, the reason that the individuals are not traveling must be because they want to protect themselves from a serious communicable disease that led to the declaration of the public health emergency or their travel is affected by the government prohibition/restriction related to a serious communicable disease.

With respect to consumers who have or are likely to have contracted a serious communicable disease, the Department requires that airlines provide travel credits or vouchers to them regardless of whether their travel is during a public health emergency and regardless of when they purchased their tickets. It would not be reasonable to expect a consumer to purchase a refundable ticket or travel insurance to ensure that his or her financial interests are protected in case the consumer contracts a serious communicable disease when a public health emergency has not been declared. A consumer could not reasonably avoid the harm of financial loss under those circumstances because the consumer likely would not even think of conducting a risk assessment of contracting a serious communicable disease when a public health emergency has not been declared. For a consumer who purchased the ticket while a public health emergency is ongoing, the Department believes that this individual could have done a risk assessment and decided to purchase travel insurance or a refundable ticket if the individual wished to not risk financial harm. This individual traveling on a flight to avoid financial harm, however, will cause or is likely to cause substantial harm to the health of the other passengers on the flight. These other passengers are not reasonably able to avoid this harm as they have no control over this individual's actions and whether the airline seats them in close proximity to this individual. The Department believes that airlines not providing an incentive for the infected consumer to postpone travel is likely to cause significant harm to other passengers on the same flight by substantially increasing the likelihood of these passengers being exposed to the disease and infected during the flight and such harm cannot be reasonably avoided by these passengers as they are likely to have no knowledge about them being seated in a close proximity to an infected passenger. This harm is not outweighed by benefits to consumers or competition as suggested by airlines. The Department is of the view that the requirement to provide travel credits or vouchers would not result in the elimination of nonrefundable fares or in distorting the difference between a refundable and non-refundable fare as some commenters have suggested given that a public health emergency affecting travel to, within, and from the United States on a large scale is infrequent and this requirement only applies to consumers who purchased tickets prior to a public health emergency and are unable or advised not to travel during a public health emergency. Further, not providing vouchers and credits to consumers who are advised not to travel during a pandemic could result in some consumers risking their health or the health of others to avoid financial loss, which is not in the public interest. The Department doesn't believe there would be any benefit to consumers or competition among airlines in infected or potentially infected travelers possibly choosing to travel by air and infecting other passengers.

B. Assertion of Inconsistency With FTC Policies

Regarding A4A's comment that the proposals relating to serious communicable diseases are inconsistent with the policies of the FTC, the practices of other modes of transportation, other segments of the travel industry, or other industries, the Department notes that its unfair or deceptive practices regulations are modeled on FTC's regulations and policies. To the extent that there are differences between DOT and FTC regulations, the Department notes that when determining its own regulations and policies, it routinely considers, among other things, the unique characteristics of the aviation

[77] *Final Rule, Defining Unfair Or Deceptive Practices,* 85 FR 78707, December 7, 2020.

[78] See 85 FR 78707, 78710–78711 (Dec. 7, 2020).

environment and context as well as any problematic areas, as reflected by consumer complaints, for which a regulatory remedy should be considered. In this instance, the Department has considered the large number of consumer complaints it received during the COVID–19 pandemic regarding the hardships consumers experienced when requesting credits from airlines so they could postpone travel. These hardships include airlines' refusal to issue credits or imposing limitations on the credits that consumers view as unreasonable. In the Department's view, these complaints are clear evidence that a regulation pursuant to the Department's authority is needed. While the Department views consistency among Federal consumer protection regulations as likely to benefit consumers by reducing confusion, the Department also appreciates the importance of regulations tailored to each regulated industry.

C. Airline Deregulation Act

The Department disagrees with the comments that a requirement for airlines to provide travel credits or vouchers for passengers unable to travel due to a serious communicable disease is inconsistent with the Airline Deregulation Act of 1978 and 49 U.S.C. 40101(a). These commenters argue that the proposals interfere with airlines' freedom of pricing, including the freedom of offering tiered fare structure that incorporates different pricing reflecting the levels of flexibilities for consumers to cancel or change tickets. In essence, the commenters argue that the proposals will largely require more flexibility for non-refundable tickets, blurring the lines between refundable fares and non-refundable fares, resulting in higher prices for all consumers and reduced load factors that also, in some cases, impact the commercial viability of small and remote markets. IATA and A4A also note, in their substantive comments on the Regulatory Impact Analysis for the proposed rule, that the proposal to require travel credits and vouchers may result in airlines eliminating basic economy fares if airlines can't enforce basic economy change restrictions.

First and foremost, the proposals that we are finalizing here do not affect the restrictions applicable to non-refundable tickets in most cases outside of the context of a serious communicable disease outbreak, such as the COVID–19 pandemic. The requirements protecting consumers who are prohibited or restricted from travel by a government order or consumers who are advised not to travel during a public health emergency to protect themselves apply only to very specific cases in which non-refundable ticket holders are impacted by an unforeseeable event relating to a serious communicable disease and, as the result of the impact of the event, consumers are either unable or advised not to travel. Further, the Department is revising the proposal to enhance measures airlines and ticket agents may adopt to prevent fraud and abuse. For similar reasons, the Department disagrees with Air Canada's comment that the proposals violate the pricing freedom principle set forth in the bilateral aviation agreement between the United States and Canada. Airlines can fully comply with the consumer protection requirements finalized in this rule and continue to exercise freedom of pricing and offer a variety of air travel products, including non-refundable fares with lower prices and more restrictions, to meet the market demands for adequate, economic, and efficient air transportation services.

D. Safe and Adequate Interstate Air Transportation

With regard to the application of the legal authority under 49 U.S.C. 41702, which requires air carriers to provide safe and adequate interstate air transportation, airline and ticket agent commenters argue that the RIA prepared by the Department concludes that the proposals would not decrease the spread of a serious communicable disease by a measurable amount. The commenters state that the RIA conclusion contradicts the NPRM's stated purpose of ensuring safe and adequate interstate air transportation. We disagree. The Department acknowledges that the RIA accompanying the NPRM stated that the proposals would not have decreased the spread of serious communicable disease by a measurable amount. In the RIA accompanying this final rule, the Department estimates that 0.7% of COVID–19 infections were transmitted on aircraft.[79] The Department continues to believe that the requirement to provide travel credits or vouchers to consumers who have or are likely to have contracted a serious communicable disease and would pose a direct threat to the health of others will reduce the likelihood of passengers contracting communicable diseases in air travel. As stated in the NPRM, it is the Department's understanding that airlines in general would allow and prefer that a passenger with a serious communicable disease in the contagious stage not travel, and airlines would likely grant an exception from the tickets' non-refundability to allow the passenger to reschedule travel. The Department believes the low COVID–19 transmission rate was influenced by airlines' actions of allowing passengers to reschedule travel. By making the airlines' voluntary action mandatory, this rule would further ensure safe and adequate interstate air transportation as passengers would be assured that they can reschedule travel for when they are well without facing financial loss.

2. Need for Rulemaking

The NPRM: In the NPRM, the Department stated its view that a regulation is needed to ensure consumers are consistently treated fairly when they are unable or advised not to travel due to reasonable concerns related to a serious communicable disease. The Department further explained that the Department's existing regulation does not require airlines to issue refunds or travel credits to passengers holding non-refundable tickets when the airline operated the flight and the passengers do not travel, regardless of the reason that the passenger does not travel. The Department described its goal as protecting consumers' financial interests when the disruptions to their travel plans were caused by public health concerns beyond their control. The Department also shared that it expects that the financial protection would further incentivize individuals to postpone travel when they are advised by a medical professional or determine consistent with public health guidance not to travel because they have or may have a serious communicable disease that would pose a threat to others. The Department described how the COVID–19 pandemic imposed unprecedented challenges on air travelers when numerous consumers were caught off guard by the sudden events of government travel restrictions or the widespread incidence of a serious communicable disease that impacted their travel plans. The Department expressed its view that the need for regulatory intervention arises when, despite airlines voluntarily offering travel credits or vouchers in situations where a passenger states that he or she was unable to travel or advised not to travel due to COVID–19 related reasons, consumers were frustrated by the short validity periods of the credits and vouchers, the strict conditions imposed

[79] See, *Barnett, A., Fleming, K. Covid-19 Infection Risk on US Domestic Airlines.* July 2, 2022, *https://link.springer.com/article/10.1007/s10729-022-09603-6#Sec3.*

on them, and the difficulties to obtain and redeem them.

The Department stated its view that consumers are acting reasonably when they decide to not travel because they have or may have contracted a serious communicable disease that may pose risks to others during air travel, or because their own health conditions are such that traveling during a public health emergency may put them at higher risk of harm to their health. Further, the Department pointed out that consumers may be unable to travel due to government travel restrictions related to the pandemic. In the NPRM, the Department stated its tentative position that a regulation is needed to ensure consumers are consistently treated fairly when they are unable or advised not to travel due to reasonable concerns related to a serious communicable disease. It further stated that a regulation defining the baseline of accommodations to non-refundable ticket holders and identifying the specific circumstances that would give rise to the need to accommodate passengers when they cancel or postpone their travel would greatly enhance consumer protection. The Department pointed out that without such requirements, airlines and ticket agents may have different interpretations of what types of events would be sufficient to justify a deviation from the non-refundable terms of a ticket, and such different application of interpretations may result in increased consumer confusion and frustration, as well as increased administrative cost to airlines and ticket agents for handling customer service requests and complaints from consumers with different perspectives.

Comments Received: Most ticket agent representatives argued that the proposals may create tremendous financial burden and disincentivize airlines from offering non-refundable fares. Global Business Travel Association argued that airlines should have the flexibility to deal with public health emergency related issues. It further added that the Department, airlines, and ticket agents lack public health expertise to navigate the proposals.

FlyersRights asserted that without the proposed protections, consumers would be forced to forfeit the money they paid for the tickets or to take a flight against the orders, recommendations, or medical advice of government health agencies or medical professionals, resulting in some passengers making the financial decisions to fly while sick, contagious, or immunocompromised, or with the strong suspicion of being sick.

National Consumers League expressed its view that the Department should require airlines and ticket agents to provide travel credits or vouchers to consumers who cannot fly due to health-related reasons, regardless of public health emergency declarations, public health agency guidance, or serious risk of communicable disease. It commented that developing a health condition that would make air travel dangerous to the passenger or others after purchasing the airline ticket is something beyond the passenger's control. It suggested that it is in the public interest for the passenger to be protected from losing the ticket investment. Travelers United also supported a broader ''airline sick passenger rule'' that would require airlines to allow passengers with legitimate illnesses to postpone flights without additional costs. Travelers United provided examples of inflight disease outbreaks and argues that airlines charging change fees for sick passengers to postpone travel could result in additional cost to airlines.

U.S. Travel Association asserted that the proposals affect passengers who have bought travel insurance policies because they would have to wait until the credits or vouchers expire before they can be reimbursed by the insurance carrier, and many passengers would not prefer vouchers. It further stated that the proposals introduce fraud risk because some consumers may attempt to file insurance claims and also receive credits or vouchers. Travel Tech supported a rulemaking to address consumer protection in the context of communicable disease but argued that the requirements should exempt ticket agents.

DOT Responses: The Department continues to be of the view that a regulation is needed to ensure consumers are consistently treated fairly when they are unable or advised not to travel due to reasonable concerns related to a serious communicable disease. Approximately 20% of the refund complaints that the Department received from January 1, 2020 to June 30, 2021, involved instances in which passengers with non-refundable tickets chose not to travel because of considerations related to the COVID–19 pandemic.[80] As for U.S. Travel Association's comment that insurance companies require consumers to wait until credits or vouchers expire before consumers can be reimbursed, the Department anticipates that insurance companies will offer a variety of products that meet consumers' different needs to stay competitive after the final rule takes effect. The Department also acknowledges the concerns by several consumer rights advocacy groups regarding the need for a broader regulation requiring airlines to allow passengers with any legitimate illness to postpone travel without additional cost. Because the NPRM's focus is on the three categories of consumers affected by a serious communicable disease, however, and the public did not have the opportunity to fully consider and comment on this broader issue, we decline to address it here.

[80] See Report to the White House Competition Council, p. 11.

3. Covered Entities

The NPRM: The Department proposed to require the entity that ''sold'' an airline ticket (*i.e.,* the entity identified in the consumer's financial statement, such as credit card statement), whether a carrier or a ticket agent, provide travel credits or vouchers to eligible consumers affected by a serious communicable disease. The Department noted, however, that it is open to suggestions on whether the entity obligated to issue credits or vouchers should be determined based on other criteria and solicited comment on whether airlines should solely be responsible for issuing credits or vouchers because they are the direct providers of the air transportation paid for by consumers and the ultimate recipients of the consumer funds. The Department asked how it can best ensure that credits and vouchers issued by an airline is prompt if a ticket agent is the entity that ''sold'' the ticket. The Department inquired about what role and responsibility it should place on ticket agents that sold airline tickets to facilitate the issuance of credits or vouchers by airlines when the ticket agents are the principals of the transactions.

Comments Received: A4A supported the proposal to require ticket agents to provide travel credits valid for use within the ticket agent's system, arguing that ticket agents cannot issue credits valid for use on a carrier. National Consumers League supported the Department's proposal as applicable to airlines and ticket agents. Ticket agent representatives expressed concerns about applying the proposals to ticket agents. USTOA stated that the Department did not consider the training and administrative costs for ticket agents to screen passenger documentation. It further stated that such a requirement has never been placed on ticket agents, only on airlines. Travel Management Coalition commented that airlines should issue

credits to eligible travelers, but that for business travelers, the corporate clients would not want the travelers to get credits that can be used for their personal travel. It suggested that ticket agents should be involved in those situations for the issuance and management of credits. Travel Tech provided the following reasons for which it believes that the proposals should not apply to ticket agents: (1) airlines should be the origination of the credits that are airline instruments designed for future travel on the airline on which the consumer originally scheduled to travel, even when the ticket agents are the merchants of record; (2) airline fare rules dictate the conditions of the credits; (3) ticket agents may have assisted the issuance of credits during the COVID–19 pandemic according to the instructions provided by airlines; requiring ticket agents to issue their own credits is administratively wasteful because ticket agents will have to work with each airline and create their own credits; and (4) requiring ticket agents to issue credits can be confusing to consumers because there could be situations in which the rule empowers both airlines and ticket agents to evaluate consumer documentation, which may create inconsistency.

DOT Responses: The Department is requiring that airlines are the sole entities responsible for issuing travel credits or vouchers to eligible consumers whose travel is affected by a serious communicable disease, even if the original tickets were purchased from a ticket agent who acted as the merchant of record. The comments from airlines and ticket agents noted that ticket agents cannot issue credits valid for future travel with a carrier. The Department also agrees with the comment that it is a significant burden to create and manage their own credits or voucher systems including coordinating with various airlines to ensure that the credits or vouchers are usable. The Department considers this burden to be particularly substantial for small ticket agents. In addition, like Travel Tech, the Department believes having both airlines and ticket agents issue travel credits and vouchers could further increase the likelihood of consumer confusion. Airlines that are the merchants of record for the ticket transactions will be responsible for issuing the travel credits or vouchers to eligible consumers. When a ticket agent is the merchant of record, each operating carrier is responsible for issuing a travel credit or voucher to the consumer. Under this final rule, although a fee-for-service carrier operating the flight is ultimately responsible for issuing travel credits or vouchers for ticket agent-transacted itineraries, it is permissible for the carrier to rely on other entities, such as their marketing codeshare partner, to process and issue travel credits or vouchers to consumers on its behalf.

This does not mean that ticket agents don't have a role to play in the issuance of travel credits or vouchers. The Department encourages ticket agents to assist airlines by providing information that airlines may need to complete the issuance of the travel credit or voucher, such as consumers' contact information or the price paid by consumers for the original tickets.

4. Definition of Serious Communicable Disease

The NPRM: The Department proposed to define a serious communicable disease to mean a communicable disease as defined in 42 CFR 70.1 [81] that has serious consequences and can be easily transmitted by casual contact in an aircraft cabin environment. The Department did not propose to include a list of communicable diseases under the definition. Instead, it stated that the analysis of whether a communicable disease is ''serious'' under the NPRM is similar to the analysis of ''direct threat'' under the Department's Air Carrier Access Act regulation,[82] which considers the significance of the consequences of a communicable disease and the degree to which it can be readily transmitted by casual contact in an aircraft cabin environment. The Department further provided examples of diseases that do and do not meet the two-prong analysis under the proposed definition—readily transmissible in the aircraft cabin and likely to result in significant health consequences. For example, the Department explained that the common cold is readily transmissible in an aircraft cabin environment but does not have severe health consequences. AIDS has serious health consequences but is not readily transmissible in an aircraft cabin environment. Both the common cold and AIDS would not be considered serious communicable diseases. SARS is readily transmissible in an aircraft cabin environment and has severe health consequences. SARS would be considered a serious communicable disease. The Department asked whether it is sufficiently clear to the regulated entities and the public as to which types of communicable diseases would and would not be considered serious.

Comments Received: Airline commenters were concerned about the proposed definition for ''serious communicable disease,'' stating it uses terms that are too vague. A4A asked for more clarity on the terms ''easily transmissible in the aircraft cabin'' and ''casual contact.'' IATA further commented that the term ''serious consequence'' in the analysis for serious communicable disease does not consider that the consequence of a disease could differ from person to person.

Airline commenters also disputed statements in the NPRM that COVID–19 is easily transmissible in aircraft cabins. In written comments, IATA and A4A separately asserted that the NPRM's claim that COVID–19 is easily transmissible in aircraft cabin is inconsistent with the research that shows it is not highly transmissible in aircraft cabin due to the filtration and air circulation system. During the March 21, 2023 public hearing, however, an IATA Medical Advisor suggested that the final rule should highlight only those diseases that medical consensus suggests is likely to be spread by aerosols or droplets in an aircraft environment as ''serious communicable diseases,'' which he stated is likely to include only respiratory infections that are highly contagious such as measles or COVID–19 and perhaps in unusual cases, gastrointestinal ones such as Norovirus. He opined that any medical assessment even by medical professionals needs to have the information on what is a ''serious communicable disease'' to adequately determine the risk onboard. The IATA Medical Advisor also pointed out that certain diseases that could be considered communicable in other locations may be less threatening in aircraft environment due to cabin conditioning flow rates, filtration systems, and other aircraft characteristics making transmission significantly less likely than in other public gathering locations.

DOT Responses: The Department is adopting the proposed definition for ''serious communicable disease,'' which means a communicable disease as defined in 42 CFR 70.1 that has serious health consequences and can be easily transmitted by casual contact in an aircraft cabin environment. The Department declines to adopt a definition with an exclusive list of

[81] 42 CFR 70.1 states ''Communicable diseases means illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.''

[82] See 14 CFR 382.21(b)(2).

communicable diseases or highlight only those communicable diseases that are spread by aerosols or droplets in an aircraft environment because the Department does not believe a list based on currently known diseases would serve its purpose in the long term. The definition of serious communicable disease continues to include the examples provided in the NPRM to demonstrate that a ''serious communicable disease'' must meet both prongs of the definition—''serious health consequence'' and ''can be easily transmitted by casual contact in an aircraft cabin environment.''

The Department acknowledges that the consequence of contracting a communicable disease on an individual may vary depending on the individual's health condition. ''Serious health consequence'' is referring to the health of an average person rather than health of each individual. For example, the average person would not have serious health consequences from a common cold, though it can be life threatening for people with weak immune systems, such as a cancer patient undergoing treatment.

As for the meaning of ''can be easily transmitted by casual contact in an aircraft cabin environment,'' the Department has reviewed public health guidance issued by CDC and WHO, which find that although modern aircraft ventilation and air filtration systems do play an important role in reducing the likelihood of disease transmissions, transmissions of infection may occur [83] between passengers who are seated in the same area of an aircraft, usually by contact with infectious droplets (as a result of the infected individual coughing or sneezing) or by touch (direct contact or touching communal surfaces that other passengers touch).[84] Accordingly, the Department determines that a communicable disease that ''can be easily transmitted by casual contact in the aircraft cabin environment'' to mean a disease that is easily spread to others in an aircraft cabin through general activities of passengers such as sitting next to someone, shaking hands, talking to someone, or touching communal surfaces.

[83] A study led by MIT scholars estimated that between June 2020 and February 2021, the probability of contracting COVID–19 onboard an average domestic flight was about 1 in 2000. *See* fn. 75, *supra.*

[84] See, *CDC Air Travel Yellow Book 2024, https://wwwnc.cdc.gov/travel/yellowbook/2024/air-land-sea/air-travel#inflight;* World Health Organization Air Travel Advice, *https://www.who.int/news-room/questions-and-answers/item/air-travel-advice.*

5. Passengers Who Are Advised by a Medical Professional Not To Travel To Protect Themselves During a Public Health Emergency

The NPRM: The Department proposed that, when there is a public health emergency, airlines and ticket agents must provide non-expiring travel credits or vouchers to non-refundable ticket holders who are advised by a medical professional or determine consistent with public health guidance issued by the CDC, comparable agencies, or WHO not to travel by air to protect themselves from a serious communicable disease. Under this NPRM, to be eligible for the travel credits or vouchers, the non-refundable ticket holder must have booked the ticket before the beginning of the public health emergency and the travel date must be during the public health emergency. The Department proposed to define ''public health emergency'' based on the U.S. Department of Health and Human Services (HHS) regulation addressing measures taken by CDC to quarantine or otherwise prevent the spread of communicable diseases, 42 CFR 70.1.[85] The Department sought comments regarding whether the proposal is reasonable with respect to the passengers protected, asking whether the protection should be extended to passengers who purchased their tickets after the public health emergency is declared but did not develop the underlying health condition until after the tickets are purchased. The Department also sought comments regarding whether it is reasonable to extend the proposed requirements to passengers who sought to defer travel because they are the caregivers of persons with a health condition and at a higher risk, and passengers who would have difficulty traveling alone when their travel companion qualifies for a voucher or refund. The Department also asked whether there are obstacles airlines and ticket agents faced when some of them voluntarily provided travel vouchers to consumers who decided not to travel during the COVID–19 pandemic. The Department also solicited comment on whether consumers experienced difficulties in redeeming credits and vouchers issued to them and what the Department should consider in the proposed regulation to address or resolve these difficulties.

Comments Received: Airline commenters stated that the proposal includes vague and unclear terms and subjective standards that will cause substantial consumer and carrier confusion. A4A commented that the proposed definition for ''public health emergency'' is too broad. It noted that there are over 100 events during the past five years that would qualify under the definition. It further argued that there needs to be a connection between a passenger's travel and the public health emergency, and that an event in another country should not be used to protect domestic passengers. IATA argued that governments around the world took different approaches towards COVID–19, from being very restrictive to extremely permissive, but the NPRM presupposes that all governments take a uniform approach. Both A4A and IATA also commented that more clarity is needed on what are ''comparable agencies in other countries'' that would be qualified to issue the public health guidance. AAPA opined that it is difficult for airlines to verify the authenticity of the documentation from various governments that passengers may provide airlines to prove their eligibility for travel credits or vouchers. Further, A4A and IATA commented that the term ''medical professional'' is a vague term that is not defined. A4A and IATA both opposed the proposal to allow passengers to ''determine'' whether they should travel. A4A argued that this is a subjective standard and IATA added that allowing passengers to self-determine whether they should travel based on public health guidance is inconsistent with the rule text that allows airlines to request medical documentation.

A4A suggested and IATA supported that: (1) the requirement cover only a public health emergency that occurs in the United States at a national level; (2) eligible passengers must have purchased their tickets before the public health

[85] The definition for public health emergency in 42 CFR 70.1 is: (1) Any communicable disease event as determined by the Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or (2) Any communicable disease event described in a declaration by the Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d (a)); or (3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or (4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or (5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

emergency declaration; (3) the travel must have been planned to occur during the public health emergency; and (4) the reason that an eligible passenger is not traveling must be because of the public health emergency. Similar to A4A, U.S. Chamber of Commerce also suggested that the Department should limit travel credits or vouchers to medical situations when there is a Public Health Emergency and to situations that inhibit travel (such as a prohibition by a government entity). U.S. Chamber of Commerce commented that the Department's proposal would be subject to abuse by bad actors. SATA opposed the proposal and stated that when passengers holding non-refundable tickets are not comfortable with traveling and the flight is operated, airlines offer higher fares with more flexibilities and airlines should not be obligated to issue refunds or credits.

Regarding the Department's inquiry in the NPRM on whether the credits or vouchers protection should be extended to passengers who are the caregivers of persons with a health condition and at a higher risk, and passengers who would have difficulty traveling alone when their travel companion qualifies for a voucher, A4A opposed the expansion of the proposal and argued that including flight credits to caregivers will exacerbate the potential for mistakes, misunderstandings, and fraud by introducing another undefined and unclear mandate. IATA also opposed the expansion of the credits to caregivers. It further argued that children should not be eligible for credits based on the provision of a credit to their adult companion because parents concerned about such a possibility can purchase travel insurance. AAPA opposed the idea of providing travel credits or vouchers to passengers who are caregivers of individuals with underlying health conditions, arguing that this is too broad a scope that would be open to fraud. USTOA also opposed requiring credits or voucher to be issued to caregivers of persons with health conditions, either though family relationship or employment.

Many individual consumers expressed their general support for the proposals relating to serious communicable diseases, including the proposal to provide travel credits and vouchers to passengers who do not travel during a public health emergency because of concerns about their health. Consumer rights groups commented that the proposals should be expanded to cover medical situations beyond public health emergency or communicable diseases. The ACPAC voted to support the Department's proposal to protect travelers affected by a serious communicable disease, including the proposal to require airlines and ticket agents to issue travel credits or vouchers to passengers who purchased the airline ticket before a public health emergency was declared, the consumer is scheduled to travel during the public health emergency, and the consumer is advised by a medical professional or determines consistent with public health guidance issued by CDC, comparable agencies in other countries, or the WHO not to travel by air to protect himself or herself from a serious communicable disease.[86] At least one individual commenter supported providing regulatory protections for caregivers.

DOT Responses: After reviewing and carefully considering the comments, the Department is requiring airlines to provide travel credits or vouchers to passengers who have been advised by licensed treating medical professionals not to travel during a public health emergency to protect themselves from a serious communicable disease. The Department is not expanding this requirement to provide travel credits and vouchers to cover situations beyond a public health emergency or serious communicable diseases as suggested by consumer groups. The Department agrees with A4A and U.S. Chamber of Commerce that the requirement for travel credits or vouchers should be limited to medical situations when there is a public health emergency. Under this rule, to be eligible for a travel credit or voucher, the passenger must have purchased the airline ticket before the public health emergency was declared, and the ticket must be for an itinerary to, from, or within the United States that involves traveling to or from a point affected by the public health emergency during the public health emergency.

The Department does not agree with the suggestion from airlines to limit the requirement to provide travel credits or vouchers to only public health emergencies that occur in the United States because an outbreak of a serious communicable disease in another country can affect passengers traveling between the United States and that country. However, the Department agrees that there needs to be a connection between a passenger's travel and the public health emergency. For example, a public health emergency relating to an outbreak of Ebola in another country would be grounds for a passenger to request a travel credit or voucher only if the passenger's planned travel, as reflected in a single itinerary, is between the United States and that country. In that regard, if the passenger booked two separate tickets, one from the United States to a connecting third country not subject to the public health emergency, and the other from the third country to the outbreak country, the Department would not require airlines to issue credits or vouchers based on the passenger's health-related concerns about traveling to the outbreak country.

The Department is persuaded by comments that its proposal to allow individuals to self-determine consistent with public health guidance whether to travel to protect themselves from a serious communicable disease is subjective. Unless otherwise directed by HHS, this rule allows airlines to require medical documentation from passengers who state that they do not wish to travel during a public health emergency for a medical reason to protect themselves. An airline may not require passengers to provide documentation from a medical professional if HHS issues public health guidance declaring that requiring such medical documentation is not in the public interest.

The Department further acknowledges comments from industry seeking clarity about the meaning of the terms ''medical professional'' and ''comparable agencies in other countries.'' In this final rule, the term ''medical professional,'' is defined in the regulation. The Department is adopting a definition for the term ''licensed treating medical professional'' to mean an individual, including a physician, a nurse practitioner, and a physician's assistant, who is licensed or authorized under the law of a State or territory in the United States or a comparable jurisdiction in another country to engage in the practice of medicine, to diagnose or treat a patient for a specific physical health condition that is the reason for the passenger to request a travel credit or voucher. The Department is providing further explanation of this definition in the section that discusses medical documentation. The Department no longer uses the term ''comparable agencies in other countries'' when referencing public health guidance that the consumers' licensed treating medical professionals may rely on or reference when providing professional opinions regarding whether the consumers should travel because that term is also subjective. In this final rule, the Department states ''consistent with

[86] Among the four members of ACPAC, three members voted in support of this recommendation and the member representing airlines abstained, stating that there are many terms in the proposal that are not clear and may cause more passenger confusion.

public health guidance issued by the Centers for Disease Control and Prevention (CDC) or the World Health Organization (WHO).''

Regarding whether caregivers of high-risk passengers should be protected, the Department is persuaded that extending the requirement to provide travel credits or vouchers to caregivers of people who have health conditions that place them at a higher risk of contracting a serious communicable disease may increase the risk of fraud. The Department also agrees that the complexity of appropriately defining this expanded group and verifying their eligibility can be burdensome for airlines. While not expanding the scope of the rule to these consumers, the Department encourages carriers to provide good customer service by offering maximum flexibilities to consumers who request to postpone their travel due to a genuine concern about the health of their families and others who are dependent upon them for care.

6. Passengers Who Are Prohibited From Travel or Required To Quarantine for a Substantial Portion of Trip by Government Entity

The NPRM: The Department proposed to require airlines and ticket agents to provide travel credits or vouchers to ticket holders who are unable to travel because of a U.S. (Federal, State, or local) or foreign government restriction or prohibition related to a serious communicable disease regardless of whether there is a public health emergency. Examples of such government restrictions or prohibitions include government issued ''stay at home'' orders, ''shelter in place'' orders, or government-instituted border closure or entry restrictions because of a serious communicable disease for certain types of passengers. The Department further explained that under the proposal, the requirement would cover passengers who can travel under the government order, but the restriction has rendered the passenger's travel ''meaningless.'' Passengers would not be entitled to a travel credit or voucher if they simply failed to exercise due diligence to ensure that all conditions for travel imposed by the governments of the departure, transit, or arrival locations are met (*e.g.,* negative test result for a communicable disease). The Department solicited comments on whether the proposed requirement for a non-expiring voucher or credit strikes the right balance given that the travel restrictions are out of the airlines' and ticket agents' control and the differential economic impact of a refund mandate versus a travel credit or voucher on airlines and ticket agents in these circumstances.

Comments Received: Airlines in general were concerned about the scope of the proposal which, in their view, is too broad and subjective, making it difficult to determine whether a passenger is eligible for a travel credit or voucher. Spirit opposed the proposal, stating that it shifts the risk of whether a consumer can fly entirely to airlines when the restriction is not the fault of airlines or consumers. It commented that there should be a reasonable balance of risks between airlines and passengers. A4A commented that the proposal does not explicitly require that a government order prevent the passenger from traveling, instead, by using the term ''restriction'' it implies that passengers could be eligible for credits even if they have partial discretion to travel. Several airline commenters argued that determining whether a passenger is ''unable to travel'' or the restriction renders travel ''meaningless'' requires a case-by-case analysis looking into the purpose of each passenger's travel, subject to different interpretations. They were also concerned about significant resources needed for airlines to determine whether a passenger has exercised ''due diligence'' to comply with each jurisdiction's travel requirements. Also, airlines were concerned about the proposal's language that does not limit the eligible travel to ''air travel.'' In that regard, they argued that the Department is burdening carries with obligations to provide travel credits when the non-air portion of the travel, not under the carrier's control, may be prohibited by a government order.

A4A provided several suggestions on how the proposal should be revised. First, A4A suggested that the term ''unable to travel'' should be replaced by the term ''prohibited from travel by air.'' Second, A4A recommended that the Department should remove the ''rendering travel meaningless'' standard from the regulation. Third, A4A asked the Department to include an explicit list of all scenarios that would disqualify a passenger for receiving travel credits. Fourth, A4A suggested that carriers should be required to issue travel credits only when the government order directly and substantially impacts the origination or destination of the passenger's itinerary. Over 1,500 individual consumers expressed their general support for the proposed protections for consumers affected by a serious communicable disease. Consumer rights advocacy groups did not specifically comment on the proposal of requiring airlines and ticket agents to issue travel credits or vouchers to passengers who are unable to travel due to a government restriction or prohibition relating to a serious communicable disease.

Among ticket agent's representatives, ASTA, DWHSA, Travel Tech, and ABTA supported this proposal. ASTA commented that consumers should be provided credits or a voucher because they are prevented from travel by government actions and failing to so do meets the standard for unfair practice. USTOA stated that modifications of the proposal are needed because ''unable to travel'' is too broad and vague and the term ''prohibited from travel'' should be used instead. It also opposed the inclusion of situations in which travel is rendered ''meaningless'' because this term is too subjective. GBTA commented that the proposal is enormously burdensome to airlines and ticket agents because it would require them to consider foreign government orders and public health guidance when determining passenger's eligibility to travel credits or vouchers, and also consider the timing of these documents' issuance relative to the ticket purchase date and the travel date. The ACPAC voted to support the Department's proposal to, regardless of whether there is a public health emergency, require airlines and ticket agents to provide travel credits or vouchers to consumers who are unable to travel because of a U.S. (Federal, State or local) or foreign government restriction or prohibition (*e.g.,* stay at home order, entry restriction, or border closure) in relation to a serious communicable disease that is issued after the ticket purchase.[87]

DOT Responses: Having fully considered the comments, the Department has decided to adopt a final rule largely along the lines set forth in the NPRM, with a few changes to address comments received from airlines about the difficulty and cost in determining which government restrictions would render travel ''meaningless'' and whether a passenger exercised ''due diligence'' to comply with each jurisdiction's travel requirements. These changes also further ensure the Department's actions are within its statutory authority. In this final rule, the Department is requiring airlines to provide travel credit or vouchers to non-refundable ticket holders who are prohibited from travel or required to quarantine for a

[87] Among the four members of ACPAC, three members voted in support of this recommendation and the member representing A4A voted against the recommendation, stating that there are many terms in the proposal that are not clear, and it will cause more passenger confusion.

substantial portion of the planned trip by the U.S. or foreign government in relation to a serious communicable disease. The Department has decided to replace the term ''unable to travel'' by the term ''prohibited from travel'' and to remove the ''rendering travel meaningless'' standard as suggested by airline commenters. In place of ''rendering travel meaningless,'' the Department is specifying that the travel restriction that would entitle a consumer to a travel credit or voucher is a mandatory quarantine for more than 50% of the length of the passenger's scheduled trip at the destination (excluding travel dates) as shown on the passenger's itinerary. In addition, the Department is limiting the requirement for airlines to provide travel credits and vouchers to consumers who purchased the airline ticket before a public health emergency affecting the passenger's origination or destination was declared or, if there is no declaration of a public health emergency, before the government prohibition or restriction for travel to or from the affected region is imposed. Passengers cannot reasonably avoid the harm of financial loss under these circumstances because they would have no reason to think there would be a government prohibition from travel or mandatory quarantine requirement at the passenger's origination or destination in relation to a serious communicable disease when a public health emergency has not been declared.

Beginning in January 2020, governments all over the world began taking various measures to try to curb the spread of COVID–19, including government-issued stay-at-home orders, business closure orders, border entry limits or quotas, quarantine requirements for arrivals, and restrictions or bans for commercial flights from certain originations. Many of these government orders impacted air travelers directly by making travel impossible through prohibitions from travel or indirectly by severely limiting the activities that travelers intended to engage in at the destinations through mandatory quarantines. Based on the comments, it appears that all stakeholders agree that passengers who are banned or prohibited from travel by air should be protected by the proposed requirement. The Department does not agree, however, that the scope of the consumer protection requirement should be limited to these passengers. The proposal's goal is to mitigate the financial losses suffered by air travelers during a communicable disease outbreak so severe that it triggers drastic actions by governments to restrict the movements of people. It is the Department's view that consumers who bought their airline tickets before the issuance of a public health emergency or, if there is no declaration of a public health emergency, before a government order prohibiting travel or restricting movement through mandatory quarantines should have the ability to retain the value they paid into the airline tickets.

The Department acknowledges the concerns about certain language used in the NPRM that could be construed as vague and subjective. As such, in finalizing this proposal, we are amending the rule text to provide more clarity. Specifically, the term ''unable to travel'' is replaced by ''prohibited from travel.'' The Department notes that the government order does not have to prohibit *air* travel. A passenger is entitled to a travel voucher or credit if the passenger is prohibited from travel by a government order (*i.e.,* an order prohibiting the passenger from traveling to or from the airport at the origination or destination) from entering the destination country/city as show in the passenger's itinerary or from boarding the flight(s). As proof of eligibility, airlines may require these passengers to provide the relevant government order and any appropriate supporting documentation to show the nexus between the government order and their inability to travel. For example, if a passenger states that he or she is prohibited from entering the destination country by a government order because of the passenger's nationality, carriers may require proof of the passenger's nationality in addition to the relevant government order prohibiting passengers of certain nationalities from entering.

With respect to government orders that do not prohibit travel but substantially restrict travel, the Department has considered airline comments that ''the restriction that renders travel meaningless'' standard is subjective and requires a case-by-case analysis into the purpose of each passenger's travel. As a result, the Department has removed the ''rendering travel meaningless'' standard. In the NPRM, the Department had explained what it meant by renders travel meaningless through an example of a passenger who plans to spend a week at the vacation destination and the local government imposes a seven-day quarantine requirement for all arriving passengers, which eliminates the purpose of the travel. Allegiant Air criticized the Department for picking the ''low-hanging fruit'' by providing this example and asked that the Department also opine on whether a passenger would be eligible for the proposed protection if only a part of the time at the destination is lost. The Department agrees that more clarity is needed in this respect so that airlines have more certainty on their obligation and consumes are treated consistently from airline to airline.

In place of the ''rendering travel meaningless'' standard, the Department specifies in this final rule that the travel restriction that would entitle a consumer to a travel credit or voucher is a mandatory quarantine at the passenger's destination for more than 50% of the length of the passenger's planned trip. As proof of eligibility, airlines may require passengers to provide the relevant government order mandating a quarantine which includes information about the length of the quarantine and documentation to show the length of the passenger's planned time at the destination, excluding the travel dates. This amendment should address carriers' concern about fraud and abuse.

7. Passengers Who Are Advised by a Medical Professional Not To Travel To Protect the Health of Others

The NPRM: Beyond widespread infections of a communicable disease that lead to a ''public health emergency'' declaration or government orders restricting or prohibiting travel, the Department also proposed to require airlines and ticket agents to issue travel credits or vouchers to passengers who are advised or determine not to travel to protect the health of others because they have or may have contracted a serious communicable disease, regardless of whether there is a public health emergency. The Department stated that it believes that airlines in general would allow and prefer that a passenger with a serious communicable disease in the contagious stage not travel, and airlines would likely grant an exception from the tickets' non-refundability to allow the passenger to reschedule travel. The Department described airlines' current practices in assessing whether a passenger with a communicable disease would pose a direct threat to the health of others such as requesting medical documentation and in minimizing risk to other passengers such as taking precautions to prevent the transmission of the disease in the cabin while transporting the passenger, or if appropriate, denying boarding and allowing the passenger to reschedule travel. The Department expressed its belief that it would be in the interest of carriers, passengers, and the public at

large for the travel to be postponed. The Department noted that this proposal would cover only passengers who have or may have contracted a serious communicable disease and the consumer's condition is such that traveling on a commercial flight would pose a direct threat to the health of others based on advice from a medical professional or the consumer's determination consistent with public health authorities issued by CDC, comparable agencies in other countries, or WHO.

The Department noted that using economic tools as incentives to discourage passengers who would pose a risk to the health of others from traveling is consistent with its mission to ensure that the air transportation system is safe and adequate for the public. It also noted its expectation that requests for credits or vouchers under this circumstance should be infrequent and will likely place minimal burden on the airlines outside of the context of public health emergencies. The Department solicited comment on the potential for abuse and whether a documentation requirement is sufficient to prevent abuse. Further, the Department asked for suggestions on alternative methods to protect consumers who are advised by a medical professional or determine consistent with public health guidance not to travel because they have or may have a serious communicable disease.

Comments Received: A4A expressed its concern about this proposal not being tied to either a public health emergency or a government-issued order. It argued that the proposal allowing passengers to subjectively determine that they should not travel ''consistent with'' public health guidance will cause tremendous confusion and impose significant costs to carriers. Like A4A, several other airline commenters expressed their concerns about the broad scope of the proposal that protects not only passengers advised by a medical professional not to travel due to contracting a serious communicable disease, but also passengers who rely on public health guidance issued by governments around the world to determine that they should not travel. Airline commenters were generally concerned about allowing consumers who ''may have'' a serious communicable disease to receive travel credits or vouchers. Commenters asserted that this broad scope will would lead to bad faith actors engaging in fraud and abuse and good faith consumers cancelling travel based on misinformation, creating a huge workload for carriers and the Department to resolve complaints. A4A also asked the Department to clarify whether the ''comparable agencies in other countries'' whose guidance may be relied on by consumers include third-party non-government entities if these entities' guidance is relied on by state or local level governments.

IATA and AAPA stated that airlines already have policies in place to accommodate passengers who are not able to travel due to a communicable disease, including requiring medical documentation. They argued that the Department has offered no evidence to show that these policies do not work. NACA stated that it is too broad to impose the proposal irrespective of a public health emergency. A4A also commented that the proposal does not require that passengers must have purchased their tickets before contracting the disease, which could result in passengers who purchased tickets while knowing they have a serious communicable disease to be eligible for the protection.

Travelers United stated that an airline ''sick-passenger rule'' would help stop disease spread and should be enforced all the time, not just during public health emergencies. It commented that airlines' current ''sick passenger rule,'' which allows postponing travel but with a fee, has resulted in sick passengers deciding to continue travel. On the other hand, according to Travelers United, airlines that allow sick passengers to postpone travel without charge have reported no problems of fraud.

Similar to airlines, ticket agent representatives raised concerns about the scope and ambiguity of certain terms used in the proposal. USTOA commented that requiring credits or vouchers be issued to passengers who ''may have'' contracted a serious communicable disease will invite abuse and fraud. It stated that the protection should be tied to a public health emergency. GBTA asserted that the NPRM does not define ''serious communicable disease'' in an actionable way and the Department, airlines, and ticket agents lack the public health expertise to navigate the requirements of the proposed definition. It further commented that the proposal leaves it open on who would need to verify a passenger's health status and what mechanism would be used to settle disputes. ABTA suggested that if the Department moves forward with this proposal, airlines and ticket agents should be allowed to require clear evidential documentations issued by certificated and qualified medical professionals. Travel Tech opined that instead of the proposed requirement, airlines should be required to rebook without charge to accommodate passengers who have or may have contracted a serious communicable disease. The ACPAC discussed this proposal and recommended to the Department to adopt a rule that requires airlines and ticket agents to provide travel credits or vouchers when a consumer is advised by a medical professional or determines consistent with public health guidance issued by CDC, comparable agencies in other countries, or WHO not to travel by air because the consumer has or may have contracted a serious communicable disease, and the consumer's condition is such that traveling on a commercial flight would pose a direct threat to the health of others. The ACPAC recommended that the requirement apply regardless of whether there is a public health emergency.[88]

Public Hearing: The March 21, 2023, public hearing held under the requirement of 14 CFR 399.75 discussed the subject of whether a consumer can make reasonable self-determination regarding contracting a serious communicable disease. In the Notice announcing the hearing, the Department requested interested parties to provide information on airlines' and ticket agents' current practice in handling consumers' requests to cancel or postpone travel due to contracting a serious communicable disease. The Department further asked for data on the volume of such requests, the volume of requests that were considered fraudulent, and the volume of requests that were not considered fraudulent but were rejected because they were deemed ''unreasonable self-determination.'' The Department also requested information on the costs to airlines and ticket agents to verify consumers' claims regarding contracting a serious communicable disease and the type of diseases being claimed as a reason to postpone or cancel travel.

During the March 21 public hearing, a representative of FlyersRights commented that consumers can make reasonable self-determinations regarding contracting a serious communicable disease. He specifically mentioned that during the COVID–19 pandemic, many passengers avoided flying when they self-determined that they were COVID-positive. A representative from National

[88] Among the four members of ACPAC, three members voted in support of this recommendation and the member representing airlines abstained, stating that there are many terms in the proposal that are not clear and may cause more passenger confusion.

Consumers League stated that the Department should not accept the assumption that consumers cannot make reasonable self-determinations and that consumers will abuse this proposed right. He further argued that the proposal is consistent with the CDC's longstanding approach that advises people to stay home while they are sick. On the subject of abuse, he stated that should an airline determine that a passenger is serially abusing this right, nothing would prevent the airline from refusing service to such a passenger in the future. On the cost of the proposal, he commented that the Department should not accept the assertion that consumers exercising this right will significantly increase cost to airlines. In that regard, he pointed out that airlines are required to issue credits, not refunds, which means they can continue to earn interest from the money consumers used to purchase the tickets, until the credits are used. He further commented that airlines can also sell the vacated seats, likely for a higher price because it would be closer to travel dates.

Several airline representatives provided comments during the public hearing. One A4A representative commented that nearly all the data sought by the Department in the public hearing notice does not answer the question that is the subject of the hearing because there is no current standard applied for seeking credits or refunds for a ''serious communicable disease'' and that the information sought by the Department would have nothing to do with the reasonableness of consumers' self-determinations. Two representatives from MedAire spoke at the hearing at the request of A4A and IATA. One speaker commented that from his experiences as a medical doctor for MedAire, he strongly believes that self-determining a medical condition regarding communicable disease is not a simple matter. He opined that properly trained medical professionals are the only ones who can ultimately make these determinations. He concluded that if the practice of self-determination is to be entertained, strict and specific criteria need to be applied, and such criteria should be subject to changes according to prevailing public health guidance issued by central health authorities. The other speaker from MedAire commented that the Department should analyze the topic from an operational perspective. He stated that MedAire trains crew members on how to handle medical conditions and how to comply with the Air Carrier Access Act regulation, 14 CFR part 382. He stated that there could be confusion among crew members and customer service agents regarding the requirement of this NPRM and the requirement of Part 382. He expressed his concern that the terminology associated with Part 382 and the terminology proposed in this NPRM, such as ''direct threat'' and ''serious communicable disease,'' is not aligned and that the Department should look into achieving some alignment to avoid confusion. A doctor from Harvard medical school also spoke at the request of A4A and IATA. As an expert in airborne transmission of disease during transportation and a lung physician, he stated that his perspective is to try to assess the potential for individuals to judge whether they have a serious transmissible infection. He indicated that for diseases such as COVID that can be tested at home, there is consensus that an individual who tested positive should not travel. He commented that, however, there are a variety of viral respiratory infections for which there are no tests. He opined that even erring on the side of assuming there was a respiratory infection, particularly when accompanied by a fever, during a pandemic or endemic, it is still difficult for an individual to be sure that they have a disease that is communicable. He expressed his concerns about the accuracy of self-determination as well as the potential for a reasonable public health precaution being used by individuals who change travel plan for reasons not related to health. He concluded that it is very difficult to self-determine that one has a serious communicable disease in a way that is operationally honest and fair to both sides.

Next, an IATA medical advisor specializing in occupational and air space medicine provided comments. He pointed out that airlines today already regularly accommodate passengers by offering travel credits or vouchers to passengers who have been diagnosed by a medical doctor as having a communicable disease that could threaten the health of other passengers on an aircraft, and airlines normally make the determination on the validity of the passenger's claim through reviews of the medical documentation provided by airline medical advisers, either in house or contracted by external organizations such as MedAire. He stated that he believes a final rule in this area must provide greater guidance as to what should or should not be considered a threat to other passengers in an aircraft environment. He stated that the medical system is based on the premise that trained medical professionals are best positioned to diagnosis diseases, weigh medical risks, and prescribe appropriate management. He concluded that any final rule in this area must require passengers seeking a refund or voucher to present documentation verifying that a medical professional has seen the passenger and assessed them for a particular serious communicable disease and that the presence of that passenger in the aircraft threatens the safety of other passengers. In that regard, he urged the Department to eliminate the self-diagnose option from any final rule, to provide a short list of likely conditions of concern, to require that any definition of communicable disease recognize the unique nature of aircraft environment, and to provide that the airline's medical service be given the final determination in any case of doubt.

Following the March 21 public hearing, A4A and IATA filed supplemental comments to reiterate their positions that consumers cannot reasonably self-diagnose and medical professionals are best positioned to diagnose and proscribe appropriate treatments. This position is supported by Spirit. USTOA also supported the airlines' position and added that, if the Department moves forward with this proposal, it should be limited to consumers who present a medical attestation completed by a licensed physician who is actually treating the individual.

DOT Responses: After considering all the comments, the Department is requiring airlines to provide travel credits or vouchers to consumers who are advised by a medical professional not to travel, irrespective of a public health emergency, because the consumers have or are likely to have contracted a serious communicable disease and would pose a direct threat to the health of others. An airline may require documentation from a passenger under these circumstances absent a public health directive or order issued by HHS stating that requiring medical documentation is not in the public interest.

This final rule differs from the proposal in that it allows airlines to require documentation from a licensed medical professional that the passenger has or is likely to have a serious communicable disease and the consumer's condition is such that traveling on a commercial flight would pose a direct threat to the health of others. Under this final rule, unless directed otherwise by HHS, airlines are not required to accept consumers' self-diagnosis as evidence that they

contracted a serious communicable disease ''consistent with'' public health guidance as proposed. The Department has determined that a documentation requirement is in the public interest as it would prevent consumer confusion on whether they should or shouldn't take a flight and minimize likelihood of fraud or abuse.

In addition to allowing airlines to require medical documentation, the Department has made other smaller changes in response to the comments received in the docket and at the public hearing. Regarding covered passengers, we agree with airline and ticket agent commenters that the phrase the consumer ''may have contracted a serious communicable disease'' could potentially be misunderstood should individuals self-diagnose whether they have a communicable disease. As stated in the prior paragraph, under this final rule, airlines are not required to accept the assertion by consumers, based on self-diagnosis, that they contracted or may have contracted a serious communicable disease as evidence of their eligibility for credits or vouchers. However, the Department disagrees with some airlines' suggestion that the Department eliminate the term ''may have'' entirely and only include passengers who have been clinically confirmed to have a serious communicable disease. As medical professionals indicated during the public hearing, some communicable disease cannot be diagnosed with a simple test that can be administered at home or at a clinic. Instead, diagnosing certain serious communicable diseases would require much more comprehensive medical procedures. Also, at the public hearing, a medical expert stated that during a pandemic or epidemic when a communicable disease is known to be widespread, public health experts may tend to be in favor of erring on the side of assuming infection when an individual displays typical symptoms of a communicable disease and there is no confirmation of infection available. Further, requiring a confirmed diagnosis for a disease, particularly when readily available testing is not an option, does not serve the public interest. Accordingly, instead of a passenger who ''may have'' contracted a serious communicable disease, the final rule uses the term ''is likely to have'' contracted a serious communicable disease and, in absence of HHS stating that requiring medical documentation is not in the public interest, an assertion that a passenger ''has or is likely to have'' a serious communicable disease must be supported by credible medical documentation. The Department believes that this amendment to the NPRM proposal enhances clarity and will reduce fraud and abuse, while ensuring that the rule appropriately includes passengers who don't have a confirmed diagnosis but were considered likely to have an infection by a treating medical professional so they are incentivized to postpone travel while medically considered to be potentially contagious.

Also, on the scope of protected passengers, the final rule clarifies that when a passenger who has or is likely to have a serious communicable disease purchased a ticket is irrelevant to the passenger's eligibility for a travel credit or voucher. As stated in the legal authority section, the Department believes that it is unreasonable to expect a passenger to purchase a refundable ticket or travel insurance for the purpose of gaining more flexibility to postpone travel due to contracting a serious communicable disease when a public health emergency has not been declared. Passengers who purchased their tickets during a public health emergency, however, could reasonably have imagined contracting a serious communicable disease and could have purchased a refundable ticket or travel insurance to avoid risk of financial loss. Nevertheless, an airline's practice of not providing travel credits or vouchers to those passengers is an unfair practice because it is likely to cause harm to the health of other passengers, which they cannot reasonably avoid if the potentially infected passengers choose to continue travel to avoid financial loss as set forth in section IV.1(i).

Regarding comments to align the definition of ''direct threat'' and ''serious communicable disease'' in this proposed rule to the definition of those terms in the Department's disability regulation, the Department views that these terms as used in this final rule to be consistent with the terms as used in the disability regulation. The Department's regulation implementing the Air Carrier Access Act, 14 CFR part 382, provides that a ''direct threat'' is a significant risk to the health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures, or by the provision of auxiliary aids or services.[89] We note that the context for the ''direct threat'' assessment under Part 382 is different from the context here. In Part 382, the regulatory goal of requiring carriers to conduct a ''direct threat'' assessment is to ensure that carriers apply reasonable standards to determine that the carriage of a passenger would pose a direct threat to others before imposing travel restrictions on or denying boarding of the passenger who wishes to travel despite having contracted a communicable disease. Here, however, the goal of the regulation is to ensure that carriers apply a reasonableness standard to determine whether the assertion by the passenger's treating medical professional of posing a direct threat is sufficiently valid to warrant the issuance of travel credits or vouchers to a passenger who wishes to postpone travel. Nonetheless, in both regulations, the determination of ''direct threat'' is based on the same set of objective, factual, and science-based standards that looks into the nature of the communicable disease, the consequence of the disease, the likelihood of disease transmission in the aircraft cabin by casual contact. With respect to the term ''serious communicable disease,'' as explained earlier in this document, the definition of this term as adopted in this final rule is consistent with that of Part 382.

8. Supporting Documentation

The NPRM: The Department proposed to allow carriers and ticket agents, as a condition for issuing travel credits or vouchers, to require certain documentation dated within 30 days of the initial departure date of the affected flight. For consumers stating an inability to travel due to a government restriction or prohibition in relation to a serious communicable disease, the Department proposed to allow carriers to require the government order or other document demonstrating how the consumer's ability to travel is restricted. The Department explained that a quarantine isolation order or a border closure notice or entry restriction issued by a government would all be acceptable documents. The Department added that even a local stay at home order that restricts local travel would be reasonable if it impacts the passenger's entry or exit of the local vicinity through air travel. For consumers stating that they are not traveling because they have been advised by a medical professional or have self-determined consistent with public health guidance not to travel by air to protect themselves from a serious communicable disease, the Department proposed to allow carriers to require the applicable guidance or a written statement from a licensed medical professional attesting that it is the medical professional's opinion that the consumers should not travel by commercial air transportation to protect themselves. The Department

[89] 14 CFR 382.3.

made clear that a general fear about traveling when there is a public health emergency declared would not be sufficient to entitle that passenger to a travel credit or voucher. For consumers stating that they have been advised by a medical professional or self-determined consistent with public health guidance not to travel because they have or may have contracted a serious communicable disease that poses a direct threat to the health of others, the Department proposed to allow carriers to require the applicable guidance or a written statement from a licensed medical professional attesting that it is the medical professional's opinion that the consumer should not travel by commercial air transportation to protect the health of others. Under the proposal, the type of document that a carrier could require of consumers seeking not to travel to protect themselves or others would be dependent on whether the consumer was advised by a medical professional or making a self-determination based on public health guidance. To the extent that a passenger is providing a written statement from a medical professional, the Department proposed to permit airlines and ticket agents to request that the documentation be current.

The Department asked whether the types of information that the Department would allow airlines and ticket agents to seek from passengers is adequate; whether there are ways to reduce or prevent passengers from falsely claiming that they have a serious communicable disease without airlines and ticket agents requesting documentation from passengers about their health; whether the Department should specify that the medical documentation explain the reason that the passenger is more susceptible than others to contracting a serious communicable disease during air travel and whether there are any implications on privacy concerns; and whether the proposal that medical documentation be dated within 30 days of the initial departure date is reasonable and appropriate.

Comments Received: Several airline commenters were concerned about the term ''medical professional,'' asserting that the term is too broad and potentially invites fraud. Commenters stated that this issue is analogous to the emotional support animal (ESA) situation under the Department's Air Carrier Access Act rule prior to its revision in 2020, which required carriers to accept ESAs as service animals provided that passengers present medical documentation from a licensed mental health professional. They further asserted that like the ESA regulation, the proposed rule here allows unscrupulous passengers to take advantage of the undefined term by seeking documentations from a broad range of medical professionals who may have no knowledge about the relevant information sought, or even purchasing documentations from online sources without actual medical treatment or evaluation.

A4A commented that a more robust documentation scheme will reduce the likelihood of travel credits being sought by ineligible passengers. A4A suggested that similar to the 2020 service animal final rule,[90] the Department should prescribe a government form that includes a warning of the potential Federal criminal penalty under 18 U.S.C. 1001 for any person to knowingly or willfully make materially false or fraudulent statements to obtain travel credits. A4A further suggested that the form should be dated within 15 days of the departure and should require certain information including the passenger's name, date of birth, diagnosis, method of diagnosis, test result, information regarding the medical professional (name, license information, location, signature), a clear statement that the passenger should not travel, a statement regarding when the passenger can travel again. IATA supported A4A's suggestion that the medical documentation should include a criminal penalty warning and that the documentation should be dated within 15 days of departure. IATA further commented that it does not see any privacy concerns on requiring medical attestation from passengers because passengers are choosing to waive their rights to privacy to avoid losing the money invested in the tickets. Allegiant commented that the proposed documentation requirement creates opportunities for abuse when passengers only need to present a doctor's note stating that they may have a serious communicable disease. Allegiant opined that this will become a refuge for passengers who want to avoid paying ticket change fees.

Air Canada expressed its concerns about the burden of carriers' manually reviewing and assessing documentations, arguing that different public health policies adopted by different countries and subjective interpretations will create a complex and ever-changing set of rules that would greatly interfere with carriers' ability to sell seats with predictability. It further suggested that the Department should remove all documentary evidence that requires a subjective assessment of a passenger's condition or reason not to travel to avoid the burden and costs to carriers associated with a manual review process.

A number of individual commenters also provided their views on the proposed documentation requirement. One individual commenter recommended that medical documentation should be required only when the communicable disease is not demonstrable via a test result. Another commenter stated that the ''medical professionals'' issuing the documentation should include not only physicians, but also other primary care providers such as nurse practitioners or physician's assistants. In contrast, another individual opined that the proposal failed to provide guidance regarding the types of medical professionals who are qualified to issue the documentation, resulting in a broad scope of the type of medical professionals that is untenable to airlines. One individual commented that the scope of the types, formats, and language of the proposed documentation requirement is enormous, and verifying their authenticity will be burdensome, with a high possibility of fraud. This commenter suggested that the Department consider imposing stricter requirements to prevent abuse. Another individual commenter expressed concerns about fraud and abuse and argued that consumers should be required to provide a certification from a registered medical professional or positive test result from a professional third party (as opposed to a home test kit).

The Department also received comments from ticket agent representatives on the issue of documentation. USTOA agreed with airline commenters and argued that the Department should define the scope of qualifying public health guidance and medical professionals to ensure clarity on the required documentation. It further echoed airlines' comments that the Department should prescribe the medical form that includes a warning of Federal crime for false statements. USTOA further commented that ticket agents should be able to require that documentation be in English or in any other language of their choice to avoid the cost of translation. Travel Management Coalition stated that it should be entirely airlines' responsibility to require health-related evidentiary documents and that ticket agents should not be involved in determining whether passengers are

[90] *Final Rule, Traveling by Air With Service Animals,* 85 FR 79742, Dec. 10, 2020.

entitled to travel credits. In that regard, it offered that, to limit the number of parties involved and to protect passenger privacy, passengers should provide documentation directly to airlines even if ticket agents are the merchants of record for the ticket sales.

The ACPAC discussed the issue of defining ''medical professional'' and recommended to the Department to replace the term ''medical professional'' with the term ''treating physician,'' and adopt the definition for ''treating physician'' as the following:

A ''treating physician'' means an individual who is licensed or authorized under state law to engage in the practice of medicine or the practice of osteopathic medicine and surgery, who furnishes a consultation or treats a patient for a specific physical or mental health condition, and who may use the results of a diagnostic test in the management of the patient's specific physical or mental health condition. For purposes of this rule alone, the term ''treating physician'' includes physicians, osteopaths, nurse practitioners, social workers, licensed professional counselors, psychiatrists, physician's assistants, and other medical providers who are licensed in the state in which the treatment is or has been provided and who are allowed, pursuant to state and federal licensing regulations, to provide individualized care to the patient without medical supervision by another medical provider.[91]

Public Hearing: DOT also addressed the topic of whether the proposed documentation requirements (medical attestation and/or public health guidance) are sufficient to prevent fraud in the notice announcing the March 21, 2023, public hearing. In the notice, DOT asked participants to provide information on whether medical attestations currently provided to airlines from consumers seeking to cancel or postpone travel are primarily based on consumers' self-assessments, medical professionals' assessments, or a combination of both; the types of medical professionals currently providing the attestations accepted by airlines and ticket agents; the types of public health authority-issued guidance currently affecting air travel; and airlines' validation of medical attestations, including the procedures, the volume, and the costs associated with the validation.

During the hearing, the representative from FlyersRights and the representative from National Consumers League both spoke against airlines' argument that the situation of passengers fraudulently claiming a communicable disease is analogous to the situation where a small percentage of passengers fraudulently obtain paperwork that allows them to bring a pet animal onboard as an ESA. They stated that in the matter regarding ESAs, airlines faced potential injury of losing revenue for transporting the animals as a pet as well as potential safety and health concerns. They pointed out that in contrast, there is little incentive for consumers to engage in fraud here because the appeal of fraud is to net a monetary gain and there is no monetary gain in this instance when a consumer simply avoids a loss of the money that they already paid by obtaining a travel credit or a voucher. They view DOT's proposed requirement as sufficient and well-conceived and urge the Department to disregard the industry petitioners' concerns, which they believe rest on a flawed assumption that consumers will have such an incentive to obtain travel credits under the proposal and that the cost will outweigh public health and consumer protection benefits. The consumer advocates argued that no rule will completely prevent fraud, and instances of fraud should be investigated and punished.

A representative from A4A commented that the hearing request initiated by the airline industry on this issue is broader than the questions posed by the Department in the hearing notice. He commented that the data sought by the Department in the hearing notice will not answer the questions at hand. Specifically, he stated that both the basis of current medical attestations provided to airlines by consumers, and the types of medical professionals currently providing such attestations have no bearing on the actual adequacy of the documentation to prevent fraud under the proposed standards for credits or refunds, especially when airlines' current standards differ from those proposed. He further stated that U.S. airlines typically don't provide credits or refunds when the passenger only *may have* a communicable disease or when the consumer wants to protect him or herself from a communicable disease. He noted that Part 382 requires the medical professional to be, at least, the passenger's physician, and even with that, the airline can require the passenger to undergo specific review under certain circumstances. He also commented that the types of guidance ''affecting air travel'' issued by public health authorities currently has no bearing on whether providing such information is adequate to prevent fraudulent claims. He opined that what matters is the guidance related to communicable diseases and whether, with no other information presented to the airline, simply providing such guidance would allow the airline to determine whether the consumer is making a fraudulent claim. He concluded that the proposed documentation standard will only confuse consumers into believing that they can submit unsubstantiated attestations or public health guidance to support their claims.

A representative from MedAire, which provides medical advisory services to airlines, stated that he was commenting strictly from a medical standpoint and without considering the economic aspects around the question. From that perspective, the MedAire medical expert stated that a public health authority-issued criteria and guidelines in concert with a properly trained medical professional to diagnosis and to attest the presence of a transmissible disease is the ideal and the best practice possible to minimize fraud and abuse to a manageable level.

A representative from A4A commented that A4A's concerns regarding the proposals go beyond fraud and asserted A4A's belief that the proposal is impractical and unworkable and an example of regulatory overreach by a transportation regulatory agency lacking expertise in the area of public health. He offered that A4A members that currently accept medical documentation in connection with passenger-initiated itinerary changes typically require the documentation to be in the form of a medical professional document issued by a treating physician, and in cases where documentation from a non-treating physician is allowed, the airlines would require the documentation to be on official letterhead. He stated that the current level of fraud is low because most airlines' policies would not contemplate allowing passengers to self-certify their conditions or produce public health guidance without accompanying statement by a treating physician.

On the Department's request for information regarding the types of public health authorities that issue guidance affecting air travel, the A4A representative stated that many airline

[91] This definition, based on Michigan law and regulation of Centers for Medicare & Medicaid Services, is provided by the State Attorney General of Michigan, who is a member and chair of the ACPAC. Two additional members representing consumer rights advocacy groups and airports, respectively, support this recommendation. The member representing A4A is against the recommendation, stating that it includes practitioners such as social workers and psychiatrists who would not be treating an infectious or communicable disease. The member further reiterated that A4A's belief that ''treating physician'' should be treating the person for the infectious disease or serious communicable disease based on which the consumers are seeking flight credit.

members do not routinely track this information because, in the current environment, change and cancellation fees for most fare types have been eliminated. He further identified various aspects of the NPRM that A4A believes depend on factual issues that are genuinely in dispute. First, he stated that DOT assumes in the NPRM that the medical professional completing the attestation possesses sufficient knowledge of not only the communicable disease but also the passenger's current condition. He asserted that if this medical professional is not the passenger's treating physician and has not examined the passenger, the reliability of the documentation becomes highly questionable and the possibility of fraud is heightened. Second, he stated that DOT's finding that the required production of relevant public health guidance will reduce fraud assumes such guidance will be given due to the person's condition. He asserted that, for example, guidance recommending an individual having been exposed to serious disease refrain from travel for a set number of days would not prevent unscrupulous individuals who have not had any exposure from misusing the guidance. Third, he stated that the NPRM assumes that the guidance produced by the passenger will be authentic, yet there's no provision in the draft rule text addressing validation by airlines. Fourth, he commented that DOT's implicit assumption is that airlines have the ability, if they so choose, to confirm the authenticity of the documentation through reasonable inquiry without external efforts. He offered that this is not the case, for example, with public health guidance not widely posted on a governmental website. Lastly, he disputed two claims made in the NPRM. Regarding DOT's claim that the proposal will promote public health by discouraging travel by persons who have contracted or been exposed to a communicable disease, he commented that this is highly questionable given that there's little to no correlation between the non-expiring travel credit proposal and slowing communicable disease spread, a point that A4A asserts the Department's own regulatory impact analysis concedes. Regarding DOT's claim that it will benefit consumers by protecting their financial interests and expenditures made on tickets, he commented that any such benefit may be eliminated by the proposal's longer-term impact on ticket pricing. He elaborated that airlines will not be able to resell seats suddenly returned to inventory because of passengers who have availed themselves of the non-expiring travel option. He stated that to recoup their losses and account for the longer-term liability of non-expiring travel credit, airlines may have to increase fares, and, in some cases, that means routes may be rendered uneconomical, potentially leading to service cuts.

An economist from A4A spoke on data aggregated by A4A on significant fraud associated with customers who claim that their pets were ESAs, arguing that the topic of ESA is relevant to this hearing because it demonstrates why carriers are concerned about the potential fraud that will result from this rulemaking. He commented that the ESA issue also demonstrated that fraud occurs when a regulation fails to define or loosely defines terms and allows passengers to make suggestive interpretations that carriers are prevented from disputing, questioning, or validating. He stated that the ESA data clearly demonstrates that fraud was extensive and substantial. According to the speaker, from 2016 to 2019, the number of ESAs traveled had more than doubled, skyrocketing from 540,000 in 2016 to 1.13 million in 2019. He stated that DOT ultimately changed the definition of a service animal to exclude ESAs. He commented that this rulemaking similarly creates new, ambiguous, and inconsistent standards, including medical related standards unknown to Federal health agencies regarding ''serious communicable disease.'' Next, he commented that U.S. airlines have been and remain responsive to refund requests and frequently exceed DOT recommendations regarding consumer protections. He provided that the annual cash refunds in 2021 and 2022 exceeded pre-pandemic 2019 level and in 2022, the 11 largest U.S. carriers issued $11.2 billion in refunds. He noted that DOT received less than one complaint about refunds for every 100,000 passengers. He concluded his presentation by stating that there is no evidence of a market failure or unfair or deceptive practice in this area.

DOT Responses: The Department is continuing to allow airlines, as a condition for issuing travel credits or vouchers, to require certain documentation. This final rule differs from the proposal in that it allows airlines to require current medical documentation from consumers as evidence that they are not traveling to protect themselves or others from a serious communicable disease. Airlines are not required to accept consumers' self-diagnoses that they contracted or may have contracted a serious communicable disease ''consistent with'' public health guidance and providing the applicable guidance as proposed. An airline's ability to require medical documentation from a passenger under these circumstances is conditioned on the absence of a public health directive or order issued by HHS stating that requiring medical documentation is not in the public interest. For consumers stating an inability to travel due to a government restriction or prohibition in relation to a serious communicable disease, the Department has not changed the documentation allowed from what was proposed at the NPRM stage but specifies that the documentation must be current. This final rule permits carriers to require passengers provide a *current* government order or other document demonstrating how the consumer's ability to travel is restricted. A government order is current if it is valid for the planned travel date.

After carefully reviewing the comments provided, as well as the ACPAC recommendation, the Department has decided to specify that the medical documentation must be from a licensed *treating* medical professional and define that term. The Department is adopting a definition for ''licensed treating medical professional,'' to mean an individual, including a physician, a nurse practitioner, a physician's assistant, or other medical provider, who is licensed or authorized under the law of a State or territory in the United States or a comparable jurisdiction in another country to engage in the practice of medicine, to diagnose or treat a patient for a specific physical health condition that is the reason for the passenger to request a travel credit or voucher. The Department believes that limiting the medical professionals to those who provide or have recently provided diagnoses or treatment to passengers for the specific health condition that is the reason for requesting the travel credits or vouchers will better ensure passengers do not rely on persons who have no medical knowledge about their health conditions. The Department notes that the licensed treating medical professional may provide in-person medical diagnosis and treatment as well as virtual diagnosis and treatment, as deemed appropriate by common medical practice. The Department also notes that treating medical professionals may include a primary care provider or a specialist that treats the passenger on a regular basis, as well as medical professionals that the passenger sees on an ad hoc basis, such as care providers

from a walk-in clinic, an emergency care facility, or a medical facility that the passenger visits while away from home.

Regarding the treating medical professional's license, the definition requires that the medical professional be licensed in a State or territory of the United States or a comparable jurisdiction in another country. In that regard, the rule allows carriers to require that the documentation be on the medical professional's letterhead and include information on the type and date of the medical professional's license, the license number, and the state or other jurisdiction in which it was issued. The Department interprets ''comparable jurisdiction in another country'' to mean the appropriate governing body in a foreign country that oversees the issuance of medical licenses, either at a national or state level.

For medical documentation provided by passengers who seek travel credits or vouchers due to an underlying health condition, the rule allows carriers to require that the medical documentation be current, specify that the passenger has an underlying health condition that is being treated or has recently been treated by the medical professional, and that based on the licensed treating medical professional's opinion, including references to relevant public health guidance if available and applicable, the passenger should not travel on a commercial flight during a public health emergency to protect his or her own health. To protect passengers' privacy, carriers may not insist that the documentation specify what the underlying health condition is. Further, because this medical documentation specifically concerns the passenger's planned travel during a public health emergency, to ensure that the medical documentation is ''current'' with respect to the passenger's medical condition, carriers may require that it be dated after the declaration of the public health emergency but be within one year of the scheduled travel date.

For medical documentation provided by passengers seeking travel credits or vouchers because the passenger has contracted or is likely to have contracted a serious communicable disease, the rule allows carriers to require that the documentation be current, specify that the medical professional has recently diagnosed and/or provided medical care to the passenger with regard to a serious communicable disease, and be based on the licensed treating medical professional's opinion, including reference to relevant public health guidance if available and applicable, that the passenger has contracted or is likely to have contracted a serious communicable disease and should not travel on commercial flights to protect the health of others on the flights. The carriers may further require the medical documentation provide a medically reasonable timeframe during which the passenger is advised against travel. The purpose of the medical documentation under this rule is to attest that it is the medical professional's opinion, based on current medical knowledge about the serious communicable disease at issue and the passenger's current health condition, that the passenger should not travel to protect others from that serious communicable disease. This rule allows carriers to apply a reasonable standard to determine whether medical documentation is current. For example, if according to public health guidance on a particular communicable disease, an individual would normally remain contagious for 15 days from the date of diagnose or onset symptom, it would be reasonable for carriers to interpret that ''current'' medical documentation means the documentation is dated within 15 days of the scheduled departure. The Department believes that this flexibility serves the public interest by allowing carriers to tailor the medical documentation's validity period based on objective and scientific information, *i.e.,* the common contagious period of a particular communicable disease, therefore screening out passengers who would generally have passed the contagious period on the travel date while ensuring that passengers who are likely to pose a direct threat during travel will not be unduly burdened to seek medical documentation very close to the travel date.

In addition to addressing the date of the supporting documentations that must be ''current,'' the Department has considered the timing of passengers providing the current documentation to airlines when requesting a travel credit or vouchers. Although it is conceivable that passengers requesting travel credits or vouchers based on a government travel restriction would have the ability to provide the documentation right away because the government orders are readily available to the public, passengers requesting travel credits or vouchers based on a health condition may need additional time to schedule a visit with a medical professional and obtain the documentation. The Department is concerned that the rule would not effectively protect consumers as intended if airlines are permitted to require that the medical documentation must be provided before the planned travel date. For example, if a public health emergency was declared right before a passenger's travel date, and the passenger has an underlying health condition that would put the passenger at risk during travel, the passenger would be deprived the required credit or voucher because there is no time to obtain a medical documentation before the travel date. Further, passengers could be infected with a serious communicable disease very close to the travel date but there is not enough time to seek an appointment with a treating medical professional and obtain a medical documentation before the scheduled travel date. In such situations, the final rule requires that carriers allow a reasonable time for the passenger to provide relevant medical documentation after the scheduled travel date as long as the passenger notifies the carrier before the flight's departure about the illness. The carrier may wait to issue the travel credit or voucher until receiving current medical documentation within that time period. The Department notes that, although the medical documentation may be dated after the scheduled travel date, carriers may require that the documentation specify that based on the licensed treating medical professional's opinion, including reference to relevant public health guidance if available and applicable, the passenger has contracted or is likely to have contracted a serious communicable disease and should not travel by air on the scheduled travel date to protect the health of others on the flight. The Department believes that requiring airlines to provide a reasonable time for passengers who suffer acute illness close to travel dates to submit medical documentation allows passengers to seek medical diagnoses and obtain written documentation to prove their eligibility for travel credits or vouchers and avoid the situation that passengers choose to travel while feeling ill for fear of losing the money paid for the tickets, potentially endangering others on the flight.

The Department has also decided against creating a Federal medical form that includes a criminal penalty warning for false statements, as some carriers and ticket agents have suggested. We do not agree that a DOT form is the best format to incorporate all the information permitted by the rule. Each passenger's health condition (including the underlying heath condition increasing their risk level while traveling during a public health emergency or their personal medical history of a serious communicable

disease infection) may be different, which warrants more flexibilities for medical professionals to customize content in the medical documentations that they prepare. The Department has also taken into account consumer rights advocacy groups' view that consumers in situations discussed here may be less likely to commit fraud or abuse the regulatory protection in comparison to situations related to ESAs as suggested by carriers because consumers requesting travel credits or vouchers due to a serious communicable disease have already paid airlines for their travel and the potential net gain of abusing the consumer protection requirement is simply avoiding paying a ticket change fee. The Department also agrees with consumer rights advocacy groups that airlines have effective tools to investigate and pursue punitive actions against serial offenders who repeatedly engage in fraudulent actions to receive travel credits or vouchers, including banning the individual from traveling on their flights. In conclusion, the Department is confident that the criteria for the documentations listed in the rule that carriers may request and carriers' own deterrence tools would place adequate safeguards against fraud and abuse.

9. Travel Credits or Voucher

The NPRM: In the NPRM, the Department addressed various issues regarding the travel credits and vouchers to be provided to passengers due to government restrictions or health concerns related to a serious communicable disease. These issues concern: (1) the appropriate validity period of the credits or vouchers provided to consumers, including whether an indefinite validity period for credits or vouchers issued under this proposal is reasonable (2) the transferability of the travel credits or vouchers to others; (3) the value of the travel credits or vouchers, including establishing a minimum value of equal to or greater than the airfare and allowing a deduction from the credit or voucher for service charges by ticket agents when issuing the original ticket and credit/voucher processing fees by airlines and ticket agents; and (4) the disclosure of any material restrictions, limitations, or conditions on the use of the credits and vouchers. More specifically, the Department proposed to require airlines and ticket agents provide covered passengers non-expiring credits or vouchers for future travel and invited comment on requiring that the travel credits or vouchers be transferrable at the consumers' discretion. The Department also proposed that the travel credits or vouchers issued to these consumers be ''a value equal to or greater than the fare (including government-imposed taxes and fees and carrier-imposed fees and surcharges).'' Further, the Department proposed to allow airlines and ticket agents to charge a processing fee for the issuance of credits or vouchers and sought comment on whether allowing ticket agents to retain the service fees charged when issuing the original ticket is reasonable and appropriate.

(1) Validity Period and Transferability

The Department proposed to require that airlines and ticket agents provide non-expiring credits or vouchers for future travel to qualifying consumers. The Department sought comments on whether an indefinite validity period for credits or vouchers issued under this proposal is reasonable, and if not, why and what a reasonable minimum validity period should be. Commenters were encouraged to provide information on what challenges airlines and ticket agents may face when accommodating the redemptions of travel credits and vouchers that have no expiration dates. Also, the Department sought comments on whether it should require that the travel credit or voucher be transferrable at the consumers' discretion. The Department explained that transferability would ensure that eligible consumers who spent money on tickets that they no longer need wouldn't completely lose the value of the tickets.

(2) Value of Tickets and Processing Fees To Issue Travel Credits and Vouchers

The Department proposed that the travel credits or vouchers issued to qualified consumers be ''a value equal to or greater than the fare (including government-imposed taxes and fees and carrier-imposed fees and surcharges).'' The Department also proposed that the credits or vouchers include any prepayment of unused ancillary services such as baggage fees or seat selection fees as those services have not been provided by the carrier.[92] The Department asked whether airlines should be required to offer an option to consumers in which consumers may choose to receive the travel credit or voucher redeemable for the same itinerary as the original ticket, regardless of what the ticket cost is at the time of redemption, noting that as airfare fluctuates, some consumers may benefit from and prefer this option if they plan to travel on the same itinerary in the future without worrying about price increases, while airlines may benefit when the redeemed tickets are priced less than the original purchase price of the ticket.

Based on the Department's view that neither the airline or ticket agent initiated the communicable disease-related change that is resulting in the need for a credit or voucher, we proposed to allow airlines and ticket agents to charge a processing fee for the issuance of credits or vouchers to non-refundable ticket holders when consumers' travel plans are affected by concerns related to a serious communicable disease, provided that the fee is on a per passenger basis and appropriate disclosures were made to the consumer prior to the consumer purchasing the airline tickets. The Department sought comments on whether it is reasonable to permit airlines and ticket agents to charge a processing fee for the issuance of travel credits or vouchers, and if so, what type and manner of disclosure would be sufficient to avoid consumer confusion for fees applicable for these specific circumstances.

(3) Restrictions and Disclosures

The Department proposed to prohibit conditions, limitations, and restrictions imposed on the credits and vouchers that are unreasonable and would materially reduce the value of the credits and vouchers to consumers as compared to the original purchase prices of the airline tickets. The Department provided a list of examples that would be deemed unreasonable under the proposal. These examples included a credit or voucher that: would severely restrict bookings with respect to travel date, time, or routes; can only be used on one booking and voids any residual value; or would impose a booking fee for a new ticket that reduces the value of the voucher or credit available to be used on the new ticket. With regard to material restrictions, limitation, and conditions on the use of the credits and vouchers that are not deemed unreasonable, the Department proposed to require airlines and ticket agents provide full disclosure. The Department sought comments on whether regulating the terms and conditions of the credits or voucher in this specific context is reasonable and what other steps the Department should consider ensuring that passengers

[92] The Department's rulemaking on *Refunding Fees for Delayed Checked Bags and Ancillary Services That Are Not Provided* proposes that airlines must refund any ancillary service fees when a passenger traveled on the scheduled or an alternative flight and the service was not provided. *See* 81 FR 75347. That proposal is discussed and finalized in Section III of this rule.

receiving credits and vouchers for future travel are adequately protected.

Comments Received: The Department received comments on these issues from airlines, ticket agents, and consumer rights advocates with the validity period for the travel credits and vouchers being the most controversial.

(1) Validity Period and Transferability

A4A expressed strong concerns about the proposal requiring that the credits or vouchers be non-expiring, arguing that such requirement would lead to rampant fraud and abuse, exposing carriers to significant financial and accounting liabilities. A4A commented that the requirement would (1) impose financial hardship on carriers by building up significant liability on their accounting books that materially harm credit ratings; (2) impose administrative costs to carriers by requiring permanent record retention and data access on ticket and voucher records; (3) cause technical issues to distribution systems as those systems need an expiration date populated to function; (4) raise tax issues because airlines have to absorb taxes remitted to governments that cannot be refunded and repurposed if consumers elect to not travel within a reasonably short timeframe; and (5) raise legal compliance issues under State escheat laws, if they are not preempted by the Department's authority. For these reasons, A4A recommended that the Department should not mandate the validity period of credits or vouchers longer than one year, and if the credits or vouchers are issued during a public health emergency and that emergency lasts beyond one year, the Department would require that the airlines extend the validity period by one year at a time. A4A's position was supported by IATA, RAA, Spirit, Qatar Airways, and SATA. These commenters also were against requiring the travel credits or vouchers be transferable, arguing that it would create a second-hand market that could lead to fraud.

The ACPAC discussed this issue and voted to recommend that the final rule require the travel credits or vouchers be non-expiring and transferrable.[93] Travelers United also supported the proposal to require the credits or vouchers to be non-expiring, stating that they should be treated as a store credit with no restrictions on booking and transferability. It further argued that the current airline credit rules are different from airline to airline and the Department should adopt a uniform and clear rule for credits and vouchers.

Most ticket agent representatives, including Travel Management Coalition, ABTA, USTOA, and Travel Tech, opposed requiring credits or vouchers be non-expiring. They argued that the non-expiring requirement creates uncertainties and long-term liability for airlines and ticket agents and unreasonable administrative and reporting burdens to them. DWHSA, on the other hand, supported the proposal to require credits or vouchers be non-expiring, arguing that if some airlines are currently offering non-expiring credits, all airlines should be able to do so.

(2) Value of Tickets and Processing Fees To Issue Travel Credits and Vouchers

On the value of the credits or vouchers, A4A commented that the Department should allow airlines to adjust the amount to reflect non-refundable foreign taxes. Several airline commenters expressed their support for the proposal to allow airlines and ticket agents to charge a service fee for the issuance of the credits or vouchers, and some commenters also support the disclosure requirement in relation to the service charge. On booking restrictions, A4A opined that DOT should not regulate specific terms and conditions of the credits or vouchers. Qatar Airways suggested that clarity is needed on the term ''severe restriction.'' A4A and IATA commented that the Department should let the market determine whether the credits or vouchers can be used for booking with one carrier or others. Qatar Airways, on the other hand, stated that the credits or vouchers should only be redeemed with the issuing airline.

Travelers United commented that all credits or vouchers issued under the proposals should be uniform and clear to passengers and the Department should ensure that any residual values after one booking be available to consumers. It further stated that the only limitation on the credits or vouchers should be that they must be used on the issuing airline. Travelers United also provided examples of existing restrictions that it believes to be unreasonable, including the requirement that the credits or vouchers cannot be used to pay ancillary service fees and the requirement that the credits or vouchers issued for a business class ticket can only be used to book another business class ticket.

As for processing fees, IATA, Spirit, AAPA, and Qatar Airways supported the proposal to allow airlines and ticket agents to charge a processing fee for issuing credits or vouchers. Several ticket agent representatives also supported the proposal. Two individual consumers commented that if airlines are allowed to charge a processing fee, there should be a cap or clearly defined limit to these fees. This individual opined that if airlines are given too much leeway to determine the amount of the fee, consumers may end up paying the fee that is the majority of the cost. Another individual commented that allowing airlines to charge a processing fee for vouchers would result in airlines charging a high fee, removing the consumer protection provided by the rule. Another individual commented that it is inconsistent for the Department to propose that the credits or vouchers be ''a value equal to or greater than the fare'' yet allow airlines to charge a processing fee.

(3) Restrictions and Disclosures

On booking restrictions, A4A opined that DOT should not regulate specific terms and conditions of the credits or vouchers. Qatar Airways suggested that clarity is needed on the term ''severe restriction.'' A4A and IATA commented that the Department should let the market determine whether the credits or vouchers can be used for booking with one carrier or others. Qatar Airways, on the other hand, stated that the credits or vouchers should only be redeemed with the issuing airline.

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ABTA opposed imposing a blanket requirement on what restrictions are permissible for the credits or vouchers, stating that these decisions should be made by each business on a case-by-case basis. USTOA also commented that the Department should not dictate the contractual terms of credits or vouchers.

DOT Responses:

[93] Three members representing consumer rights advocacy groups, State Attorneys General, and airports, respectively, voted for the recommendation. The member representing A4A voted against the recommendation, stating that the issue of transferability has not been analyzed and that requiring transferrable credits may result in fraud and abuse.

(1) Validity Period and Transferability

The Department has considered airlines' arguments against requiring non-expiring travel credits and vouchers and is convinced that although the non-expiring feature would provide consumers the maximum flexibility to use the credits or vouchers, the difficulty for airlines to manage and track these technically perpetual liabilities is not trivial. The Department, however, disagrees with airlines' suggestion that a one-year validity period is adequate to ensure that consumers have sufficient time to use the credits and vouchers. Although airlines suggest that the one-year period can be extended if a public health emergency extends beyond a year, the Department believes that the extension of travel credits or vouchers imposes administrative burdens to airlines and potential confusion and uncertainty to consumers. As such, we are adopting a final rule requiring that the travel credits or vouchers issued under the conditions related to a serious communicable disease be valid for at least five years from the date of the issuance. The Department views a five-year validity period to be a sufficient timeframe to ensure passengers who are affected by a serious communicable disease can use the credits or vouchers for future travel while not imposing undue burdens on airlines. The Department also notes that the five-year validity period is consistent with the Credit Card Accountability Responsibility and Disclosure Act of 2009 (CARD Act) [94] and the CFPB regulation implementing the CARD Act, 12 CFR 1005.20, which require that the expiration date of a store gift card or gift certificate cannot be earlier than 5 years after the date on which the gift certificate was issued. Although the travel credits or vouchers issued pursuant to this final rule are not ''gift certificates'' or ''store gift cards'' that are subject to the CARD Act and the CFPB rule,[95] the Department views that adopting a similar restriction on the validity period as the CARD Act and its implementing rule benefits consumers by avoiding potential confusions arising from different regulatory entities' regulations on electronic financial documents issued by businesses.

Further, the Department is requiring that the credits or vouchers issued under this final rule be transferrable to address concerns from numerous consumers regarding the situations relating to a serious communicable disease that make them unable able to use the travel credit or voucher due to their age, health condition, or other reasons. For example, in complaints received by the Department during the COVID–19 pandemic, some elderly passengers with a severe underlying health condition expressed that given their ages and the medical conditions they have, air travel will not be an activity that they would consider in the future even with the COVID–19 public health emergency coming to an end. Also, infrequent travelers who booked travel for a specific event that was canceled due to a serious communicable disease expressed concerns that they have no use for the credits or vouchers because they are not likely to have the need to travel in the foreseeable future. The Department views these concerns as reasonable grounds for requiring the travel credits or vouchers be transferrable so the air transportation that these consumers invested their money in can be utilized by others of their choosing before expiring.

The Department is not convinced by the airlines' arguments that transferability will invite and increase fraud. The initial issuance of the credits and vouchers under this rule are subject to conditions airlines are permitted to impose, including documentation proof for eligibility. Once they are issued to eligible consumers, whether the eligible consumers choose to redeem the credits or vouchers on their own or transfer to another individual would not make a difference to the airlines financially. We are also not troubled by a secondary market made possible by the transferability feature of the credits or vouchers in which consumers who obtained the credits or vouchers on legitimate grounds can trade them with other consumers in order to recoup the value, or the partial value, they paid into the airline tickets. To comply with the transferability requirement, airlines may simply eliminate the requirement that only the passengers in the original bookings may use the credits or vouchers, similar to a store gift card that can be redeemed by anyone.

(2) Value of Credits and Vouchers and Service Fee for Processing Credits and Vouchers

The Department is adopting the proposal to require airlines to issue credits or vouchers in a value equal to or greater than the fare, including carrier-imposed fees and surcharges and government-imposed taxes and fees that are not refunded to consumers. To the extent other Federal agencies require airlines to refund certain government-imposed fees to consumers when the air transportation is not used by consumers,[96] carriers may deduct the amounts of those fees that have been refunded to consumers from the value of the travel credits or vouchers. With regard to prepaid ancillary service fees, the Department notes that the situation discussed here is distinguishable from the situations in which airlines are required to refund ancillary service fees for services that are not provided. In the situations here, the passenger chooses not to travel, and as a result, the pre-paid ancillary services are not used. As such, the Department is not requiring airlines to refund the ancillary service fees in the form of the original payment, and instead, we are requiring that the value of the ancillary service fees be included in the value of travel credits or vouchers issued.

Based on the comments received, the Department is adopting the proposal to allow airlines to impose a processing fee for issuing travel credits or vouchers to eligible passengers, provided that the fee is assessed on a per-passenger basis and appropriate disclosures regarding the existence and amount of the fee were made to the consumer prior to the consumer purchasing the airline ticket. Given that the airline is not initiating the change that is resulting in the need for a credit or voucher, the Department believes that this strikes the right balance between ensuring that consumers receive travel credits and vouchers when they do not travel because of government restrictions or health concerns related to a serious communicable disease and avoiding having airlines bear all the cost for something that was also outside their control. If the Department determines that airlines' processing fees appear to circumvent the intent behind the requirement for consumers to obtain credits or vouchers in equal or greater value as the fare, the Department will consider whether further action is appropriate.

(3) Restrictions and Disclosures

With respect to limitations, restrictions, and conditions on the

[94] Public Law 111–24, May 22, 2009.

[95] The CARD Act and the CFPB implementing rule definitions for ''gift certificate'' and ''store gift card'' require that the instruments must be purchased or issued ''on a prepaid basis'' ''in exchange for payment.'' As the travel credits or vouchers under this final rule are not purchased or issued on a prepaid basis in exchange for payment, they are not considered ''gift certificate'' or ''store gift card'' that are subject to the CARD Act and the CFPB rule in 12 CFR 1005.20.

[96] See, *e.g.,* the Transportation Security Administration's regulation provides that any changes by the passenger to the itinerary are subject to additional collection or refund of the September 11th Security service fee by the direct air carrier or foreign air carrier, as appropriate. 49 CFR 1510.9(b).

credits or vouchers issued under this section, the Department is adopting the proposed prohibition on unreasonable terms that would materially reduce the value of the credits and vouchers to consumers as compared to the original purchase prices of the airline tickets. The Department confirms its tentative view stated in the NPRM that unreasonable terms include severe restrictions on travel date, time, or routes, a requirement that a voucher can only be used on one booking and that any residual value would be void afterwards, a restriction that the voucher can only be used to cover the base fare of a new booking and not taxes and fees or ancillary service fees, a requirement that redeeming the credits or vouchers would be subject to a rebooking fee or a change fee [97] that reduces the value of the voucher or credit applicable to the new ticket, or a restriction limiting the rebooking to certain class(es) of fares such as business class or first class. A restriction on the travel date, time, or routes is severe when the restriction eliminates a substantial number of choices passenger may have for rebooking and is a case-by-case analysis. A restriction on what airline(s) the credit or voucher can be used to book with, on the other hand, would not be viewed as unreasonable as long as the credit or voucher allows, at a minimum, rebooking on the airline for the original ticket. Further, for material restrictions, limitation, and conditions on the use of the credits and vouchers that are not deemed unreasonable, the final rule require airlines provide clear disclosure to consumers at the time of issuing credits or vouchers.

10. Consumer Rights After Acceptance of Travel Vouchers and Credits

The NPRM: The Department described its tentative view that if an airline cancels or makes a significant change to a flight after a passenger has already requested to cancel his or her flight due to government restrictions or health concerns and received a credit or voucher, then the airline or ticket agent should not be required to replace that voucher with a refund. The Department stated that it is overly burdensome and costly for airlines to apply refund eligibility to itineraries that have already been cancelled pursuant to passengers' requests prior to the airline's decision to cancel or significantly change the flight. The Department cautioned that its Office of Aviation Consumer Protection has the authority to investigate whether an airline or a ticket agent has engaged in an unfair or deceptive practice when it fails to inform a passenger making a request to cancel the itinerary that the passenger is eligible for a refund, if the airline or ticket agents knows or should have known at the time that a flight has been cancelled or significantly changed.

Comments Received: IATA supported the Department's view that if an airline cancels or makes a significant change to a flight after a passenger has already requested to cancel his or her a travel itinerary and received a credit or voucher, then the airline or ticket agent should not be required to replace that voucher with a refund.

DOT Response: The Department maintains its view that an airline or ticket agent should not be required to replace a voucher with a refund when an airline cancels or makes a significant change to a flight after a passenger has already requested to cancel his or her flight due to government restrictions or health concerns and received a credit or voucher.

V. Contract of Carriage Provisions Must Not Contradict Requirements of This Final Rule

The Ticket Refund NPRM proposed to include in the new 14 CFR part 260 a provision that would require airlines to ensure that the terms or conditions in their contracts of carriage are consistent with the proposed regulation, including the proposals pertaining to airline ticket refunds due to airline-initiated cancellation or significant change, and the proposals pertaining to refunds of baggage fees for significantly delayed bags and refunds of ancillary service fees for services that are not provided. In response to this proposal, Travelers United urged the Department to require airlines to incorporate their customer service plans in their contract of carriage. Several individual commenters noted that the language that airlines use in their contract of carriage restrict the rights of passengers. In this final rule, the Department makes clear that carriers' inclusion of terms and conditions in their contract of carriage that are inconsistent with the carriers' obligations to provide refunds as specified in this rule will be considered an unfair and deceptive practice. In addition, the Department prohibits carriers' inclusion of terms and conditions in their contract of carriage that are inconsistent with the carriers' obligations to provide travel credits or vouchers to travelers affected by a serious communicable disease as required by this final rule. Reasonable consumers would be misled with inaccurate information in airlines' contract of carriage regarding their right to a refund, travel credits, vouchers, or other compensation. This information is material to consumers as it could result in significant financial loss because consumers would incorrectly believe that they cannot obtain refunds, travel credits, or vouchers that they are entitled to receive under DOT rules. The Department has long considered airlines with terms and conditions in their contract of carriage that are inconsistent with requirements imposed on them to be engaging in an unfair and deceptive practice. The Department is not requiring carriers to include their customer service plans in their contracts of carriage as suggested by Traveler's United but will monitor consumer complaints in this area and determine if we need to revisit this issue in the future.

VI. Refunding Airline Tickets to Passengers Affected by a Serious Communicable Disease Due to Airlines or Ticket Agents Receiving Significant Government Financial Assistance

To address the concerns by consumers, consumer advocacy groups,[98] and members of Congress [99] that it is fundamentally unfair for airlines receiving government financial assistances during the COVID–19 to refuse to provide refunds to consumers who were not able to travel due to the COVID–19 pandemic, the Department proposed that if a covered airline or ticket agent receives significant government financial assistance during a public health emergency, the airline or ticket agent would be required to provide refunds to consumers who are otherwise eligible for travel credits or vouchers under the NPRM. The Department further proposed a set of procedures to determine whether a covered entity has received ''significant government financial assistance,'' which

[97] The NPRM's proposed rule text suggests that carriers may charge an ''administrative fee'' for rebooking tickets using the credits or vouchers. After further consideration, especially considering that the rule allows carriers to charge a processing fee for issuing the credits or vouchers, the Department believes that it is unreasonable for consumers to be charged again when redeeming the credits or vouchers. Therefore, the final rule determines that charging an administrative fee at the time of rebooking is an unreasonable condition.

[98] See, *e.g., Airlines: Give Us Refunds, Not Vouchers,* petition by Consumer Reports, *https://action.consumerreports.org/20200420_finance_airlinerefundpetition. Consumer Reports, Letter to Sect. Buttigieg, https://advocacy.consumerreports.org/wp-content/uploads/2021/11/CR-letter-to-Sec-Buttigieg-consumer-complaints-11-18-21-FINAL-2.pdf.*

[99] See, *e.g.,* Senator Edward J, Markey and Richard Blumenthal press release, *https://www.markey.senate.gov/news/press-releases/senators-markey-and-blumenthal-blast-airlines-inadequate-response-to-their-request-to-eliminate-expiration-dates-for-all-pandemic-related-flight-credits.*

includes: applying relevant factors such as the size of the entity, revenue, the amount of government financial assistance accepted, and total enplanements to the entities; issuing tentative determinations on which entities have received significant government assistance; and finalizing the determinations based on public comments.

The Department received numerous comments from airline and ticket agent representatives, expressing their concerns about the Department's authorities for this proposal as well the practicality of the proposed procedure to determine which entity has received ''significant government financial assistance.'' Consumers and their representatives supported this requirement but did not articulate the reason(s) for their support of this proposal. Although the Department continues to view that airlines and ticket agents receiving significant financial assistance from governments during a public health emergency should do more to assist airline passengers who are impacted by the public health emergency, we have concluded that more time is needed to consider the information provided to the Department and to determine whether additional information is needed for a final rule that is beneficial to consumers. As such, we are deferring whether to finalize this proposal to another rulemaking action.

VII. Effective Date and Compliance Periods

The NPRM: The Ticket Refund NPRM proposed that any final rule adopted would take effect 90 days after the publication in the **Federal Register**. The Department invited comments on whether 90 days is the appropriate interval for implementation of the proposed requirements if adopted. The Ancillary Fee Refund NPRM did not propose an effective date for provisions finalized under that NPRM.

Comments Received: On the Ticket Refund NPRM, a number of airline commenters asserted that the proposed 90-day implementation timeframe is inadequate, reasoning that airlines need additional time to revise refund policies regarding when a passenger is entitled to a refund and to train their staff. They also commented that additional time is needed to adjust IT systems to reflect how vouchers should be granted. Some airlines suggested that a 180-day implementation period is warranted while others argued that an implementation period of no shorter than one year should be granted. ASTA also asserted that ticket agents will need additional time to assess how a final rule would impact them and decide whether they want to continue to sell airline tickets as merchants of record and make necessary adjustments accordingly. ASTA further requested that the Department clarify how it interprets the application of the rule's effective date with respect to ticket sale date, travel date, and the date a refund request is submitted.

On the Ancillary Fee Refund NPRM, the NPRM did not propose an implementation period. A4A and IATA in their comments requested that the Department provide one-year for airlines to implement the requirements relating to refunding baggage fees for delayed bags and ancillary service fees for services not provided. A4A specified that if the Department requires ''automatic'' refunds for baggage fees, carriers will need significant amount of time to work with distribution channel stakeholders to build, test, and implement new payment and refund channels beyond airfare. IATA also commented that additional time is needed due to the complexity of airline systems and procedure and the potential involvement of multiple airlines and distribution channels. The ACPAC recommended that all final provisions of the final rule be effective after 90 days of its publication in the **Federal Register**.[100]

DOT Responses: The Department has considered the comments and determined that an extended implementation period for certain provisions is warranted. First and foremost, although this final rule will become effective 60 days after its publication in the **Federal Register**, carriers and ticket agents will have different implementation periods for different provisions. For provisions regarding ticket refunds due to airline cancellation or significant change, refunds of baggage fees for significantly delayed bags, and refunds of ancillary service fees when services are not provided, regulated entities will have six months from the date of publication of the final rule, or October 28, 2024, to implement the relevant requirements. The Department views the six-month implementation period as appropriate for airlines and ticket agents to modify their policies, procedures and IT systems and to train staff on the relevant requirements on ticket and ancillary fee refunds (including refunding fees for significantly delayed checked bags). The Department considers the six months compliance period to be necessary for carriers and ticket agents to establish or enhance processes and procedures to communicate with one another to comply with these requirements.

For the provision regarding issuing travel credits or vouchers to passengers who are affected by a serious communicable disease, carriers will have 12 months from the date of the final rule's **Federal Register** publication, or April 28, 2025, to fully implement the requirements. The Department believes that this implementation period is sufficient for carriers to revise IT systems for the issuance, tracking, and redemption of travel credits or vouchers meeting the regulatory requirements, to establish procedures with respect to requesting and reviewing supporting medical documentations from passengers, and to train staff with regard to providing customer service on related matters.

VIII. Severability

This final rule includes four major components that enhance protections of airline passengers (ticket refunds due to airline cancellation or significant change, baggage fee refunds for significantly delayed bags, ancillary service fee refunds for services not provided, and consumer protections for airline passengers affected by a serious communicable disease), each of which is issued pursuant to separate and independent legal authorities and operates independently on its own. Were any component of this final rule stayed or invalidated by a reviewing court, the components that remained in effect would continue to provide vital protections to airline passengers. The implementation of each component and the consumer protection provided by each component do not hinge on other components of the rule. Therefore, each of the four components of the final rule are severable. In the event of a stay or invalidation of any part of any rule, or of any rule as it applies to certain regulated entities, the Department's intent is to otherwise preserve the rule to the fullest possible extent.

Regulatory Analyses and Notices

A. Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures and Executive Order 13653 (Improving Regulation and Regulatory Review)

The final rule meets the threshold for a significant regulatory action as defined

[100] The three members representing consumer rights advocacy groups, State Attorneys General, and airports support this recommendation. The member representing A4A opposes this recommendation, stating that some of the provisions, if finalized, will require airlines to make significant changes and the 90-day implementation period is not adequate to implement those changes.

in section (3)(f)(1) of Executive Order (E.O.) 12866, ''Regulatory Planning and Review,'' as amended by E.O. 14094, ''Modernizing Regulatory Review,'' because it is likely to have an annual effect on the economy of $200 million or more, as adjusted by OMB pursuant to section 3(f)(1). Table X summarizes the expected economic impacts of the final rule.

The lack of universal definitions for ''cancellation'' and ''significant itinerary change'' has created inconsistency among carriers in granting consumers airline ticket refunds. The final rule will reduce these inconsistencies by defining these terms and will reduce the resources consumers need to expend to obtain the refunds they are owed. Consumer time savings are estimated to be about $3.8 million annually.

This rule implements a 2016 statutory mandate and requires that airlines refund baggage fees when a bag is delivered to a consumer with a delay of 12 hours or more for domestic flights, 15 hours for international flights with a duration of 12 hours or less, and 30 hours for international flights with a duration of over 12 hours. The final rule also implements a 2018 mandate and requires airlines to refund fees collected for ancillary services they fail to provide. The expected economic impacts of these provisions consist of $16.0 million annually in increased refunds to consumers and $7.1 million annually in administrative costs for the airlines.

The final rule requires airlines to provide transferable travel credits or vouchers, valid for at least five years, to passengers who cancel travel for reasons related to a serious communicable disease. The impacts of this requirement depend upon many factors, including the presence and nature of a pandemic, whether airlines can enforce basic economy change restrictions though collecting documentation from consumers regarding whether they have or may have a serious communicable disease, and the value assigned to a case of avoided disease. Expected societal benefits are from infected air passengers canceling planned air travel due the option of receiving the five-year travel credit and the reduction in exposure of uninfected passengers to serious contagious disease. Estimated annual costs would be $3.4 million outside of a pandemic or $482.0 million during a pandemic. While data to quantify benefits are insufficient, a break-even analysis illustrates the thresholds for the monetized value for a case of avoided disease and the travel credit effectiveness rates that could yield benefits that exceed costs.

TABLE 3—SUMMARY OF ANNUAL ECONOMIC IMPACTS

[Millions of 2022 dollars]

Cancelled flight and significant change of flight itinerary	
Benefits (+):	
Consumer time savings	$3.8
Costs (−)	*de minimis*
Net benefits (costs)	$3.8
Transfers:	
Increased airline ticket refunds (airlines to consumers)	Unquantified.
Refunds of fees for significantly delayed bags and ancillary fees not provided	
Benefits (+)	n/a
Costs (−):	
Administrative	$7.1
Net benefits (costs)	($7.1)
Transfers:	
Baggage fee refunds (airlines to consumers)	$16.0
Vouchers or travel credits for passengers affected by a serious communicable disease	
Benefits (+):	
Reduction in cases of serious communicable disease	Unquantified.
Costs (−):	
Documentation	$3.4 (non-pandemic) or $482.0 (pandemic).
Net benefits (costs)	Unquantified.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601, *et seq.*) requires Federal agencies to review regulations and assess their impact on small entities unless the agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities. This final rule would have some impact on air carriers and ticket agents that qualify as small entities. To assess the impact of this final rule, the Department has prepared a final regulatory flexibility analysis (FRFA), as set forth in this section.

As required by the Regulatory Flexibility Act (5 U.S.C. 601, *et. seq.,* the FRFA includes:

- A statement of the need for and objectives of the rule;
- A statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA Advocacy) in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
- A description and estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- A description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of

professional skills necessary for preparation of the report or record; and

• A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

A statement of the need for and objectives of the rule is provided elsewhere in the preamble to this final rule and not repeated here. Similarly, the Department provides in the COMMENTS AND RESPONSES section a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis or the economic impacts of the rule and explains how DOT assessed these issues and made changes, if any, to the final rule as a result. DOT did not receive any comments from the Chief Counsel for Advocacy of the Small Business Administration (SBA Advocacy) in response to the proposed rule, the initial regulatory flexibility analysis, or the economic impacts of the rule.

Small Entities Affected

The proposed rule would affect air carriers and ticket agents that qualify as small entities. For air carriers, the Department defines small entities based on the standard published in 14 CFR 399.73. An air carrier is a small entity if it provides air transportation exclusively with small aircraft, defined as any aircraft originally designed to have a maximum passenger capacity of 60 seats or less or a maximum payload capacity of 18,000 pounds or less. In 2022, 24 air carriers meeting these criteria reported passenger traffic data to the Bureau of Transportation Statistics.[101] These carriers reported operating revenues in 2018 ranging from $1 million to $84 million.

TABLE 4—AFFECTED SMALL AIRLINES

40-Mile Air.
Air Excursions LLC.
Alaska Central Express.
Bering Air Inc.
Empire Airlines Inc.
FOX AIRCRAFT, LLC.
Grant Aviation.
Iliamna Air Taxi.
Island Air Service.
J&M Alaska Air Tours, Inc. (Alaska Air Transit).
Junipogo, LLC (70 North Air).
Kalinin Aviation LLC (Alaska Seaplanes).
Katmai Air.
Maritime Helicopters, Inc.
New Pacific Airlines (Ravn Alaska).
Paklook Air, Inc (Airlift Alaska, Yute Commuter).
PM Air, LLC.
Ryan Air.
Scott Air LLC (Island Air Express).
Smokey Bay Air Inc.
Spernak Airways Inc.
Venture Travel LLC (Taquan Air Service).
Warbelow.
Wright Air Service

Source: *BTS Air Carrier Summary Data (Form 41 and 298C Summary Data). ''T1: U.S. Air Carrier Traffic and Capacity Summary by Service Class.'' BTS Air Carrier Report (Form 298C–F1).*

For ticket agents, the Department defines small entities based on the size standards published by the Small Business Administration in 13 CFR 121.201. These size standards use the North American Industry Classification System (NAICS), which does not have a category specifically for ticket agents. Instead, the closest corresponding industry is travel agencies (NAICS code 561510). Establishments in this industry primarily act as agents in selling travel, tour, and accommodation services to the public and commercial clients. An establishment in this industry is a small entity if it has total annual revenues below $22 million. This amount excludes funds received in trust for an unaffiliated third party, such as bookings or sales subject to commissions, but includes commissions received.

Data from the 2017 Economic Census provide an estimate of the number of small-entity ticket agents in the United States.[102] This survey, conducted every five years by the US Census Bureau, is the official national measure of businesses and includes information on employment and revenue by industry. The survey groups firms by NAICS code and by revenue size, with $25 million being the closest threshold amount to the small-entity standard of $22 million. In 2017, 7,827 travel agency establishments had annual revenues of less than $25 million (Table 5). Not all travel agencies serve as ticket agents, however, making the number an over-estimate of affected small entities. The number is also an over-estimate because some of the firms may have annual revenues greater than $22 million.

TABLE 5—TRAVEL AGENCY ESTABLISHMENTS BY REVENUE, 2017

Annual revenue	Firms
Less than $100,000	1,470
$100,000 to $249,999	1,774
$250,000 to $499,999	1,441
$500,000 to $999,999	1,290
$1,000,000 to $2,499,999	1,069
$2,500,000 to $4,999,999	462
$5,000,000 to $9,999,999	221
$10,000,000 to $24,999,999	100
Total	7,827

Notes: NAICS code 561510.
Source: U.S. Census Bureau, 2017 Economic Census.

Compliance Requirements and Costs

As described in more detail elsewhere in the preamble of this final rule, the Department provides definitions and refund requirements for cancelled flight and significant change of flight itinerary. The Department also specifies requirements for significantly delayed bags and ancillary fees that passengers pay for that are not provided. The Department also establishes requirements for airlines to provide vouchers or travel credits to passengers whose travel plans are disrupted by circumstances beyond their control related to a serious communicable disease.

As described in the Regulatory Impact Analysis for the final rule, the primary costs for the final rule that would be incurred by business are administrative costs from baggage and ancillary fee refund requirements and those related to the collection of documentation of serious contagious disease from passengers. Some small carriers that qualify as small businesses operate flights as part of a code-share arrangement with a larger carrier. In these cases, the larger carrier collects the baggage fees and other ancillary service fees and would be responsible for the refunds under the proposal. Therefore, overall costs to small businesses are likely lower than if small carriers collected the fees in all cases, though the Department acknowledges that some small carriers still collect the fees and would therefore be responsible for any refunds due as a result of the rule. As described in the baggage fee refund analysis, estimated annual refund payments and administrative costs for carriers ($9.3 million + $3.9 million) would account for about 0.2

[101] Bureau of Transportation Statistics. ''T1: U.S. Air Carrier Traffic and Capacity Summary by Service Class.'' *https://www.transtats.bts.gov/Fields.asp?gnoyr_VQ=FJH.* Small entities have a ''CarrierGroupNew'' code of 5. Accessed Nov. 15, 2023.

[102] U.S. Census Bureau. 2022. ''Economic Census.'' *https://www.census.gov/programs-surveys/economic-census.html.*

percent of airlines' annual baggage fee revenues ($6.8 billion in 2022, the year used in the analysis). The Department acknowledges that the annual bag fee revenues for small carriers are likely lower than those of large carriers, but their estimated annual refund payments and administrative costs are also likely lower than those of large carriers. As baggage handling and tracking technologies improve, we expect that the percentage of delayed bags affected by the rule and resulting economic effects will decrease further.

The number of passengers who would submit documentation to small carriers is difficult to predict, but a hypothetical example illustrates the potential economic costs associated with the documentation for small air carriers. In 2022, small air carriers in the United States made over 1.02 million passenger trips.[103] If passengers needed to restrict travel for 5% of the trips and provide airlines with documentation, passengers would submit approximately 51,000 forms. We assume that a customer service representative working for an airline or ticket agent would need an average of 5 minutes (0.083 hours) to review documentation and request additional documentation if needed, for a total of approximately 4,236 hours.

To estimate the value of the time air carriers would spend reviewing documentation, we use median wage data from the Bureau of Labor Statistics. For customer service representatives, the fully loaded wage rate is $25.68, using a $18.16 median hourly wage for customer services representatives in May 2022,[104] multiplied by 1.41 to account for employer benefit costs. The total estimated annual cost of the forms would be approximately $109,000, or about $4,500 per small carrier on average. This amounts to about 0.1 percent of total operating revenue per small carrier on average. Some of these costs, or additional costs, could be borne by small ticket agents.

Regulatory Alternatives and Minimization of Impacts on Small Entities

As described in the following paragraphs, several alternatives considered by the Department have had would different impacts on small businesses. The Department considered these alternatives and describes in the paragraphs that follow the steps the Department has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the reasons for selecting the alternative adopted in the final rule and why the Department rejected other significant alternatives that affect the impact on small entities.

One alternative considered as part of the proposed rule was to require cash refunds to consumers as a condition of accepting significant government assistance. After considering the comments received, the Department concluded that more time is needed to consider the information provided and determine whether additional information is needed for a final rule that benefits consumers. Therefore, the Department did not adopt this alternative, and the final rule will therefore have a smaller impact on small businesses.

The Department also considered an alternative to limit the scope of the rule to specifying definitions for ''significant change in itinerary'' and ''cancellation.'' The Department rejected this alternative, however, based on its conclusion that removing the portion of the rule related to serious communicable diseases would undermine the Department's goal to protect consumers' financial interests when the disruptions to their travel plans were caused by public health concerns beyond their control. The Department also believes that protecting consumers' financial interests would further incentivize persons not to travel if they have or may have a serious communicable disease. Nonetheless, in adopting the final rule to protect consumers affected by a serious communicable disease, the Department imposes the requirements only on airlines but not ticket agents, including ticket agents that qualify as small businesses, thereby decreasing the impact on these small entities. For airlines that qualify as small businesses, although they are required to provide travel credits or vouchers to consumers who choose not to travel to protect themselves or others from a serious communicable disease, they are not required to accept a consumer's self-diagnosis of a medical condition consistent with public health guidance issued by CDC, comparable agencies in other countries, or WHO. The Department views this change as a way to reduce fraud and abuse and decrease the impact on small airlines.

In determining what constitutes a significant itinerary change, the Department evaluated three alternative timeframes for early departures or delayed arrivals that would constitute a significant itinerary change. The first alternative reflects the timeframes set forth in the proposed rule: three hours for domestic itineraries and six hours for international itineraries as the times that would be considered significant. A second alternative left the timeframes for early departure and late arrival undefined, essentially maintaining the status quo. A third alternative considered was to adopt a tiered structure based upon such factors as total travel time. The final rule adopts the three- and six-hour timeframes from the proposed rule. The Department rejected the alternative of leaving the timeframes undefined. While leaving the timeframes undefined grants the most flexibility to the airlines, it would not achieve the same consistency as a uniform standard, which is an objective sought by this rulemaking. The Department rejected a tiered approach because of its complexity and potential difficulties in implementation for airlines as well comprehension on the part of consumers.

With regard to the significant change in flight itinerary because of a downgrade in available amenities, the proposed rule included aircraft changes that lead to a significant downgrade of available amenities or travel experiences for all passengers. For the final rule, except for a downgrade in the class of service, the downgrade of available amenities applies to passengers with disabilities. The final rule clarifies that it refers to travel on a substitute aircraft that results in one or more accessibility features needed by the passenger being unavailable and changes in connecting airport for persons with disabilities. The Department altered the scope of passengers covered because of the ambiguity and subjectivity of what constitutes significant downgrade in amenities and travel experience. By retaining applicability to persons with disabilities, the final rule recognizes that aircraft substitutions can result in discomfort and inconveniences when an accessible feature needed by a passenger with a disability is unavailable.

Another alternative considered by the Department and adopted in the final rule is to extend the length of baggage delivery delay for long-haul international flights (flights with a duration of more than 12 hours) under which a refund of baggage is required, from the 25-hour standard proposed in the NPRM to the 30-hour standard adopted in the final rule. This final rule, however, also shortened the length of baggage delivery delay for other

[103] Bureau of Transportation Statistics. *Air Carrier Statistics (Form 41 Traffic)—All Carriers: T–100 Segment (All Carriers).* United States Department of Transportation. *https://www.transtats.bts.gov/Fields.asp?gnoyr_VQ=FMG.* Accessed 10 Jan 2024.

[104] Bureau of Labor Statistics. ''Occupational Employment and Wage Estimates, May 2022: National estimates for customer service representatives.'' *https://www.bls.gov/oes/current/oes434051.htm.*

international flights (flights with a duration of 12 hours or less) under which a refund of baggage fee is required, from the 25-hour standard proposed in the NPRM to the 15-hour standard adopted in the final rule. The final rule decreases the impact on small carriers operating long-haul international flights and increases the impact on small carriers operating shorter international flights. The Department made the changes based on its view that setting a different standard for long-haul international flights incentivizes carriers to deliver the delayed bags as soon as possible to avoid refunding baggage fee, which benefits consumers and airlines. The Department further views that a shorter timeframe for delivering delayed bags on shorter international flights is beneficial to consumers and ensures that the baggage delivery delay standard is appropriate considering the ability of carriers to transport the delayed bags on its next available flight, other carriers' flights, or through courier services.

The Department also considered whether to finalize the proposed requirement that airlines and ticket agents give non-expiring travel credits or vouchers to passengers who do not travel due to government restrictions or advice from a medical professional related to a serious communicable disease. Although the non-expiring feature would provide consumers the maximum flexibility to use the credits or vouchers, the Department recognizes the difficulty in managing and tracking them indefinitely. Thus, the Department adopted a final rule requiring that the travel credits be valid for at least five years from the date of the issuance. The Department views a five-year validity period a sufficient timeframe to ensure passengers who are affected by a serious communicable disease can use the credits while reducing burdens on airlines.

C. Executive Order 13132 (Federalism)

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This notice does not propose any provision that: (1) has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government; (2) imposes substantial direct compliance costs on State and local governments; or (3) preempts State law. States are already preempted from regulating in this area by the Airline Deregulation Act, 49 U.S.C. 41713. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13175

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Because none of the provisions finalized in this rule would significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13175 do not apply.

E. Paperwork Reduction Act

This final rule imposes a new collection of information that would require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 49 U.S.C. 3501 *et seq.* The Department has sought approval from OMB for the collection of information established in this final rule. The Department will publish a separate notice in the **Federal Register** announcing OMB approval of the new collection and advising the public of the OMB control number associated with the new collection.

The new collection of information established in this final rule relates to allowing airlines to require passengers requesting travel credits or vouchers because their travel is affected by a serious communicable disease to provide documentation. Specifically, the Department allows airlines to require passengers wishing to cancel a flight itinerary that is still operated to provide documentation demonstrating that that they are prohibited from travel or are required to quarantine for a substantial portion of the trip by a governmental entity in relation to a serious communicable disease, or that they are advised by a licensed treating medical professional not to travel to protect themselves or others from a serious communicable disease. For this information collection, a description of the respondents and an estimate of the annual recordkeeping and periodic reporting burden are set forth below:

Requirement to Prepare and Submit to Airlines Documentations Demonstrating a Passenger is Eligible for Travel Credits or Vouchers Due to a Reason Related to A Serious Communicable Disease.

Respondents: Passengers prohibited or required to quarantine for a substantial portion of the trip by a governmental entity in relation to a serious communicable disease, passengers advised by a licensed treating medical professional not to travel by air because they have or may have contracted a serious communicable disease such that their travel would pose a threat to the health of others, and passengers advised by a licensed treating medical professional not to travel to protect themselves from a serious communicable disease during a public health emergency.

Number of Respondents: The number of respondents would vary greatly depending on whether there is a public health emergency and the magnitude of that public health emergency. When there is a public health emergency with a similar magnitude of the COVID–19 pandemic, the number of respondents could potentially be very high. According to data provided by A4A, the airlines provided exchanges of tickets to about 180 million passengers between March 2020 and February 2021. Industry further suggests in comments on the proposed rule that about 15 percent of consumers who need to make ticket changes might opt for a travel credit instead of an immediate ticket change. Thus, we estimate that of the 180 million consumers provided ticket changes in the baseline, 27 million would be the number of respondents who need to submit the documentation to receive the five-year travel credit under the final rule.[105] For purposes of this PRA burden analysis, we assume that the number of medical assistants developing the documentation and airline customer service representatives reviewing the documentation equal the number of customers providing responses.[106]

Estimated Annual Burden on Respondents: We estimate that each respondent would need 30 minutes (0.5 hours) to obtain a documentation from a medical professional per response, per year. We also estimate that a medical assistant would need 15 minutes (0.25 hours) to provide consultation to the passenger or to prepare the documentation. We further estimate that a customer service representative working for an airline would need an

[105] In the NPRM, we estimated 5.58 million respondents based on the Department's data showing that in 2020, U.S. airlines enplaned 558 million fewer passengers in domestic air transportation than in 2019. We estimated that if 1% of this reduction was due to passengers unable or are advised to not travel for a qualifying reason and required by airlines and ticket agents to submit documentation, there would be 5.58 million respondents. For the final rule, we increased this number based on the data provided by A4A as a reasonable upper bound, because not all of the 15% of passengers who seek a travel credit or voucher would be entitled to one under this final rule.

[106] This number may be an overestimate because the same airline customer service representatives likely review multiple documentation submissions.

average of 5 minutes (0.083 hours) to review the documentation and request additional documentation if needed. Passengers would spend a total of approximately 13.5 million hours per year (0.5 hours × 27 million passengers) to obtain the documentation. Medical assistants would spend a total of 6.75 million hours per year (0.25 hours × 27 million forms) to prepare the forms. Airline customer service representatives would spend approximately 2,241,000 hours (0.083 hours × 27 million forms) per year to review the documentation.

To calculate the hourly value of time spent on the documentation, we used median wage data from the Bureau of Labor Statistics as of May 2022. Respondents would obtain, present, and submit the documentation on their own time without pay and we estimate the value of this uncompensated activity using a post-tax wage estimate of $18.48 per hour ($22.26 median hourly wage for all occupations minus a 17% estimated tax rate). For medical assistants, we used a fully loaded wage of $25.94 ($18.40 hourly wage multiplied by 1.41 to account for employer benefit costs.) For customer service representatives, we use an estimate of $25.61 per hour ($18.16 median hourly wage times a wage multiplier of 1.41). In the scenario that there is a public health emergency, the total annual estimated documentation costs of the forms would be approximately $482 million (Table 6).[107]

TABLE 6—EXAMPLE ANNUAL COST ESTIMATE FOR DOCUMENTATION

Group	Forms	Hours per form	Total hours	Hourly time value	Estimated costs (millions)
People restricting travel	27,000,000	0.5	13,500,000	$18.48	$249,480,000
Medical assistants	27,000,000	0.25	6,750,000	25.94	175,095,000
Customer service representatives	27,000,000	0.083	2,241,000	25.61	57,392,010

The Department has identified a number of disclosure requirements in this final rule subject to approval by the Office of Management and Budget under the PRA. These requirements are: (1) as specified in 14 CFR 259.5(b)(6), carriers must disclose to consumers in their customer service plans that consumers are entitled to a refund if this is the case when offering travel credits, vouchers, or other compensation in lieu of refunds, and to disclose any material restrictions, conditions, or limitations on travel credits, vouchers, or other compensation offered, regardless of whether consumers are entitled to a refund; (2) as specified in 14 CFR 259.5(b)(7), carriers must include in their customer service plans a statement regarding compliance with the requirements of part 262 regarding vouchers for consumers in circumstances relating to serious communicable diseases; (3) as specified in 14 CFR 260.4(d), carriers that failed to provide ancillary services paid for by a passenger must notify another carrier that is responsible for refunding the ancillary service fee about the service failure; (4) as specified in 14 CFR 260.5(c), carriers that receive MBRs must notify another carrier that is responsible for refunding baggage fees about the baggage delay; (5) as specified in 14 CFR 260.6(d), carriers that set a deadline for consumers to respond to alternative transportation offers must adopt and post on their websites their policies regarding how to treat consumers not responding by the deadlines; (6) as specified in 14 CFR 260.6(e), carriers must notify affected consumers about cancellation or significant changes, rights to refunds, offers of alternatives, and any deadline to respond; (7) as specified in 14 CFR 260.6(f), carriers must notify ticket agents that are the merchants of record for the ticket sales whether a consumer is eligible for a refund; (8) as specified in 14 CFR 262.8, carriers must disclose material restrictions, conditions, or limitations on vouchers provided to consumers in relation to a serious communicable disease; (9) as specified in 14 CFR 399.80(l), ticket agents must disclose to consumers that they are entitled to a refund if this is the case when offering travel credits, vouchers, or other compensation in lieu of refunds, and must also disclose any material restrictions, conditions, or limitations on travel credits, vouchers, or other compensation offered, regardless of whether consumers are entitled to a refund; and (10) as specified in 14 CFR 399.80(l), ticket agents must disclose at the time of ticket purchase any service fees that are not refundable. DOT will request comment on and seek approval from OMB for these disclosure requirements and publish separate notice in the **Federal Register** advising of the OMB Control Number(s) when OMB approves the information collection(s).

Notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule 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. As described elsewhere in the preamble, this final rule may have an effect on the private sector that exceeds this threshold. The UMRA permits agencies to provide the assessment required by UMRA as part of any other assessment prepared in support of the rule, and the Department has provided the assessment required by UMRA within the RIA prepared in support of the final rule.

G. National Environmental Policy Act

The Department has analyzed the environmental impacts of this action pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, October 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an

[107] The estimated costs calculated here assume that there is a public health emergency. The Regulatory Impact Analysis accompanying this rule estimated the cost to be about $3.4 million when there is not a public health emergency.

environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. Paragraph 4.c.6.i of DOT Order 5610.1C categorically excludes ''[a]ctions relating to consumer protection, including regulations.'' This final rule relates to consumer protection. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Signed this 1st day of April, 2024, in Washington DC.

Peter Paul Montgomery Buttigieg,

Secretary of Transportation.

List of Subjects

14 CFR Part 259

Air Carriers, Consumer Protection, Reporting and Recordkeeping Requirements.

14 CFR Part 260

Air carriers, Consumer protection.

14 CFR Part 262

Air carriers, Consumer protection.

14 CFR Part 399

Administrative practice and procedure, Air carriers, Air rates and fares, Air taxis, Consumer protection, Small businesses.

For the reasons set forth in the preamble, the Department amends title 14 CFR Chapter II as follows:

PART 259—ENHANCED PROTECTIONS FOR AIRLINE PASSENGERS

■ 1. The authority citation for 14 CFR part 259 continues to read as follows:

Authority: 49 U.S.C. 40101(a)(4), 40101(a)(9), 40113(a), 41702, 41708, 41712, and 42301.

■ 2. Amend § 259.3 by adding the definitions for ''Business days,'' ''Prompt refunds,'' and ''Serious communicable disease,'' in alphabetical order to read as follows:

§ 259.3 Definitions.

Business days means Monday through Friday excluding Federal holidays in the United States.

* * * * *

Prompt refunds means refunds made within 7 business days of a refund becoming due as required by 14 CFR 374.3 for credit card purchases, and within 20 calendar days of a refund becoming due for cash, check, debit card, or other forms of purchases.

Serious communicable disease means a communicable disease as defined in 42 CFR 70.1 that can cause serious health consequences (*e.g.,* breathing problems, organ damage, neurological difficulties, death) and can be easily transmitted by casual contact in an aircraft cabin environment (*i.e.,* easily spread to others in an aircraft cabin through general activities of passengers such as sitting next to someone, shaking hands, talking to someone, or touching communal surfaces). For example, the common cold is readily transmissible in an aircraft cabin environment but does not have severe health consequences. AIDS has serious health consequences but is not readily transmissible in an aircraft cabin environment. Both the common cold and AIDS would not be considered serious communicable diseases for purposes of this part. SARS is readily transmissible in an aircraft cabin environment and has severe health consequences. SARS would be considered a serious communicable disease for purposes of this part.

* * * * *

■ 3. Amend § 259.5 by revising paragraphs (a), (b)(3), and (b)(5); redesignating paragraphs (b)(6) through (b)(12) as paragraphs (b)(8) through (b)(14), and adding new paragraphs (b)(6) and (b)(7); and revising the newly designated paragraphs (b)(8) and (b)(11) to read as follows:

§ 259.5 Customer Service Plan.

(a) *Adoption of Plan.* Each covered carrier must adopt a Customer Service Plan applicable to its scheduled flights as specified in paragraphs (b)(1) through (14) of this section and adhere to the plan's terms.

(b) * * *

* * * * *

(3) Delivering baggage on time, including making every reasonable effort to return mishandled baggage within 12 hours for domestic flights and within 15 or 30 hours for international flights consistent with the requirement of 14 CFR 260.5, compensating passengers for reasonable expenses that result due to delay in delivery as required by 14 CFR part 254 for domestic flights and as required by applicable international treaties for international flights, and reimbursing passengers for any fee charged to transport a bag if that bag is significantly delayed or lost as required by 14 CFR 260.5;

* * * * *

(5) Providing prompt refunds in the original form of payment (*i.e.,* money is returned to an individual using whatever payment method the individual used to make the original payment, such as a check, credit card, debit card, cash, or airline miles) when ticket or ancillary service fee refunds, including checked bag fee refunds, are due pursuant to 14 CFR part 260 unless the consumer agrees to receive the refunds in a different form of payment that is a cash equivalent payment as defined in 14 CFR 260.2. Carriers may not retain a processing fee for issuing refunds that are due;

(6) Disclosing that consumers are entitled to a refund if that is the case when offering alternative transportation, travel credits, vouchers, or other compensation in lieu of refunds consistent with the requirement in 14 CFR 260.7. Disclosing any material restrictions, conditions, or limitations on travel credits, vouchers, or other compensation offered, regardless of whether consumers are entitled to a refund as described in 14 CFR 260.8 and 14 CFR 262.8.

(7) Providing, upon request, travel credits or vouchers that are transferrable and do not expire for at least five years from the date of issuance to a consumer due to a serious communicable disease impacting travel as described in 14 CFR part 262.

(8) Properly accommodating passengers with disabilities as required by part 382 of this chapter and as set forth in the carrier's policies and procedures and properly refunding passengers with disabilities and individuals in the same reservation as the individual with a disability who do not want to continue travel without the individual with a disability as required by 14 CFR 260.6(c);

* * * * *

(11) Disclosing refund policies as required by 14 CFR part 260, cancellations policies, frequent flyer rules, aircraft seating configuration, and lavatory availability on the selling carrier's website, and upon request, from the selling carrier's telephone reservations staff;

* * * * *

■ 4. Add part 260 to read as follows:

PART 260—REFUNDS FOR AIRLINE FARE AND ANCILLARY SERVICE FEES

Sec.

Authority: 49 U.S.C. 40101(a), 41702, and 41712.

§ 260.1 Purpose.

The purpose of this part is to ensure that carriers promptly refund consumers for: (1) fees for ancillary services related to air travel that consumers paid for but were not provided; (2) fees to transport checked bags that are lost or significantly delayed; and (3) airfare for a flight that is cancelled or had a significant change of flight itinerary where the consumer does not accept the change to the flight itinerary, alternative transportation, airline voucher or credit, or other compensation offered by the carrier.

§ 260.2 Definitions.

As used in this part:

Air carrier means a citizen of the United States undertaking by any means, directly or indirectly, to provide air transportation.

Ancillary service means any optional service related to air travel that a covered carrier provides for a fee, beyond passenger air transportation. Such services may include, but are not limited to, transport of checked or carry-on baggage, advance seat selection, access to in-flight entertainment programs or Wi-Fi, in-flight beverages, snacks, meals, pillows and blankets, seat upgrades, and lounge access.

Automatic refund means issuing a refund to a consumer without waiting to receive an explicit refund request, when the consumer's right to a refund is undisputed because the contracted service was not provided and either the consumer rejected the alternative offered or no alternative was offered.

Break in journey means any deliberate interruption by a passenger of a journey between a point in the United States and a point in a foreign country where there is a stopover at a foreign point scheduled to exceed 24 hours. If the stopover is 24 hours or less, whether it is a break in journey depends on various factors such as whether the segment between two foreign points and the segment between a foreign point and the United States were purchased in a single transaction and as a single ticket/itinerary, whether the segment between two foreign points is operated or marketed by a carrier that has no codeshare or interline agreement with the carrier operating or marketing the segment to or from the United States, and whether the stopover at a foreign point involves the passenger picking up checked baggage, leaving the airport, and continuing the next segment after a substantial amount of time.

Business days means Monday through Friday, excluding Federal holidays in the United States.

Cancelled flight or *flight cancellation* means a covered flight with a specific flight number scheduled to be operated between a specific origin-destination city pair that was published in the carrier's Computer Reservation System at the time of the ticket sale but not operated by the carrier.

Cash equivalent means a form of payment that can be used like cash, including but not limited to a check, a prepaid card, funds transferred to a consumer's bank account, funds provided through digital payment methods (*e.g.,* PayPal, Venmo), or a gift card that is widely accepted in commerce. It is not cash equivalent if consumers bear the burden for transaction, maintenance, or usage fees related to the payment.

Checked bag means a bag, special item (*e.g.,* musical instrument or a pet), or sports equipment (*e.g.,* golf clubs) that was provided to a covered carrier by or on behalf of a passenger for transportation in the cargo compartment of a scheduled passenger flight. A checked bag includes a gate-checked bag and a valet bag.

Class of service means seating in the same cabin class such as First, Business, Premium Economy, or Economy class, which is defined based on seat location in the aircraft and seat characteristics such as width, seat recline angles, or pitch (including the amount of legroom).

Covered carrier means an air carrier or a foreign air carrier operating to, from, or within the United States, conducting scheduled passenger service.

Covered flight means a scheduled flight operated or marketed by a covered carrier to, from, or within the United States, including itineraries with brief and incidental stopover(s) at a foreign point without a break in journey.

Foreign air carrier means a person, not a citizen of the United States, undertaking by any means, directly or indirectly, to provide foreign air transportation.

Individual with a disability has the same meaning as defined in 14 CFR 382.3.

Merchant of record means the entity (carrier or ticket agent) responsible for processing payments by consumers for airfare or ancillary services or products (including the transport of checked bags), as shown in the consumer's financial charge statements, such as debit or credit card charge statements.

Prompt refunds means refunds made within 7 business days of a refund becoming due as required by 14 CFR 374.3 for credit card purchases and within 20 calendar days of a refund becoming due for cash, check, debit card, or other forms of purchases.

Significant change of flight itinerary or *significantly changed flight* means a change to a covered flight itinerary made by a covered carrier where as the result of the change:

(1) The consumer is scheduled to depart from the origination airport three hours or more for domestic itineraries and six hours or more for international itineraries earlier than the original scheduled departure time;

(2) The consumer is scheduled to arrive at the destination airport three hours or more for domestic itineraries or six hours or more for international itineraries later than the original scheduled arrival time;

(3) The consumer is scheduled to depart from a different origination airport or arrive at a different destination airport;

(4) The consumer is scheduled to travel on an itinerary with more connection points than that of the original itinerary;

(5) The consumer is downgraded to a lower class of service;

(6) The consumer who is an individual with a disability is scheduled to travel through one or more connecting airports different from the original itinerary; or

(7) The consumer who is an individual with a disability is scheduled to travel on substitute aircraft on which one or more accessibility features needed by the customer are unavailable.

Significantly delayed checked bag means a checked bag not delivered to or picked up by the consumer or another person authorized to act on behalf of the consumer within 12 hours of the last flight segment's arrival for domestic itineraries, within 15 hours of the last flight segment's arrival for international itineraries with a non-stop flight segment between the United States and a foreign point that is 12 hours or less in duration, and within 30 hours of the last flight segment's arrival for international itineraries with a non-stop flight segment between the United States and a foreign point that is more than 12 hours in duration. The 15-hour and 30-hour standards apply to domestic segments of international itineraries.

§ 260.3 Applicability.

This part applies to: covered carriers that are the merchants of record; covered carriers that operate the flight or, for multiple-carrier itineraries, covered carriers that operate the last segment of a flight where a ticket agent is the merchant of record for a checked bag fee; and covered carriers that fail to provide an ancillary service (other than checked bag service) for which the consumer paid where a ticket agent is the merchant of record for an ancillary service fee other than checked bag fee.

§ 260.4 Refunding fees for ancillary services that consumers paid for but that were not provided.

(a) A covered carrier that is the merchant of record shall provide a prompt and automatic refund to a consumer for any fees it collected from the consumer for ancillary services if the service was not provided through no fault of the consumer (*e.g.,* prepaid ancillary service not utilized by the consumer because of flight cancellation, significant change, or oversale situation; service not provided because of aircraft substitution, equipment malfunction, etc.). If a ticket agent is the merchant of record for a checked bag fee and the checked bag service was not provided (or was significantly delayed) through no fault of the consumer, the carrier that operated the flight, or for multiple-carrier itineraries, the carrier that operated the last segment of the consumer's itinerary is responsible for providing a prompt and automatic refund of the checked bag fee, consistent with § 260.5. If a ticket agent is the merchant of record for fees for all other ancillary services, the carrier that operated the flight and failed to provide the service through no fault of the consumer is responsible for providing a prompt and automatic refund.

(b) In situations where the ancillary service the consumer paid for (other than the service of transporting a checked bag) is not available for all the passengers who paid for that service (*e.g.,* Wi-Fi not available for all passengers on a flight, lounge access not available for all passengers on a certain date), a carrier's obligation under paragraph (a) of this section to provide a prompt and automatic refund begins when the information about the unavailability of the service is known by the carrier that failed to provide the service, and, if applicable, relayed as provided in paragraph (d) of this section to the carrier responsible for providing a prompt refund as specified in paragraph (a) of this section.

(c) In situations where the ancillary service the consumer paid for (other than the service of transporting a checked bag) is not available to an individual or several individuals, rather than to all the passengers who paid for that service, a carrier's obligation under paragraph (a) of this section to provide a prompt and automatic refund begins when the consumer affected by the service failure notifies the operating carrier that failed to provide the ancillary service about the unavailability of the service and that information has been confirmed and, if applicable, relayed as provided in paragraph (d) of this section to the carrier responsible for providing a prompt refund as specified in paragraph (a) of this section. Notification of the unavailability of the ancillary service by a consumer is considered a request for a refund.

(d) In situations where a carrier is the merchant of record for a fee for an ancillary service and the carrier that operates the flight where the ancillary service was not provided are different entities, the operating carrier that failed to provide the ancillary service must timely notify the carrier that is the merchant of record about the unavailability of the ancillary service. Notification by the operating carrier as set forth in this paragraph is necessary for the obligation to provide a prompt refund of ancillary service fees in paragraphs (b) and (c) of this section to apply. The obligation set forth in this paragraph for the operating carrier to timely notify the carrier that is the merchant of record does not apply when the failure to provide service relates to transporting checked bags. Timely notification requirements pertaining to refunds for fees charged to transport checked bags are set forth in § 260.5(c).

§ 260.5 Refunding fees for significantly delayed or lost bags.

A covered carrier that is the merchant of record or, if a ticket agent is the merchant of record, the covered carrier that operated the flight or the last flight segment in a multiple-carrier itinerary, must provide a prompt refund to a consumer of any fee charged for transporting a lost bag or a significantly delayed checked bag, as defined in § 260.2 of this part and determined according to paragraph (a) of this section, subject to the conditions in paragraphs (b) and (c) of this section.

(a) *Determining the length of delay for the bag.* For the purpose of determining whether a checked bag is significantly delayed as defined in § 260.2, the length of delay is calculated from the time the passenger is given the opportunity to deplane from a flight at the passenger's final destination airport (the beginning of the delay) to the time that the carrier has delivered the bag to a location agreed upon by the passenger and carrier (*e.g.,* passenger's home or hotel) or the time that the bag has been picked up by the passenger or another person acting on behalf of the passenger at the passenger's final destination airport (the end of the delay).

(b) *Notification by passenger about lost or significantly delayed bag.* A covered carrier does not have an obligation to provide a refund of the fee for a lost or significantly delayed checked bag unless a passenger files a Mishandled Baggage Report (MBR) for the lost or delayed bag with the carrier that operated the flight, or for multiple-carrier itineraries, the carrier that operated the last segment of the consumer's itinerary.

(c) *Notification by carrier that received an MBR about lost or significantly delayed checked bag.* Except when the carrier responsible for providing a prompt refund for a baggage fee as specified in this section is the same carrier that received the MBR, a covered carrier that received the MBR must timely notify the carrier responsible for providing a prompt refund that the bag has been lost or significantly delayed when this is the case. A covered carrier's obligation to provide a prompt refund of a baggage fee for a lost bag or a significantly delayed checked bag as defined in § 260.2 is conditioned upon the carrier that received the MBR notifying the carrier responsible for providing a prompt refund that the bag has been lost or significantly delayed.

(d) *Automatic refunds.* An automatic refund of a bag fee is due when a checked bag is significantly delayed as determined according to paragraph (a) of this section, the passenger has filed an MBR as provided in paragraph (b) of this section, and, if applicable, notification has been provided by the carrier that received the MBR as set forth in paragraph (c) of this section.

(e) *Amount of the refund.* The amount of the refund issued to a consumer must be a value equal to or greater than the fee that the consumer paid to transport his/her checked bag.

(1) For carriers that adopt an escalated baggage fee scale for multiple bags checked by one passenger, the amount of baggage fee refund issued to the passenger can be determined based on the unique identifier assigned to the significantly delayed or lost bag that correlates to the baggage fee charged for that bag at the time of checking. If there is no such unique identifier assigned, carriers must refund the highest per bag fee or fees charged for the multiple bags.

(2) For a carrier that offers a baggage fee subscription program where consumers can pay a subscription fee that covers fees for checked bags for a specified period, the carrier must refund the lowest amount of the baggage fee the carrier charges another passenger of similar frequent flyer status and in the same class of service without the subscription when a passenger subscribing to the program has a significantly delayed or lost bag.

(f) *Exemptions from the refund obligation.* A covered carrier is exempted from the obligation to refund the fee for a significantly delayed bag in situations where the delay resulted from:

(1) A passenger's failure to pick up and recheck a bag at the first international entry point into the United States as required by U.S. Customs and Border Protection;

(2) A passenger's failure to pick up a checked bag that arrived on time at the passenger's ticketed final destination due to the fault of the passenger if documented by the carrier (*e.g.,* passenger ended the travel before reaching the final destination on the itinerary—''hidden city'' itinerary, or the passenger failed to pick up the bag before taking a flight on a separate itinerary); and

(3) A passenger's voluntary agreement to travel without the checked bag on the same flight as described in paragraph (g) of this section.

(g) *Voluntary separation from bag.* A carrier may require a passenger who fails to meet the minimum check-in time requirement for a flight or is a standby passenger for a flight (*i.e.,* a passenger who lacks a reservation on that flight and is waiting at the gate for a seat to be available on the flight) to agree to a new baggage delivery date and location in situations where the carrier is unable to place the passenger's checked bag on that flight because of the limited time available. The carrier must not require the passenger to waive the right to a refund of bag fees if the bag is lost, the right to compensation for damaged, lost, or pilfered bags, or the right to incidental expenses reimbursement arising from delayed bags beyond the agreed upon delivery date, consistent with the Department's regulation in 14 CFR part 254 and applicable international treaties.

§ 260.6 Refunding fare for flights cancelled or significantly changed by carriers.

(a) *Carriers' obligation to provide prompt refunds.* A covered carrier that is the merchant of record must provide a prompt and automatic refund of the airfare (including all government-imposed taxes and fees and all mandatory carrier-imposed charges) to a consumer for a cancelled flight or a significantly changed flight as set forth in paragraph (b) of this section.

(b) *Automatic refunds.* Automatic refunds of the airfare are due to a consumer when the consumer's right to a refund is undisputed because a carrier cancels a flight or makes a significant change of flight itinerary as described in paragraphs (b)(1) through (b)(6) of this section:

(1) A carrier does not offer alternative transportation for a canceled flight or travel credits, vouchers, or other compensation in lieu of a refund to a consumer (the date the flight was canceled is considered the date the consumer requested a refund).

(2) A carrier does not offer alternative transportation for the significantly changed flight or travel credits, vouchers, or other compensation in lieu of a refund to the consumer who rejected a significantly changed flight (the date the consumer rejects the significantly changed flight itinerary is considered the date the consumer requested a refund);

(3) A carrier offers a significantly changed flight or alternative transportation for a significantly changed or a canceled flight, or offers travel credits, vouchers, or other compensation in lieu of a refund to the consumer, but the consumer rejects the alternative transportation and compensation offered (the date the passenger rejects the offers is considered the date the passenger requested a refund);

(4) A carrier offers a significantly changed flight or alternative transportation for a significantly changed or a canceled flight, but the consumer does not respond to the offers on or before a response deadline set by the carrier as described in paragraph (d) of this section and the consumer has not accepted any offer for travel credits, vouchers, or other compensation in lieu of a refund, and the carrier's policy is to treat a lack of a response as a rejection of the alternative transportation offered (the date the carrier-imposed deadline expired is considered the date the consumer requested a refund);

(5) A carrier does not offer the consumer the options of traveling on a significantly changed flight or traveling on an alternative flight, but offers travel credits, vouchers, or other compensation in lieu of a refund to the consumer, and the consumer does not respond to the alternative compensation offered within a reasonable time, in which case the lack of a response is deemed a rejection (the date the reasonable time has passed as determined by the carrier is considered the date the consumer requested a refund); or

(6) A carrier offers a significantly changed flight or alternative transportation for a significantly changed or a canceled flight and offers travel credits, vouchers, or other compensation in lieu of a refund and the carrier has not set a deadline to respond, the consumer does not respond to the alternatives offered, and the consumer does not take the flight (the date the alternative flight was operated without the passenger on board is considered the date the passenger requested a refund).

(c) *Individuals with a Disability.* A carrier that is the merchant of record must provide a prompt refund to an individual with a disability upon notification by the individual with a disability that he/she does not want to continue travel because of the significant changes described in paragraphs (c)(1) through (c)(3) of this section. The carrier must also provide a prompt refund to any individuals in the same reservation as the individual with a disability who do not want to continue travel without the individual with a disability in situations described in § 260(c)(1) through (c)(3).

(1) The individual with a disability is downgraded to a lower class of service that results in one or more accessibility features needed by the individual becoming unavailable.

(2) The individual with a disability is scheduled to travel through one or more connecting airports that are different from the original itinerary.

(3) The individual with a disability is scheduled to travel on a substitute aircraft on which one or more accessibility features available on the original aircraft needed by the individual are unavailable.

(d) *Carrier-imposed response deadline for alternative transportation.* A carrier may establish a reasonable deadline for a consumer to accept or reject an offer of a significantly changed flight or alternative transportation following a canceled flight or a significantly changed flight itinerary. Carrier refund obligations when a deadline is established are as described in paragraphs (d)(1) through (d)(3) of this section.

(1) For a consumer who rejected the offer of a significantly changed flight or alternative transportation for a significantly changed or a canceled flight by the deadline established by the carrier and has rejected any offer of travel credit, voucher, or other

compensation in lieu of a refund, the carrier must provide a refund within 7 business days of the rejection date for tickets purchased with credit cards and within 20 calendar days of the rejection date for tickets purchased with other payments.

(2) A refund is not due to the consumer if the offer of a significantly changed flight or alternative transportation for a significantly changed or a canceled flight is accepted by the deadline established by the carrier, or if an offer of travel credit, vouchers, or compensation in lieu of a refund is accepted.

(3) A carrier that sets a deadline must adopt and post on its website its policy specifying whether, upon receiving no response from the consumer at the expiration of the deadline of the offer of a significantly changed flight or offer of an alternative transportation, the carrier will deem that the offer of significantly changed flight or alternative transportation has been rejected by the consumer and issue an automatic refund for the airfare or will deem that the offer of significantly changed flight or alternative transportation has been accepted by the consumer. A carrier must not deem an offer for travel credits, vouchers, or other compensation in lieu of a refund to be an acceptance when the consumer does not respond to the offer. Carriers must adhere to their published policies.

(e) *Notification to consumers.* (1) Upon the occurrence of a flight cancellation or a significant change, a covered carrier must timely notify affected consumers about the cancellation or significant change, consumers' rights to a refund if this is the case, any offer of alternative transportation and other options such as travel credits, vouchers, or other compensation in lieu of a refund, any deadline that the carrier imposes for consumers to reject the offer of significantly changed flight or alternative transportation, and the policy that the carrier has adopted regarding consumers' not responding by any deadline established by the carrier, as provided in paragraph (d) of this section.

(2) For carriers that provide notification subscription services to passengers, notification under paragraph (e)(1) of this section must be provided through media that the carriers offer and the subscribers choose, including emails, text messages, and push notices from mobile apps.

(f) Carriers' obligation to notify ticket agents. In situations where a ticket agent is the merchant of record for the transaction, after receiving a refund request by a consumer through the ticket agent, the carrier that canceled or significantly changed the flight must inform the ticket agent without delay whether the consumer is eligible for a refund under this section (*i.e.,* whether the consumer has accepted the significantly changed flight, the alternative transportation, or other compensation offered in lieu of refunds). A ticket agent's obligation to provide a refund starts when the ticket agent receives such notification from the carrier.

§ 260.7 Notifying consumers of right to refund when offering alternative transportation or travel credit or voucher.

If a carrier offers alternative transportation or alternative forms of compensation such as travel credits, vouchers, or other compensation in lieu of the refund, the carrier must first disclose to consumers that they are entitled to a refund if that is the case. A carrier must not deem a consumer to have accepted an offer for travel credits, vouchers, or other compensation in lieu of a refund unless the consumer affirmatively agrees to the alternative form of compensation.

§ 260.8 Disclosing material restrictions, conditions, or limitations.

A carrier must clearly disclose, no later than at the time of voucher or credit offer, any material restrictions, limitations, or conditions on travel credits, vouchers, or other compensation, including but not limited to validity period, advance purchase requirement, capacity restrictions, and blackout dates, regardless of whether consumers are entitled to a refund.

§ 260.9 Providing prompt refunds.

When a refund of a fare or a fee for an ancillary service, including a fee for lost or significantly delayed checked baggage, is due pursuant to this part, the refund must be issued promptly in the original form of payment (*i.e.,* money is returned to an individual using whatever payment method the individual used to make the original payment, such as a check, credit card, debit card, cash, or airline miles) unless the consumer agrees to receive the refunds in a different form of payment that is a cash equivalent as defined in § 260.2. Carriers may not retain a processing fee for issuing refunds that are due.

§ 260.10 Contract of Carriage provisions related to refunds.

A carrier must not include terms or conditions in its contract of carriage inconsistent with the carriers' obligations as specified by this part. Any such action will be considered an unfair and deceptive practice within the meaning of 49 U.S.C. 41712.

■ 5. Add Part 262 to read as follows:

PART 262—TRAVEL CREDITS OR VOUCHERS DUE TO A SERIOUS COMMUNICABLE DISEASE

Sec.

Authority: 49 U.S.C. 40101(a), 41702, and 41712.

§ 262.1 Purpose.

The purpose of this part is to ensure that carriers provide travel credits or vouchers, upon request, to consumers who are restricted or prohibited from traveling by a governmental entity due to a serious communicable disease (*e.g.,* as a result of a stay at home order, entry restriction, or border closure) or are advised by a licensed treating medical professional consistent with public health guidance issued by the U.S. Centers for Disease Control and Prevention (CDC) or the World Health Organization (WHO) not to travel to protect themselves or others from a serious communicable disease.

§ 262.2 Definitions.

As used in this part:

Air carrier means a citizen of the United States undertaking by any means, directly or indirectly, to provide air transportation.

Break in journey means any deliberate interruption by a passenger of a journey between a point in the United States and a point in a foreign country where there is a stopover at a foreign point scheduled to exceed 24 hours. If the stopover is 24 hours or less, whether it is a break in journey depends on various factors such as whether the segment between two foreign points and the segment between a foreign point and the United States were purchased in a single transaction and as a single ticket/itinerary, whether the segment between two foreign points is operated or marketed by a carrier that has no codeshare or interline agreement with the carrier operating or marketing the segment to or from the United States, and whether the stopover at a foreign point involves the passenger picking up checked baggage, leaving the airport,

and continuing the next segment after a substantial amount of time.

Covered carrier means an air carrier or a foreign air carrier operating to, from or within the United States, conducting scheduled passenger service.

Covered flight means a scheduled flight operated or marketed by a covered carrier to, from, or within the United States, including itineraries with brief and incidental stopover(s) at a foreign point without a break in journey.

Licensed treating medical professional means an individual, including a physician, a nurse practitioner, a physician's assistant, or other medical provider, who is licensed or authorized under the law of a State or territory in the United States or a comparable jurisdiction in another country to engage in the practice of medicine to diagnose or treat a patient for a health condition that is the reason for the passenger to request a travel credit or voucher under § 262.4(b) and (c).

Merchant of record means the entity (carrier or ticket agent) responsible for processing payment by the consumer for airfare or ancillary services or products, as shown in the consumer's financial charge statements such as debit or credit card charge statements.

Foreign air carrier means a person, not a citizen of the United States, undertaking by any means, directly or indirectly, to provide foreign air transportation.

Public health emergency has the same meaning as defined in 42 CFR 70.1.

Serious communicable disease means a communicable disease as defined in 42 CFR 70.1 that can cause serious health consequences (*e.g.,* breathing problems, organ damage, neurological difficulties, death) and can be easily transmitted by casual contact in an aircraft cabin environment (*i.e.,* easily spread to others in an aircraft cabin through general activities of passengers such as sitting next to someone, shaking hands, talking to someone, or touching communal surfaces). For example, the common cold is readily transmissible in an aircraft cabin environment but does not have severe health consequences. AIDS has serious health consequences but is not readily transmissible in an aircraft cabin environment. Both the common cold and AIDS would not be considered serious communicable diseases for purposes of this part. SARS is readily transmissible in an aircraft cabin environment and has severe health consequences. SARS would be considered a serious communicable disease for purposes of this part.

§ 262.3 Applicability.

This part applies to all covered carriers that are the merchant of record for a covered flight or the operating carrier of a covered flight when a ticket agent is the merchant of record.

§ 262.4 Passengers entitled to receive travel credits or vouchers.

A covered carrier as identified in § 262.3 must provide a transferrable travel credit or voucher that does not expire for at least five years from the date of issuance to consumers described in paragraphs (a) to (c) of this section.

(a) The consumer is prohibited from travel to, from, or within the United States or is required to quarantine at the destination as shown on the consumer's itinerary for more than 50% of the length of the trip (excluding travel dates) because of a U.S. (Federal, State, or local) or foreign government restriction or prohibition (*e.g.,* stay at home order, entry restriction, border closure, or quarantine notice) in relation to a serious communicable disease. The consumer must have purchased the airline ticket before a public health emergency was declared for the origination or destination of the consumer's scheduled travel or, if there is no declaration of a public health emergency, before the government prohibition or restriction applicable to the origination or the destination of the consumer's scheduled travel was imposed.

(b) There is a public health emergency applicable to the origination or destination of the consumer's itinerary, the consumer purchased the airline ticket before the public health emergency was declared, the consumer is scheduled to travel during the public health emergency, and the consumer is advised by a licensed treating medical professional not to travel by air to protect himself or herself from a serious communicable disease.

(c) Regardless of whether there is a public health emergency, the consumer is advised by a licensed treating medical professional not to travel by air because the consumer has or is likely to have contracted a serious communicable disease, and the consumer's condition is such that traveling on a commercial flight would pose a direct threat to the health of others.

§ 262.5 Documentation.

In the absence of an applicable determination issued by the Department of Health and Human Services that requiring the documentation specified in paragraphs (b) or (c) of this section is not in the public interest, as a condition for issuing the travel credits or vouchers in § 262.4, carriers may require, as appropriate, documentation specified in paragraphs (a) to (c) of this section.

(a) For any consumer requesting a travel credit or voucher because of a government restriction or prohibition pursuant to § 262.4(a), carriers may require the consumer to provide the applicable current government order or other document demonstrating how the government order prohibits the consumer from travel to, from, or within the United States as scheduled or requires the consumer to quarantine for more than 50% of the length of the consumer's scheduled trip at the destination (excluding travel dates) as shown on the passenger's itinerary.

(b) For any consumer requesting a travel credit or voucher to protect his or her health pursuant to § 262.4(b), carriers may require the consumer to provide a valid medical certificate as set forth in paragraphs (b)(1) and (b)(2) of this section.

(1) For purposes of paragraph (b) of this section, a medical certificate means a written statement from a licensed treating medical professional stating that it is his/her professional opinion, based on the medical condition of the individual and current medical knowledge on the relevant serious communicable disease, including public health guidance issued by CDC or WHO, if available, that the individual should not travel during the current public health emergency by commercial air transportation to protect his or her health from a serious communicable disease.

(2) To be valid, a medical certificate under paragraph (b) of this section must be dated after the declaration of the relevant public health emergency and no earlier than one year before the scheduled travel date and include information regarding the licensed treating medical professional's license (the date of issuance, type of the license, State or other jurisdiction in which the license was issued).

(c) For any consumer requesting a travel credit or a voucher to protect the health of others pursuant to § 262.4(c), carriers may require the consumer to provide a valid medical certificate as set forth in paragraphs (c)(1) through (c)(3) of this section. For any consumer who informed carriers that there is not adequate time to obtain and submit a valid medical certificate as set forth in paragraphs (c)(1) through (c)(3) of this section before the scheduled travel date, carriers must allow submission of the medical certificate within a reasonable time after the scheduled travel date.

(1) For purposes of paragraph (c) of this section, a medical certificate means

a written statement from a licensed treating medical professional stating that it is his/her professional opinion, based on the medical condition of the individual and current medical knowledge of the relevant serious communicable disease, including public health guidance issued by CDC or WHO, if available, that the individual should not travel by commercial air transportation on the date of the scheduled travel to protect the health of others from a serious communicable disease because the individual has or is likely to have contracted a serious communicable disease .

(2) To be valid, a medical certificate under paragraph (c) of this section must include information regarding the licensed treating medical professional's license (the date of issuance, type of the license, State or other jurisdiction in which license was issued).

(3) For a medical certificate under paragraph (c) of this section, carriers may require that it be dated close to the travel date, as determined based on the current medical knowledge and applicable public health guidance issued by CDC or WHO regarding the contagious period of the relevant serious communicable disease.

§ 262.6 Value of travel credits or vouchers.

Upon confirming a consumer's eligibility for a travel credit or voucher pursuant to this paragraph, a carrier must promptly issue the travel credit or voucher with a value equal to or greater than the fare (including government-imposed taxes and fees and carrier-imposed charges and prepaid ancillary service fees for services not utilized by the consumer). If a consumer has obtained a refund of the September 11th Security Fee or other government-imposed taxes and fees, then those fee amounts may be deducted from the consumer's travel credit or voucher. Nothing in this section relieves the carrier of its obligation to comply with the requirements of other Federal agencies relating to the refund of government-imposed taxes and fees.

§ 262.7 Processing fee.

A carrier may retain a processing fee for issuing the travel voucher or credit, as long as the fee is on a per-passenger basis and the existence and amount of the fee is clearly and prominently disclosed to consumers at the time they purchased the airfare.

§ 262.8 Disclosure of restrictions, conditions or limitations.

A carrier shall not impose unreasonable restrictions, conditions or limitations on the travel credits or vouchers, including a validity period that is shorter than five years from the date of issuance, a restriction on the transferability of the credits or vouchers to another individual, conditions that severely restrict booking with respect to travel date, time, route, or class of service; a limitation that allows redemption only in one booking and renders any residual value void; or a limitation that only allows the value of the credits or vouchers to apply to the base fare of a new booking but not government-imposed taxes or fees, carrier imposed fees, or ancillary service fees. A carrier must clearly disclose, no later than at the time of voucher or credit issuance, any material restrictions, limitations, or conditions on the use of the credits and vouchers that are not deemed unreasonable, including but not limited to advance purchase requirement or capacity restrictions and blackout dates.

§ 262.9 Contract of carriage.

A carrier shall not include terms or conditions in its contract of carriage inconsistent with the carriers' obligations as specified by this part. Any such action will be considered an unfair and deceptive practice within the meaning of 49 U.S.C. 41712.

PART 399—STATEMENTS OF GENERAL POLICY [AMENDED]

■ 6. The authority citation for part 399 continues to read as follows:

Authority: 49 U.S.C. 40113(a), 41712, 46106, and 46107.

■ 7. Amend § 399.80 by revising paragraph (l) to read as follows:

§ 399.80 Unfair and deceptive practices of ticket agents.

* * * * *

(l) Failing to make a prompt refund of airfare (including all government-imposed taxes and fees and all mandatory carrier-imposed charges) to a consumer, upon request, for a cancelled flight or a significantly changed flight itinerary if the consumer chooses not to travel or accept compensation in lieu of a refund in situations described in 14 CFR 260.6(b)(1) through (6) and 14 CFR 260.6(c)(1) through (3) when the ticket agent is the merchant of record. Failing to provide a prompt refund of airfare (including all government-imposed taxes and fees and all mandatory carrier imposed charges), upon request, for a significantly changed flight itinerary to consumers on the same reservation as an individual with a disability who does not want to continue travel because of a significant change described in paragraph (l)(1)(vii)(E) of this section related to downgrades or paragraph (l)(1)(vii)(G) of this section related to aircraft substitution which result in one or more accessibility features needed by the individual with a disability becoming unavailable or because of the significant change described in paragraph (l)(1)(vii)(F) of this section related to change in connecting airports. A prompt refund is one that is made within 7 business days of the ticket agent receiving information from a carrier as specified in 14 CFR 260.6(f), as required by 12 CFR part 1026 for credit card purchases, and within 20 calendar days of refund becoming due for cash, check, debit card, or other forms of purchases. Ticket agents must provide the refunds in the original form of payment (*i.e.,* money is returned to individual using whatever payment method the individual used to make the original payment, such as a check, a credit card, a debit card, cash, or airline miles), unless the consumer agrees to receive the refund in another form of payment that is cash equivalent. A ticket agent may retain a service fee charged when issuing the original ticket to the extent that service is for more than processing payment for a flight that the consumer found. That fee must be on a per-passenger basis and its existence, amount, and the non-refundable nature if that is the case must be clearly and prominently disclosed to consumers at the time they purchase the airfare. Ticket agents may offer alternative transportation, travel credits, vouchers, or other compensation in lieu of refunds, but must first inform consumers that they are entitled to a refund if that is the case. Ticket agents must clearly disclose any material restrictions, conditions, and limitations on travel credits, vouchers, or other compensation they offer.

(1) For purposes of paragraph (l) of this section, the following definitions apply:

(i) *Business days* means Monday through Friday, excluding Federal holidays in the United States.

(ii) *Cancelled flight* or *cancellation means* a flight with a specific flight number scheduled to be operated between a specific origin-destination city pair that was published in a carrier's Computer Reservation System at the time of the ticket sale but was not operated by the carrier.

(iii) *Cash equivalent* means a form of payment that can be used like cash, including but not limited to a check, a prepaid card, funds transferred to the passenger's bank account, funds provided through digital payment methods (*e.g.,* PayPal, Venmo), or a gift

card that is widely accepted in commerce. It is not cash equivalent if consumers bear the burden for maintenance or usage fees related to the payment.

(iv) *Class of service* means seating in the same cabin class such as First, Business, Premium Economy, or Economy class, which is defined based on seat location in the aircraft and seat characteristics such as width, seat recline angles, or pitch (including the amount of legroom).

(v) *Covered flight* means a scheduled flight to, from, or within the United States.

(vi) *Merchant of record* means the entity responsible for processing payments by consumers for airfare, as shown in the consumer's financial charge statements such as debit or credit card charge statements.

(vii) *Significant change of flight itinerary* or *significantly changed flight* means a change to a flight itinerary consisting of covered flight(s) made by a U.S. or foreign carrier where:

(A) The consumer is scheduled to depart from the origination airport three hours or more for domestic itineraries and six hours or more for international itineraries earlier than the original scheduled departure time;

(B) The consumer is scheduled to arrive at the destination airport three hours or more for domestic itineraries or six hours or more for international itineraries later than the original scheduled arrival time;

(C) The consumer is scheduled to depart from a different origination airport or arrive at a different destination airport;

(D) The consumer is scheduled to travel on an itinerary with more connection points than that of the original itinerary;

(E) The consumer is downgraded to a lower class of service;

(F) The consumer with a disability is scheduled to travel through one or more connecting airports that are different from the original itinerary; or

(G) The consumer with a disability is scheduled to travel on substitute aircraft on which one or more accessibility features needed by the passenger are unavailable.

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Part IV

Department of Labor

Wage and Hour Division

29 CFR Part 541

Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees; Final Rule

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 541

RIN 1235–AA39

Defining and Delimiting the Exemptions for Executive, Administrative, Professional, Outside Sales, and Computer Employees

AGENCY: Wage and Hour Division, Department of Labor.

ACTION: Final rule.

SUMMARY: The Department of Labor (Department) is updating and revising the regulations issued under the Fair Labor Standards Act implementing the exemptions from minimum wage and overtime pay requirements for executive, administrative, professional, outside sales, and computer employees. Significant revisions include increasing the standard salary level, increasing the highly compensated employee total annual compensation threshold, and adding to the regulations a mechanism that will allow for the timely and efficient updating of the salary and compensation thresholds, including an initial update on July 1, 2024, to reflect earnings growth. The Department is not finalizing in this rule its proposal to apply the standard salary level to the U.S. territories subject to the Federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry.

DATES: The effective date for this final rule is July 1, 2024. Sections 541.600(a)(2) and 541.601(a)(2) are applicable beginning January 1, 2025.

FOR FURTHER INFORMATION CONTACT: Daniel Navarrete, Acting Director, Division of Regulations, Legislation, and Interpretation, Wage and Hour Division, U.S. Department of Labor, Room S–3502, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693–0406 (this is not a toll-free number). Alternative formats are available upon request by calling 1–866–487–9243. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

Questions of interpretation or enforcement of the agency's existing regulations may be directed to the nearest Wage and Hour Division (WHD) district office. Locate the nearest office by calling the WHD's toll-free help line at (866) 4US–WAGE ((866) 487–9243) between 8 a.m. and 5 p.m. in your local time zone, or log onto WHD's website at *https://www.dol.gov/agencies/whd/contact/local-offices* for a nationwide listing of WHD district and area offices.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

The Fair Labor Standards Act (FLSA or Act) requires covered employers to pay employees a minimum wage and, for employees who work more than 40 hours in a week, overtime premium pay of at least 1.5 times the employee's regular rate of pay. Section 13(a)(1) of the FLSA, which was included in the original Act in 1938, exempts from the minimum wage and overtime pay requirements ''any employee employed in a bona fide executive, administrative, or professional capacity[.]'' [1] The exemption is commonly referred to as the ''white-collar'' or executive, administrative, or professional (EAP) exemption. The statute expressly gives the Secretary of Labor (Secretary) authority to define and delimit the terms of the exemption. Since 1940, the regulations implementing the EAP exemption have generally required that each of the following three tests must be met: (1) the employee must be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test); (2) the amount of salary paid must meet a minimum specified amount (the salary level test); and (3) the employee's job duties must primarily involve executive, administrative, or professional duties as defined by the regulations (the duties test). The employer bears the burden of establishing the applicability of the exemption.[2] Job titles and job descriptions do not determine EAP exemption status, nor does merely paying an employee a salary.

Consistent with its broad authority under the Act, in this final rule the Department is setting compensation thresholds for the standard test and the highly compensated employee test that will work effectively with the respective duties tests to better identify who is employed in a bona fide EAP capacity for purposes of determining exemption status under the Act. Specifically, the Department is setting the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region ($1,128 per week or $58,656 annually for a full-year worker) [3] and the highly compensated employee total annual compensation threshold at the annualized weekly earnings of the 85th percentile of full-time salaried workers nationally ($151,164). These compensation thresholds are firmly grounded in the authority that the FLSA grants to the Secretary to define and delimit the EAP exemption, a power the Secretary has exercised for 85 years.

The increase in the standard salary level to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region better fulfills the Department's obligation under the statute to define and delimit who is employed in a bona fide EAP capacity. Upon reflection, the Department has determined that its rulemakings over the past 20 years, since the Department simplified the test for the EAP exemption in 2004 by replacing the historic two-test system for determining exemption status with the single standard test, have vacillated between two distinct approaches: One used in rules in 2004 [4] and 2019,[5] that exempted lower-paid workers who historically had been entitled to overtime because they did not meet the more detailed duties requirements of the test that was in place from 1949 to 2004; and one used in a rule in 2016,[6] that restored overtime protection to lower-paid white-collar workers who performed significant amounts of nonexempt work but also removed from the exemption other lower-paid workers who historically were exempt because they met the prior more detailed duties test, an approach that received unfavorable treatment in litigation.[7] Having grappled with these different approaches to setting the standard salary level, this final rule retains the simplified standard test, the benefits of

[1] 29 U.S.C. 213(a)(1).

[2] *See, e.g., Idaho Sheet Metal Works, Inc.* v. *Wirtz,* 383 U.S. 190, 209 (1966); *Walling* v. *Gen. Indus. Co.,* 330 U.S. 545, 547–48 (1947).

[3] In determining earnings percentiles in its part 541 rulemakings since 2004, the Department has consistently looked at nonhourly earnings for full-time workers from the Current Population Survey (CPS) Merged Outgoing Rotation Group (MORG) data collected by the U.S. Bureau of Labor Statistics (BLS). As explained in section VII.B.5.i, the Department considers data representing compensation paid to nonhourly workers to be an appropriate proxy for compensation paid to salaried workers, although for simplicity the Department uses the terms salaried and nonhourly interchangeably in this rule. The Department relied on CPS MORG data for calendar year 2022 to develop the NPRM, including to determine the proposed salary level. The Department is using the most recent full-year data available for this final rule, which is CPS MORG data for calendar year 2023. The new standard salary level of $1,128 per week is $12 to $30 less than the Department estimated in the NPRM. 88 FR 62152, 62152–53 n.3 (Sept. 8, 2023).

[4] 69 FR 22122 (April 23, 2004).

[5] 84 FR 51230 (Sept. 27, 2019).

[6] 81 FR 32391 (May 23, 2016).

[7] The Department never enforced the 2016 rule because it was invalidated by the U.S. District Court for the Eastern District of Texas. *See Nevada* v. *U.S. Department of Labor,* 275 F.Supp.3d 795 (E.D. Tex. 2017).

which were recognized in the Department's 2004, 2016, and 2019 rulemakings,[8] while, through a revised methodology, fully restoring the salary level's screening function and accounting for the switch from a two-test to a one-test system for defining the EAP exemption, and also separately updating the standard salary level to account for earnings growth since the 2019 rule.

The new standard salary level will, in combination with the standard duties test, better define and delimit which employees are employed in a bona fide EAP capacity. By setting a salary level above what the methodology used in 2004 and 2019 would produce using current data, the new standard salary level will ensure that, consistent with the Department's historical approach to the exemption, fewer lower-paid white-collar employees who perform significant amounts of nonexempt work are included in the exemption. At the same time, by setting the salary level below what the methodology used in 2016 would produce using current data, the new standard salary level will allow employers to continue to use the exemption for many lower-paid white-collar employees who were made exempt under the 2004 standard duties test. The combined result will be a more effective test for determining who is employed in a bona fide EAP capacity. The applicability date of the new standard salary level will be January 1, 2025. The Department is not finalizing its proposal to apply the standard salary level to the U.S. territories subject to the federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry.[9]

The Department is also increasing the earnings threshold for the highly compensated employee (HCE) exemption, which was added to the regulations in 2004 and applies to certain highly compensated employees and combines a much higher annual compensation requirement with a minimal duties test. The HCE test's primary purpose is to serve as a streamlined alternative for very highly compensated employees because a very high level of compensation is a strong indicator of an employee's exempt status, thus eliminating the need for a detailed duties analysis.[10] The Department is increasing the HCE total annual compensation threshold to the annualized weekly earnings amount of the 85th percentile of full-time salaried workers nationally ($151,164). The new HCE threshold is high enough to reserve the test for those employees who are ''at the very top of [the] economic ladder'' [11] and will guard against the unintended exemption of workers who are not bona fide EAP employees, including those in high-income regions and industries. The applicability date of the new HCE total annual compensation threshold will be January 1, 2025.

In each of its part 541 rulemakings since 2004, the Department recognized the need to regularly update the earnings thresholds to ensure that they remain effective in helping differentiate between exempt and nonexempt employees. As the Department observed in these rulemakings, even a well-calibrated salary level that is not kept up to date becomes obsolete as wages for nonexempt workers increase over time.[12] Long intervals between rulemakings have resulted in eroded earnings thresholds based on outdated earnings data that were ill-equipped to help identify bona fide EAP employees.

To address this problem, in the 2004 and 2019 rules the Department expressed its commitment to regularly updating the salary levels.[13] In the 2016 rule, it included a regulatory provision to automatically update the salary levels.[14] Based on its long experience with updating the salary levels, the Department has determined that adopting a regulatory provision for updating the salary levels to reflect current earnings data, with an exception for pausing future updates under certain conditions, is the most viable and efficient way to ensure the EAP exemption earnings thresholds keep pace with changes in employee pay and thus remain effective in helping determine exemption status. This rule establishes a new updating mechanism. The initial update to the standard salary level and the HCE total annual compensation threshold will take place on July 1, 2024, and will use the methodologies in place at that time (*i.e.,* the 2019 rule methodologies), resulting in a $844 per week standard salary level and a $132,964 HCE total annual compensation threshold. Future updates to the standard salary level and HCE total annual compensation threshold with current earnings data will begin 3 years after the date of the initial update (July 1, 2027), and every 3 years thereafter, using the methodologies in place at the time of the updates. The Department anticipates that, by the time the first triennial update under the updating mechanism occurs, assuming the Department has not engaged in further rulemaking, the new methodologies for the standard salary level and HCE total annual compensation requirement established by this final rule will have become effective and the triennial update will employ these new methodologies. The new updating mechanism will allow for the timely, predictable, and efficient updating of the earnings thresholds.

The Department estimates that in Year 1, approximately 1 million employees who earn at least $684 per week but less than $844 per week will be impacted by the initial update applying current wage data to the standard salary level methodology from the 2019 rule, and approximately 3 million employees who earn at least $844 per week but less than the new standard salary level of $1,128 per week will be impacted by the subsequent application of the new standard salary level. *See* Table 25. As explained in section V.B.4.ii, for 1.8 million of the affected employees (including the 1 million impacted by the initial update), this rule will restore overtime protections that they would have been entitled to under every rule prior to the 2019 rule. The Department also estimates that 292,900 employees who are currently exempt under the HCE test, but do not meet the standard test for exemption, will be affected by the proposed increase in the HCE total annual compensation level. Absent an employer increasing these employees' pay to at or above the new HCE level, the exemption status of these employees will turn on the standard duties test (which these employees do not meet) rather than the minimal duties test that applies to employees earning at or above the HCE threshold. The economic analysis quantifies the direct costs resulting from this rule: (1) regulatory familiarization costs; (2) adjustment costs; and (3) managerial costs. The Department estimates that total annualized direct employer costs over the first 10 years will be $803 million with a 7 percent discount rate. This rule will also give employees higher earnings in the form of transfers of income from employers to employees. The

[8] *See* 84 FR 51243–45; 81 FR 32414, 32444–45; 69 FR 22126–28.

[9] The Department proposed in sections IV.B.1 and B.2 of the NPRM to apply the updated standard salary level to the four U.S. territories that are subject to the federal minimum wage—Puerto Rico, Guam, the U.S. Virgin Islands, and the Commonwealth of the Northern Mariana Islands (CNMI)—and to update the special salary levels for American Samoa and the motion picture industry in relation to the new standard salary level. The Department will address these aspects of its proposal in a future final rule.

[10] *See* 69 FR 22172–73.

[11] *Id.* at 22174.

[12] 84 FR 51250–51; 81 FR 32430; *see also* 69 FR 22164.

[13] 69 FR 22171; 84 FR 51251–52.

[14] 81 FR 32430.

Department estimates annualized transfers will be $1.5 billion, with a 7 percent discount rate.

II. Background

A. The FLSA

The FLSA generally requires covered employers to pay employees at least the federal minimum wage (currently $7.25 an hour) for all hours worked and overtime premium pay of at least one and one-half times the employee's regular rate of pay for all hours worked over 40 in a workweek.[15] However, section 13(a)(1) of the FLSA, codified at 29 U.S.C. 213(a)(1), provides an exemption from both minimum wage and overtime pay for ''any employee employed in a bona fide executive, administrative, or professional capacity . . . or in the capacity of [an] outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary [of Labor], subject to the provisions of [the Administrative Procedure Act] . . .).'' The FLSA does not define the terms ''executive,'' ''administrative,'' ''professional,'' or ''outside salesman,'' but rather directs the Secretary to define those terms through rulemaking. Pursuant to Congress's grant of rulemaking authority, since 1938 the Department has issued regulations at 29 CFR part 541 to define and delimit the scope of the section 13(a)(1) exemption.[16] Because Congress explicitly gave the Secretary authority to define and delimit the specific terms of the exemption, the regulations so issued have the binding effect of law.[17]

The exemption for executive, administrative, or professional employees was included in the original FLSA legislation passed in 1938.[18] It was modeled after similar provisions contained in the earlier National Industrial Recovery Act of 1933 and state law precedents.[19] As the Department has explained in prior rules, the EAP exemption is premised on two policy considerations. First, the type of work exempt employees perform is difficult to standardize to any time frame and cannot be easily spread to other workers after 40 hours in a week, making enforcement of the overtime provisions difficult and generally precluding the potential job expansion intended by the FLSA's time-and-a-half overtime premium.[20] Second, exempt workers typically earn salaries well above the minimum wage and are presumed to enjoy other privileges to compensate them for their long hours of work. These include, for example, above-average fringe benefits and better opportunities for advancement, setting them apart from nonexempt workers entitled to overtime pay.[21]

Section 13(a)(1) exempts covered EAP employees from both the FLSA's minimum wage and overtime requirements. However, because of their long hours of work, its most significant impact is its exemption of these employees from the Act's overtime protections, as discussed in section VII.C.4. An employer may employ such exempt employees for any number of hours in the workweek without paying an overtime premium. Some state laws have stricter standards to be exempt from state minimum wage and overtime protections than those which exist under federal law, such as higher salary levels or more stringent duties tests. The FLSA does not preempt any such stricter state standards.[22] If a state establishes a higher standard than the provisions of the FLSA, the higher standard applies in that state.

B. Regulatory History

The Department's part 541 regulations have consistently looked to the duties performed by the employee and the salary paid by the employer in determining whether an individual is employed in a bona fide executive, administrative, or professional capacity. Since 1940, the Department's implementing regulations have generally required each of the following three prongs to be satisfied for the exemption to apply: (1) the employee must be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test); (2) the amount of salary paid must meet a minimum specified amount (the salary level test); and (3) the employee's job duties must primarily involve executive, administrative, or professional duties as defined by the regulations (the duties test).

1. The Part 541 Regulations From 1938 to 2004

The Department's part 541 regulations have always included earnings criteria. From the first Part 541 regulations, there has been ''wide agreement'' that the amount paid to an employee is ''a valuable and easily applied index to the 'bona fide' character of the employment for which [the] exemption is claimed[.]'' [23] Because EAP employees ''are denied the protection of the [A]ct[,]'' they are ''assumed [to] enjoy compensatory privileges'' which distinguish them from nonexempt employees, including substantially higher pay.[24] Additionally, the Department has long recognized that the salary level test is a useful criterion for helping identify bona fide EAP employees and provides a practical guide for employers and employees, thus tending to reduce litigation and ensure that nonexempt employees receive the overtime protection to which they are entitled.[25] These benefits accrue to employees and employers alike, which is why, despite disagreement over the appropriate magnitude of the part 541 earnings thresholds, an ''overwhelming majority'' of stakeholders have supported the retention of such thresholds in prior part 541 rulemakings.[26]

The Department issued the first version of the part 541 regulations in October 1938.[27] The Department's initial regulations included a $30 per week compensation requirement for executive and administrative employees. It also included a duties test that prohibited employers from claiming the EAP exemption for employees who performed ''[a] substantial amount of work of the same nature as that performed by nonexempt employees of the employer.'' [28]

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[15] *See* 29 U.S.C. 206(a), 207(a).

[16] *See Helix Energy Solutions Group, Inc.* v. *Hewitt,* 143 S.Ct. 677, 682 (2023) (''Under [section 13(a)(1)], the Secretary sets out a standard for determining when an employee is a 'bona fide executive.'").

[17] *See Batterton* v. *Francis,* 432 U.S. 416, 425 n.9 (1977).

[18] *See* Fair Labor Standards Act of 1938, Pub. L. 75–718, 13(a)(1), 52 Stat. 1060, 1067 (June 25, 1938).

[19] *See* National Industrial Recovery Act, Pub. L. 73–67, ch. 90, title II, 206(2), 48 Stat 195, 204–5 (June 16, 1933).

[20] *See* Report of the Minimum Wage Study Commission, Volume IV, pp. 236 and 240 (June 1981).

[21] *See id.*

[22] *See* 29 U.S.C. 218(a).

[23] ''Executive, Administrative, Professional . . . Outside Salesman'' Redefined, Wage and Hour Division, U.S. Department of Labor, Report and Recommendations of the Presiding Officer [Harold Stein] at Hearings Preliminary to Redefinition (Oct. 10, 1940) (Stein Report) at 19.

[24] *Id.; see* Report of the Minimum Wage Study Commission, Volume IV, p. 236 (''Higher base pay, greater fringe benefits, improved promotion potential and greater job security have traditionally been considered as normal compensatory benefits received by EAP employees, which set them apart from non-EAP employees.'').

[25] *See* 84 FR 51237; *see also* Report and Recommendations on Proposed Revisions of Regulations, Part 541, by Harry Weiss, Presiding Officer, Wage and Hour and Public Contracts Divisions, U.S. Department of Labor (June 30, 1949) (Weiss Report) at 8.

[26] 84 FR 51235; *see also* Stein Report at 5, 19; Weiss Report at 9.

[27] 3 FR 2518 (Oct. 20, 1938).

[28] *Id.*

The Department issued the first update to its part 541 regulations in October 1940,[29] following extensive public hearings.[30] Among other changes, the 1940 update newly applied the salary level requirement to professional employees; added the salary basis requirement to the tests for executive, administrative, and professional employees; and introduced a 20 percent cap on the amount of nonexempt work that executive and professional employees could perform each workweek, replacing language which prohibited the performance of a ''substantial amount'' of nonexempt work.[31]

The Department conducted further hearings on the part 541 regulations in 1947 [32] and issued revised regulations in December 1949.[33] The 1949 rulemaking updated the salary levels set in 1940 and introduced a second, less stringent duties test for higher paid executive, administrative, and professional employees.[34] Thus, beginning in 1949, the part 541 regulations contained two tests for the EAP exemption. These tests became known as the ''long'' test and the ''short'' test. The long test paired a lower earnings threshold with a more rigorous duties test that generally limited the performance of nonexempt work to no more than 20 percent of an employee's hours worked in a workweek. The short test paired a higher salary level and a less rigorous duties test, with no specified limit on the performance of nonexempt work. From 1958 until 2004, the regulations in place generally set the long test salary level at a level designed to exclude from exemption approximately the lowest-paid 10 percent of salaried white-collar employees who performed EAP duties in lower-wage areas and industries and set the short test salary level significantly higher.[35] The salary and duties components of each test complemented each other, and the two tests worked in combination to determine whether an individual was employed in a bona fide EAP capacity. Lower-paid employees who met the long test salary level but did not meet the higher short test salary level were subject to the long duties test which ensured that these employees were employed in an EAP capacity by limiting the amount of time they could spend on nonexempt work. Employees who met the higher short test salary level were considered to be more likely to meet the requirements of the long duties test and thus were subject to a short-cut duties test for determining exemption status.

Additional changes to the regulations, including salary level updates, were made in 1954,[36] 1958,[37] 1961,[38] 1963,[39] 1967,[40] 1970,[41] 1973,[42] and 1975.[43] The Department revised the part 541 regulations twice in 1992 but did not update the salary thresholds at that time.[44] None of these updates changed the basic structure of the long and short tests.

The Department described the salary levels adopted in the 1975 rule as ''interim rates,'' intended to ''be in effect for an interim period pending the completion of a study [of worker earnings] by the Bureau of Labor Statistics . . . in 1975.'' [45] However, those salary levels remained in effect until 2004. The utility of the salary levels in helping to define the EAP exemption decreased as wages rose during this period. In 1991, the federal minimum wage rose to $4.25 per hour,[46] which for a 40-hour workweek exceeded the lower long test salary level of $155 per week for executive and administrative employees and equaled the long test salary level of $170 per week for professional employees. In 1997, the federal minimum wage rose to $5.15 per hour,[47] which for a 40-hour workweek not only exceeded the long test salary levels, but also was close to the higher short test salary level of $250 per week.

2. Part 541 Regulations From 2004 to 2019

The Department published a final rule in April 2004 (the 2004 rule) [48] that updated the part 541 salary levels for the first time since 1975 and made several significant changes to the regulations. Most significantly, the Department eliminated the separate long and short tests and replaced them with a single standard test. The Department set the standard salary level at $455 per week, which was equivalent to the 20th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South) and in the retail industry nationally. The Department paired the new standard salary level test with a new standard duties test for executive, administrative, and professional employees, respectively, which was substantially equivalent to the short duties test used in the two-test system.[49]

In the 2004 rule, the Department acknowledged that the switch to the single standard test for exemption was a significant change in the regulatory structure,[50] and noted that the shift to setting the salary level based on ''the lowest 20 percent of salaried employees in the South, rather than the lowest 10 percent'' of EAP employees was made, in part, ''because of the proposed change from the 'short' and 'long' test structure[.]'' [51] The Department asserted that elimination of the long duties test was warranted because ''the relatively small number of employees currently earning from $155 to $250 per week, and thus tested for exemption under the 'long' duties test, will gain stronger protections under the increased minimum salary level which . . . guarantees overtime protection for all employees earning less than $455 per week[.]'' [52] The Department acknowledged, however, that the new standard salary level was comparable to the lower long test salary level used in the two-test system (*i.e.,* if the Department's long test salary level methodology had been applied to contemporaneous data).[53] Thus,

[29] 5 FR 4077 (Oct. 15, 1940).

[30] *See* Stein Report.

[31] 5 FR 4077.

[32] *See* Weiss Report.

[33] *See* 14 FR 7705 (Dec. 24, 1949).

[34] *Id.* at 7706.

[35] *See* Report and Recommendations on Proposed Revision of Regulations, Part 541, Under the Fair Labor Standards Act, by Harry S. Kantor, Assistant Administrator, Office of Regulations and Research, Wage and Hour and Public Contracts Divisions, U.S. Department of Labor (Mar. 3, 1958) (Kantor Report) at 6–7. Under the two-test system, the ratio of the short test salary level to the long test salary levels ranged from approximately 130 percent to 180 percent. *See* 81 FR 32403.

[36] 19 FR 4405 (July 17, 1954).

[37] 23 FR 8962 (Nov. 18, 1958).

[38] 26 FR 8635 (Sept. 15, 1961).

[39] 28 FR 9505 (Aug. 30, 1963).

[40] 32 FR 7823 (May 30, 1967).

[41] 35 FR 883 (Jan. 22, 1970).

[42] 38 FR 11390 (May 7, 1973).

[43] 40 FR 7091 (Feb. 19, 1975).

[44] The Department first created a limited exception from the salary basis test for public employees. 57 FR 37677 (Aug. 19, 1992). The Department also implemented a 1990 law requiring it to promulgate regulations permitting employees in certain computer-related occupations to qualify as exempt under section 13(a)(1) of the FLSA. 57 FR 46744 (Oct. 9, 1992); *see* Pub. L. 101–583, sec. 2, 104 Stat. 2871 (Nov. 15, 1990).

[45] 40 FR 7091.

[46] *See* Pub. L. 101–157, sec. 2, 103 Stat. 938 (Nov. 17, 1989).

[47] *See* Pub. L. 104–188, sec. 2104(b), 110 Stat 1755 (Aug. 20, 1996).

[48] 69 FR 22122.

[49] *See id.* at 22192–93 (acknowledging ''de minimis differences in the standard duties tests compared to the . . . short duties tests'').

[50] *See id.* at 22126–28.

[51] *Id.* at 22167.

[52] *Id.* at 22126.

[53] *Id.* at 22171. The Department last set the long and short test salary levels in 1975. Throughout this preamble, when the Department refers to the relationship of salary levels set in this rule and the 2004, 2016, and 2019 rules to equivalent long or short test salary levels, it is referring to salary levels based on contemporaneous (at the relevant point in time) data that, in the case of the long test salary

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employees who would have been subject to the long duties test with its limit on the amount of time spent on nonexempt work if the two-test system had been updated were subject to the equivalent of the short duties test under the new standard test. For example, under the 2004 rule's standard test, an employee who earned just over the rule's standard salary threshold of $455 in weekly salary, and who met the standard duties test, was exempt even if they would not have met the previous long duties test because they spent more than 20 percent of their time performing nonexempt work. If the Department had instead retained the two-test system and updated the long test salary level to $455, that same employee would have been nonexempt because they would have been subject to the long test's more rigorous duties analysis due to their lower salary.

In the 2004 rule, the Department also created a new test for exemption for certain highly compensated employees.[54] The HCE test paired a minimal duties requirement—customarily and regularly performing at least one of the exempt duties or responsibilities of an EAP employee—with a high total annual compensation requirement of $100,000, a threshold that exceeded the annual earnings of approximately 93.7 percent of salaried workers nationwide.[55] The Department also ended the use of special salary levels for Puerto Rico and the U.S. Virgin Islands, as they had become subject to the federal minimum wage since the Department last updated the part 541 salary levels in 1975, and set a special salary level only for American Samoa, which remained not subject to the federal minimum wage.[56] The Department also expressed its intent ''in the future to update the salary levels on a more regular basis, as it did prior to 1975.'' [57]

In May 2016, the Department issued a final rule (the 2016 rule) that retained the single-test system introduced in 2004 but increased the standard salary level and provided for regular updating. Specifically, the 2016 rule (1) increased the standard salary level from the 2004 salary level of $455 to $913 per week, the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South); [58] (2) increased the HCE test total annual compensation amount from $100,000 to $134,004 per year; [59] (3) increased the special salary level for EAP workers in American Samoa; [60] (4) allowed employers, for the first time, to credit nondiscretionary bonuses, incentive payments, and commissions paid at least quarterly towards up to 10 percent of the standard salary level; [61] and (5) added a mechanism to automatically update the part 541 earnings thresholds every 3 years.[62] The Department did not change any of the standard duties test criteria in the 2016 rule,[63] opting instead to adopt a standard salary level set at the low end of the historical range of short test salary levels used in the pre-2004 two-test system.[64] The 2016 rule was scheduled to take effect on December 1, 2016.

On November 22, 2016, the U.S. District Court for the Eastern District of Texas issued an order preliminarily enjoining the Department from implementing and enforcing the 2016 rule.[65] On August 31, 2017, the district court granted summary judgment to the plaintiff challengers, holding that the 2016 rule's salary level exceeded the Department's authority and invalidating the rule.[66] On October 30, 2017, the Department of Justice appealed to the U.S. Court of Appeals for the Fifth Circuit, which subsequently granted the Department's motion to hold that appeal in abeyance while the Department undertook further rulemaking. Following an NPRM published on March 22, 2019,[67] the Department published a final rule on September 27, 2019 (the 2019 rule),[68] which formally rescinded and replaced the 2016 rule.

The 2019 rule (1) raised the standard salary level from the 2004 salary level of $455 to $684 per week, the equivalent of the 20th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South) and/or in the retail industry nationally; (2) increased the HCE total annual compensation threshold from $100,000 to $107,432, the equivalent of the 80th percentile of annual earnings of full-time salaried workers nationwide; (3) allowed employers to credit nondiscretionary bonuses and incentive payments (including commissions) paid at least annually to satisfy up to 10 percent of the standard salary level; and (4) established special salary levels for all U.S. territories.[69] The 2019 rule did not make changes to the standard duties test.[70] While using the same methodology used in the 2004 rule to set the salary threshold, the Department did not assert that this methodology constituted the outer limit for defining and delimiting the salary threshold. Rather, the Department reasoned the 2004 methodology was well-established, reasonable, would minimize uncertainty and potential legal challenge, and would address the concerns of the district court that the 2016 rule over-emphasized the salary level.[71] The Department acknowledged that the new standard salary level was, unlike the salary level set in the 2004 rule, below the long test salary level used in the pre-2004 two-test system.[72] As in its 2004 rule, the Department ''reaffirm[ed] its intent to update the standard salary level and HCE total annual compensation threshold more regularly in the future using notice-and-comment rulemaking.'' [73] The 2019 rule took effect on January 1, 2020.[74]

C. Overview of Existing Regulatory Requirements

The part 541 regulations contain specific criteria that define each category of exemption provided for in section 13(a)(1) for bona fide executive, administrative, professional, and outside sales employees, as well as teachers and academic administrative personnel. The regulations also define exempt computer employees under sections 13(a)(1) and 13(a)(17). The employer bears the burden of establishing the applicability of any exemption.[75] Job titles and job descriptions do not determine

level, would exclude the lowest-paid 10 percent of exempt EAP employees in low-wage industries and areas and, in the case of the short test salary level, would be 149 percent of a contemporaneous long test salary level. The short test salary ratio of 149 percent is the simple average of the 15 historical ratios of the short test salary level to the long test salary level. *See* 81 FR 32467 & n.149.

[54] 69 FR 22172.

[55] *See id.* at 22169 (Table 3).

[56] *Id.* at 22172.

[57] *Id.* at 22171.

[58] 81 FR 32404–05.

[59] *Id.* at 32428.

[60] *Id.* at 32422.

[61] *See id.* at 32425–26.

[62] *See id.* at 32430.

[63] *Id.* at 32444.

[64] In the 2016 rule, the Department estimated the historical range of short test salary levels as from $889 to $1,231 (based on contemporaneous earnings data). *Id.* at 32405.

[65] *See Nevada* v. *U.S. Department of Labor,* 218 F. Supp. 3d 520 (E.D. Tex. 2016).

[66] *See Nevada,* 275 F.Supp.3d 795.

[67] *See* 84 FR 10900 (March 22, 2019).

[68] *See* 84 FR 51230.

[69] The Department established special salary levels of $455 per week for Puerto Rico, Guam, the U.S. Virgin Islands, and the CNMI (effectively continuing the 2004 salary level); it also maintained the 2004 rule's $380 per week special salary level for employees in American Samoa. *Id.* at 51246.

[70] *See id.* at 51241–43.

[71] *See id.* at 51242.

[72] *Id.* at 51244.

[73] *Id.* at 51251.

[74] A lawsuit challenging the 2019 rule was filed in August 2022. The district court upheld the rule and an appeal of that decision was pending at the time the Department issued this final rule. *See Mayfield* v. *U.S. Department of Labor,* 2023 WL 6168251 (W.D. Tex. Sept. 20, 2023), *appeal docketed,* No. 23–50724 (5th Cir. Oct. 11, 2023).

[75] *See, e.g., Idaho Sheet Metal Works,* 383 U.S. at 209; *Walling,* 330 U.S. at 547–48.

exemption status, nor does merely paying an employee a salary rather than an hourly rate.

As previously indicated, to satisfy the EAP exemption, employees must meet certain tests regarding their job duties [76] and generally must be paid on a salary basis at least the amount specified in the regulations.[77] Some employees, such as doctors, lawyers, teachers, and outside sales employees, are not subject to salary tests.[78] Others, such as academic administrative personnel and computer employees, are subject to special, contingent earning thresholds.[79] The standard salary level for the EAP exemption is currently $684 per week (equivalent to $35,568 per year), and the total annual compensation level for highly compensated employees under the HCE test is currently $107,432.[80] A special salary level of $455 per week currently applies to employees in Puerto Rico, Guam, the U.S. Virgin Islands, and the CNMI; [81] a special salary level of $380 per week applies to employees in American Samoa; [82] and employers can pay a special weekly ''base rate'' of $1,043 per week to employees in the motion picture producing industry.[83] Nondiscretionary bonuses and incentive payments (including commissions) paid on an annual or more frequent basis may be used to satisfy up to 10 percent of the standard or special salary levels.[84]

Under the HCE test, employees who currently receive at least $107,432 in total annual compensation are exempt from the FLSA's overtime requirements if they customarily and regularly perform at least one of the exempt duties or responsibilities of an executive, administrative, or professional employee identified in the standard tests for exemption.[85] The HCE test applies only to employees whose primary duty includes performing office or non-manual work.[86] Employees considered exempt under the HCE test must currently receive at least the $684 per week standard salary portion of their pay on a salary or fee basis without regard to the payment of nondiscretionary bonuses and incentive payments.[87]

D. The Department's Proposal

On September 8, 2023, consistent with its statutory authority to define and delimit the EAP exemption, the Department published a Notice of Proposed Rulemaking (NPRM) to revise the part 541 regulations.[88] The Department proposed to increase the standard salary level to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South), equivalent to $1,059 per week based on earnings data used in the NPRM.[89] The Department also proposed to apply this updated standard salary level to the four U.S. territories that are subject to the federal minimum wage—Puerto Rico, Guam, the U.S. Virgin Islands, and the CNMI—and to update the special salary levels for American Samoa and the motion picture industry in relation to the new standard salary level.[90] The Department additionally proposed raising the HCE test's total annual compensation requirement to the annual equivalent of the 85th percentile of weekly earnings of full-time salaried workers nationally, equivalent to $143,988 per year based on earnings data used in the NPRM. Finally, the Department proposed a new mechanism to update the standard salary level and the HCE total annual compensation threshold every 3 years to ensure that they remain effective tests for exemption.

The public comment period for the NPRM concluded on November 7, 2023. The Department received approximately 33,300 comments in response to the NPRM during the 60-day comment period.[91] Comments came from a diverse array of stakeholders, including employees, employers, trade associations, small business owners, labor unions, advocacy groups, nonprofit organizations, law firms, academics, educational organizations and representatives, religious organizations, economists, members of Congress, state and local government officials, tribal representatives, and other interested members of the public. All timely received comments may be viewed on the *https://www.regulations.gov* website, docket ID WHD–2023–0001.

Commenter views on the merits of the NPRM varied widely. Some of the comments the Department received were general statements of support or opposition, while many others addressed the Department's proposal in considerable detail. As with previous part 541 rulemakings, a majority of the total comments came from comment campaigns using similar or identical template language. Such campaign comments expressed support or opposition to the proposed salary level, and sometimes addressed other issues including applying the salary level to teachers,[92] and concerns from nonprofit agencies. However, the Department also received thousands of unique comments. Significant issues raised in the comments are discussed in this final rule. Comments germane to the need for this rulemaking are discussed in section III, comments about the NPRM's proposals are discussed in section V, and comments about the potential costs, benefits, and other impacts of this rulemaking are discussed in section VII. The Department has carefully considered the timely submitted comments about the Department's proposal.

The Department received a number of comments on topics that are beyond the scope of this rulemaking. A significant number of commenters (including a large comment campaign) urged the Department to newly apply the part 541 salary criteria to teachers. The Department did not solicit comment about the exemption criteria for teachers in the NPRM and, as many commenters on this issue recognized, addressing this issue would require a separate rulemaking. Other topics outside the

[76] For a description of the duties that are required to be performed under the EAP exemption, *see* §§ 541.100 (executive employees); 541.200 (administrative employees); 541.300, 541.303–.304 (teachers and professional employees); 541.400 (computer employees); 541.500 (outside sales employees).

[77] Alternatively, administrative and professional employees may be paid on a fee basis for a single job regardless of the time required for its completion as long as the hourly rate for work performed (*i.e.,* the fee payment divided by the number of hours worked) would total at least the weekly amount specified in the regulation if the employee worked 40 hours. *See* § 541.605.

[78] *See* §§ 541.303(d); 541.304(d); 541.500(c); 541.600(e). Such employees are also not subject to a fee basis test.

[79] *See* § 541.600(c)–(d).

[80] *See* §§ 541.600(a); 541.601(a)(1).

[81] *See* §§ 541.100; 541.200; 541.300.

[82] *See* §§ 541.100; 541.200; 541.300.

[83] *See* § 541.709.

[84] § 541.602(a)(3).

[85] § 541.601.

[86] § 541.601(d).

[87] *See* § 541.601(b)(1); *see also* 84 FR 51249.

[88] *See* 88 FR 62152.

[89] The Department noted that the final rule would use the most recent earnings data available to set the standard salary level, which would change the dollar amount of the resulting threshold. *See* 88 FR 62152–53 n. 3.

[90] In this final rule the Department is not finalizing its proposal in section IV.B.1 and B.2 of the NPRM to apply the standard salary level to the U.S. territories subject to the federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry. The Department will address these aspects of its proposal in a future final rule. While the Department is not finalizing its proposal, it is making nonsubstantive changes in provisions addressing the territories as a result of other changes in this final rule.

[91] In *regulations.gov*, the number of comments received is listed as 33,310 and the number of posted comments is 26,280. This difference is because one commenter, WorkMoney, attached thousands of comments to their one submission.

[92] As noted above, teachers are among the employees for whom there is no salary level requirement under the part 541 regulations. *See* § 541.303(d).

scope of this rulemaking include, for example, a request that the Department extend the right to overtime pay to medical residents, create exemptions from the salary level test, allow employers to credit the value of board and lodging towards the salary level, clarify issues related to the fluctuating workweek method of calculating overtime pay, or create a ''safe harbor'' provision for restaurant franchisors. The Department is not addressing these issues in its final rule.

Several stakeholders such as Catholic Charities USA and the National Council of Nonprofits expressed concern about funding and reimbursement rates to meet potential new overtime expenses. The Department appreciates the concerns conveyed in these comments and the challenges of adjusting public funding. As discussed in section V.B.4.iv, however, the Department's EAP regulations have never had special rules for nonprofit or charitable organizations and employees of these organizations are subject to the EAP exemption if they satisfy the same salary level, salary basis, and duties tests as other employees.

III. Need for Rulemaking

The goal of this rulemaking is to set effective earnings thresholds to help define and delimit the FLSA's EAP exemption. To achieve this goal, the Department is not only updating the single standard salary level to account for earnings growth since the 2019 rule, but also to build on the lessons learned in its most recent rulemakings to more effectively define and delimit employees employed in a bona fide EAP capacity. To this end, the Department is finalizing its proposed changes to the standard salary level and the HCE test's total annual compensation requirement methodologies. Additionally, to maintain the effectiveness of these tests, the Department is finalizing an updating mechanism that will update these earnings thresholds to reflect current wage data, initially on July 1, 2024 and every 3 years thereafter. The Department's response to commenter feedback on the specific proposals included in the NPRM is provided in section V. This section explains the need for the Department to update the part 541 earnings thresholds and addresses commenter feedback on whether the earnings thresholds established in the 2019 rule should be increased.

As the Department explained in the NPRM, there is a need for the Department to update the salary level to fully restore the salary level's screening function and to account for the shift to a one-test system in the 2004 rule, which broadened the exemption by placing the entire burden of this shift on employees who historically were entitled to the FLSA's overtime protection because they performed substantial amounts of nonexempt work and earned between the long and short test salary levels, but became exempt because they passed the more lenient standard duties test. Since switching from a two-test to a one-test system for defining and delimiting the EAP exemption in 2004, the Department has followed different approaches to set the standard salary level. In 2004, the Department used a methodology that produced a salary level amount that was equivalent to the lower long test salary level under the two-test system.[93] This approach continued to perform the historical screening function of the long salary test—providing overtime protection to employees who earned less than the long test salary level. But it broadened the exemption to include employees earning between the long and short test salary levels who historically had not met the long duties test (and therefore were not considered bona fide EAP employees) and now became exempt if they met the less rigorous standard duties test.[94] The Department followed this same methodology to set the standard salary level in 2019, but applying the 2004 rule's methodology to contemporaneous data in 2019 resulted in a salary level that was lower than what would have been the equivalent of the long test salary level and thus did not fulfill the historical screening function for low-paid employees.[95] This broadened the EAP exemption even further by, for the first time, exempting a group of white-collar employees earning below the equivalent of the long test salary level.

To address the concern that the 2004 rule did not provide overtime compensation for lower-salaried white-collar employees performing large amounts of nonexempt work, in 2016 the Department set the standard salary level using a methodology that produced a salary at the low end of the historical range of short test salary levels.[96] This approach restored overtime protection to lower-salaried white-collar employees who performed substantial amounts of nonexempt work, but it also made nonexempt some employees paid below the new salary level who performed only a limited amount of nonexempt work and would have been exempt under the long duties test.[97] In the challenge to the 2016 rule, the district court expressed concern that the 2016 rule conferred overtime eligibility based on salary level alone to a substantial number of employees who would otherwise be exempt.[98]

As explained in greater detail in section V.B, setting the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region ($1,128 per week, $58,656 annually), which is below the midpoint between the long and short tests, will work effectively with the standard duties test to better define and delimit the EAP exemption, in part by more effectively accounting for the switch from a two-test to a one-test system, and will reasonably distribute the impact of the shift by ensuring overtime protection for some lower-salaried employees without excluding from exemption too many white-collar employees solely based on their salary level.[99] The new standard salary level will also account for earnings growth since the 2019 rule and fully restore the historical screening function of the salary level test. At the same time, the duties test will continue to determine exemption status for a large majority of all salaried white-collar employees subject to the part 541 regulations.

As the Department has explained,[100] earnings thresholds in the part 541 regulations gradually lose their effectiveness as the salaries paid to nonexempt employees rise over time. These impacts grow in the absence of increases to the salary threshold that keep pace with wage growth. Moreover, the longer it takes for the Department to implement such increases, the larger the increases must be to restore earning thresholds to maintain their effectiveness. More than 4 years have passed since the 2019 final rule established the current earnings thresholds. In the intervening years, salaried workers in the U.S. economy have experienced a rapid growth in their nominal wages, such that the current $684 per week salary level now corresponds to approximately the 12th percentile of earnings of full-time salaried workers in the lowest-wage Census Region and retail nationally. The longer the Department waits to update these earnings thresholds, the less effective they become in helping define

[93] *See* 69 FR 22168–69.

[94] *Id.* at 22214.

[95] *See* 84 FR 51260 (Table 4) (showing that the salary level derived from the Department's long test methodology would have been $724 per week rather than the finalized $684 per week amount).

[96] 81 FR 32405.

[97] *See* 84 FR 10908; 84 FR 51242.

[98] *See Nevada,* 275 F.Supp.3d. at 806.

[99] *See* section V.A.3.

[100] *See, e.g.,* 84 FR 51250–51.

and delimit the EAP exemption. For example, applying the 2019 standard salary level methodology to current earnings data will result in a new threshold of $844 per week—a 23 percent ($160 per week) increase over the current $684 salary level. Earnings for full-time wage and salary workers nationally have increased even more rapidly, rising by 24 percent during this period.[101]

The Department is also increasing the HCE total annual compensation threshold to the annualized weekly earnings amount of the 85th percentile of full-time salaried workers nationally ($151,164). Similar to the standard salary level, nominal wage growth among higher-wage workers has eroded the effectiveness of the HCE threshold; data shows that the $107,432 threshold now corresponds to the 70th percentile of annual earnings of full-time salaried workers nationwide. Reapplying the 2019 methodology (annualized weekly earnings of the 80th percentile of full-time salaried workers nationally) to current earnings data would result in a threshold of $132,964 per year—a 24 percent increase over the current threshold of $107,432. Increasing the HCE test's total annual compensation threshold equivalent to the 85th percentile of salaried worker earnings nationwide will result in an HCE threshold reserved for employees at the top of today's economic ladder and, unlike a lower threshold, not risk the unintended exemption of large numbers of employees in high-wage regions.

Finally, the Department is adopting a mechanism to regularly update the thresholds for earnings growth, which will ensure that the thresholds continue to work effectively to help identify EAP employees. As noted above, the history of the part 541 regulations shows multiple, significant gaps during which the salary levels were not updated and their effectiveness in helping to define the EAP exemption decreased as wages increased. While the Department has generally increased its part 541 earnings thresholds every 5 to 9 years in the 37 years between 1938 and 1975, more recent decades have included long periods without raising the salary level, resulting in significant erosion of the real value of the threshold levels followed by unpredictable increases. Routine updates of the earnings thresholds to reflect wage growth will bring certainty and stability to employers and employees alike.

The Department received many comments addressing the adequacy of the current salary and compensation thresholds set in the 2019 rule and the need for this rulemaking. Generally, employees and affiliated commenters, including labor unions, worker advocacy groups, plaintiff-side law firms, and others, supported the rulemaking as an overdue effort to restore FLSA protections that have eroded in recent decades, though a number of commenters urged the Department to adopt higher threshold increases than those proposed in the NPRM. By contrast, most employers and affiliated stakeholders opposed the main aspects of the proposal, with many urging the Department to withdraw the NPRM altogether. Some employers supported the proposal, or stated that they would support, or not oppose, some change to the current thresholds.

Many commenters agreed with the Department's assessment that the current salary level is too low.[102] *See, e.g.,* Coalition of Gender Justice and Civil Rights Organizations; Coalition of State Attorneys General; Economic Policy Institute (EPI); Schuck Law LLC; Texas RioGrande Legal Aid; United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (United Steelworkers). Several commenters asserted that the current standard salary level ''fails to provide a true incentive for employers to balance the additional hours they ask of their workers with the costs of . . . overtime pay[,]'' which they stated in turn undermines the FLSA's policy goals of providing ''extra pay for extra work . . . [and] spreading employment.'' *See, e.g.,* Center for Law and Social Policy (CLASP); Caring Across Generations; Family Values @ Work; Jobs to Move America; North Carolina Justice Center; Workplace Justice Project. Opining that the standard salary level ''has been increased too infrequently—and by too little[,]'' Business for a Fair Minimum Wage asserted that the ''current outdated overtime threshold is ripe for abuse and fosters unfair pay, worker burnout, poorer health and safety, and increased employee turnover.'' American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) asserted that the $684 per week salary level is ''so low that it risks becoming irrelevant[.]''

Finally, some supportive commenters provided reasons why, in their opinion, this rulemaking is timely. A joint comment submitted by 10 Democratic members of the House of Representatives asserted that ''[o]vertime standards are long overdue for a meaningful update.'' *See also* AFL–CIO (asserting that setting the salary level below the long test level in the 2019 rule ''led to the faster irrelevance of the current level''). The Coalition of State AGs commented that ''[r]egardless of whether [the $684 per week standard salary] level was appropriate in 2019, economic trends in the intervening years have rendered that level obsolete . . . [as] $684 in January 2020 has the same buying power as $816.90 in September 2023.'' Sanford Heisler Sharp LLP (Sanford Heisler Sharp) invoked ''the explosion of remote work since 2020'' as support for the rulemaking, asserting that the significant increase in telework since 2020 has meant that employers are ''no longer constrained by the practical limitation of the worker leaving the workplace.''

Many employer trade associations that were neutral or opposed to the NPRM's specific proposals for increasing the compensation levels expressed openness or support for a rulemaking to change the existing part 541 earnings thresholds. *See, e.g.,* Alliance for Chemical Distribution; Growmark Comment Campaign (GROWMARK); National Cotton Ginners Association; National Golf Course Owners Association. Reporting on the results of a survey taken of its members, Society for Human Resource Management (SHRM) stated that its members ''support a reasonable increase to the rule's minimum salary threshold . . . as only 4% of the total number of respondents indicated that they would not support any increase.'' Independent Sector remarked that ''a healthy and equitable nonprofit workforce requires an increase in the salary threshold beyond $35,568.'' *See also* North Carolina Center for Nonprofits (''The Center recognizes that a higher salary level threshold would benefit people served by nonprofits and many nonprofit employees, and we encourage the Department to move forward with a final rule that increases the [current] salary level threshold[.]''). National Association of Convenience Stores commented that it ''acknowledges that the minimum salary level should be revisited occasionally, and it support[s] USDOL's approach in 2019 of doing so approximately every four years[.]'' *See also* Retail Industry Leaders Association

[101] Estimate based on the change in median usual weekly earnings of full-time wage and salary workers from Q3 2019 to Q4 2023. BLS, Median usual weekly earnings of full-time wage and salary workers by sex, quarterly averages, seasonally adjusted. *https://www.bls.gov/news.release/wkyeng.t01.htm.*

[102] Commenter views on the adequacy of the current HCE threshold are addressed in section V.C.

(RILA) (''We recognize that the DOL committed itself in 2019 to engage in more regular reviews of the salary threshold level for the [EAP] exemptions and that the DOL now is following up on that commitment.'').

Other employer stakeholders disputed the need for this rulemaking. Many of these commenters, including the American Bus Association, Americans for Prosperity Foundation, Construction Industry Round Table, and National Restaurant Association, asserted that increases to the part 541 earnings thresholds were unnecessary at this time because the last update took effect on January 1, 2020. A number of commenters stated that prior salary level updates have occurred less frequently. *See, e.g.,* National Association of Manufacturers (NAM) (never less than 5 years); National Demolition Association (on average every 9 to 10 years); National Association of Wholesale Distributors (NAW) (historically 7 to 9 years). National Retail Federation (NRF) commented that ''[t]here has been no increase of the federal minimum wage since 2019, and therefore, there is no need to adjust the minimum salary threshold.'' NRF further asserted that there was no need to increase the part 541 earnings thresholds because ''market forces have already increased the compensation of lower-level exempt employees'' since 2019, echoing the sentiment from several individual employers that markets should determine employee wages rather than government regulation. *See also, e.g.,* Casa Del Mar Beachfront Suites (opposing changes to the regulations and stating that the wages it pays ''are based on free enterprise and competitive business plans''); Individual Small Business Commenter (asking the Department to ''let the market take care of the situation''). Numerous commenters also asserted that the Department should refrain from amending the part 541 regulations at this time due to current conditions in specific industries or the broader economy. *See, e.g.,* Asian American Hotel Owners Association, Inc.; American Hotel and Lodging Association (AHLA); College and University Professional Association for Human Resources (CUPA–HR); Food Marketing Institute (FMI); Indiana Chamber of Commerce; National Association of Home Builders (NAHB).

Finally, a small number of commenters opposed this rulemaking on the grounds that the Department lacks the legal authority to use any salary criteria to define and delimit the EAP exemption. *See, e.g.,* America First Policy Institute (AFPI); National Federation of Independent Business (NFIB); Pacific Legal Foundation.[103] However, the overwhelming majority of commenters did not oppose the use of salary criteria in the part 541 regulations or address the Department's authority, and a number of employer representatives expressed general support for the use of earnings thresholds. *See, e.g.,* AHLA (''[M]oving to a duties-only test would undoubtedly result in a more rigid duties test . . . [and] likely result in excessive burdens on the hospitality industry, including new and onerous recordkeeping requirements and increased litigation costs.''); National Restaurant Association (''[S]alary levels save investigators and employers time by giving them a quick, short-hand test[.]''); Transportation Intermediaries Association (''Implementing a duties-only test without considering salary would be overly complex[.]''). This sentiment is consistent with stakeholder feedback provided in earlier part 541 rulemakings.[104]

Having reviewed the comments received, the Department remains of the view that the earnings criteria in the part 541 regulations must be increased and disagrees with commenters that urged the Department to withdraw its proposal. In addition to updating the salary level to account for wage growth since 2019, an update is needed in part because the current standard salary level is too low to fully perform its screening role, as it is now significantly below the contemporary equivalent of the historical long test salary level ($942 per week).[105] Moreover, as the Department explained in the NPRM, there is a need for the Department to update the salary level to account for the shift to a one-test system in the 2004 rule, which broadened the exemption by placing the entire burden of this shift on employees who historically were entitled to the FLSA's overtime protection because they performed substantial amounts of nonexempt work and earned between the long and short test salary levels, but are now exempt because they pass the more lenient standard duties test. This effect would continue to grow over time in the absence of an increase to the current $684 per week standard salary level.

The Department disagrees with the criticism from some commenters that this rulemaking is premature due to the relative recency of the 2019 rule. In that rule, the Department ''reaffirm[ed] its intent to update the standard salary level and HCE total annual compensation threshold more regularly in the future'' than it has in the past, noting that ''long periods without updates . . . diminish the usefulness of the salary level test and cause future increases to be larger and more challenging for businesses to absorb.'' [106] Notably, the Department initially proposed in the 2019 NPRM to codify a commitment to update the part 541 earnings thresholds on a quadrennial basis (*i.e.,* once every 4 years) through notice and comment rulemaking.[107] While that proposed commitment was not adopted in the 2019 final rule, the Department reaffirmed the importance of, and its commitment to, regular updates in its 2019 final rule. The Department's 2019 final rule in no way suggested that increases to the part 541 earnings thresholds should occur only after some longer period of time.

Relatedly, the fact that employee salaries have grown substantially since 2019 underscores the need for this rulemaking. Commenter assertions to the contrary, including that the federal minimum wage has not increased since the salary level was last updated, misunderstand the purpose of the part 541 earnings thresholds, which are intended to assist in the identification of EAP employees based on the wages employees presently receive.[108] To the extent that employers have already been providing raises to exempt EAP workers since January 1, 2020 (the effective date of the 2019 final rule), as some commenters contended, those increases should be appropriately reflected in the earnings thresholds to ensure their effectiveness.

The Department is sensitive to commenter concerns about the potential impact of this rulemaking on affected employers. However, as discussed in greater detail in the regulatory impact analysis in section VII, the costs of this rule, while significant, are a necessary byproduct of ensuring a salary level that works effectively with the duties tests both now and in the future.

IV. Effective Date

The Department proposed that all aspects of the proposed rule would become effective 60 days after publication of the final rule. This proposed effective date was consistent

[103] *See* discussion in section V.A.

[104] *See supra* note 23.

[105] *See* sections V.B. and VII.C.8.

[106] 84 FR 51251–52.

[107] 84 FR 10914–15.

[108] The Department ''is not authorized to set wages or salaries for executive, administrative, and professional employees . . . [and] improving the conditions of such employees is not the objective of the [part 541] regulations.'' Weiss Report at 11.

with the 60 days mandated for a ''major rule'' under the Congressional Review Act and exceeded the 30-day minimum required under the Administrative Procedure Act (APA).[109] The Department recognized that the 60-day proposed effective date was shorter than the effective dates for the 2004, 2016, and 2019 rules, which were between approximately 90 and 180 days. The Department stated that a 60-day effective date was appropriate, however, in part because employers and employees are familiar with the procedures in the current regulations from the 2019 rulemaking and changed economic circumstances have caused a strong need to update the standard salary level. The Department also sought comments on whether to apply different effective dates to different provisions of the proposed rule. The Department is finalizing an effective date of July 1, 2024. The change to the standard salary level methodology and the change to the HCE total annual compensation methodology will have a delayed applicability date of January 1, 2025.[110] Accordingly, the standard salary level and HCE total annual compensation requirement will increase at the initial update on the effective date July 1, 2024 (to $844 and $132,964, respectively), again on the applicability date for the new methodologies on January 1, 2025 (to $1,128 and $151,164, respectively), and then every 3 years after the initial update on July 1 (using the methodology in effect at the time of each update).

The Department specifically asked for comments on whether the effective date for the increase of the standard salary level should be 60 days after publication as proposed or instead if the increase should be made effective at a later date, such as 6 months or 1 year after publication of the final rule. If the effective date were longer than 60 days, the Department sought comments on ''whether it should initially adjust the salary level to reflect recent wage growth (for example, making an initial adjustment for wage growth 60 days after publication of a final rule and having the final rule standard salary level be effective 6 months or a year after publication).'' [111] Were it to follow such an approach, the Department sought comments on the methodology it should use for an initial update, specifically ''whether to implement an initial update to the standard salary level, effective 60 days after publication of a final rule, that uses the current salary level methodology (the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region and retail nationally) and applies it to the most recent data available[.]'' [112]

The Department did not specifically request comment on delaying the effective date of the proposed HCE compensation threshold beyond 60 days or on making an initial update using current data and the existing HCE compensation methodology if it were to delay the effective date of the new total annual compensation threshold. The Department stated that it believed a 60-day effective date was appropriate for the proposed increase to the HCE compensation threshold because only a relatively small number of employees earning between the current and proposed HCE compensation thresholds would not meet the standard duties test and be affected by the proposed change. The Department sought comment on the proposed effective date for the HCE compensation threshold.

Lastly, the Department proposed that the first automatic update to the new compensation levels be effective 3 years after the proposed 60-day effective date. The Department sought comments on whether the date for the first automatic update should be adjusted if it were to make an initial adjustment to any of the compensation levels.

Many commenters that objected to the proposed rule also objected to the proposed 60-day effective date should the Department go forward with a final rule. Commenters addressed their comments to the single 60-day effective date and generally did not suggest different effective dates for different provisions. Several commenters suggested effective dates between 90 and 180 days, which the NPRM noted was the range for recent rules. *See, e.g.,* HR Policy Association (minimum of 90 days); International Foodservice Distributors Association (IFDA) (minimum of 90 days); American Society of Travel Advisors (ASTA) (90 to 180 days); RILA (at least 120 days); NAIS/NBOA (at least 120 days). Several commenters suggested a 180-day effective date. *See, e.g.,* AASA/AESA/ASBO; CUPA–HR; LeadingAge; NRF. The National Council of Young Men's Christian Associations of the United States of America (YMCA) suggested an effective date of at least 6 to 9 months. The United States Chamber of Commerce (Chamber), National Association of Convenience Stores, and NAFCU suggested an effective date of 12 months. Commenters including the U.S. Small Business Administration Office of Advocacy (SBA Advocacy), National Automobile Dealers Association, and Partnership to Protect Workplace Opportunity (PPWO) suggested an effective date of 12 to 18 months. Commenters including Seyfarth Shaw LLP (Seyfarth Shaw) and Credit Union National Association (CUNA) suggested an effective date of 150 days to align with the proposed notice period for future update amounts. A number of commenters suggested tying the effective date to the beginning of the next calendar year (January 1, 2025). *See, e.g.,* Seyfarth Shaw; SHRM; RILA; YMCA. Some commenters suggested a longer time period between the publication and effective date of the final rule for specific industries or types of employers. *See, e.g.,* Boy Scouts of America (requesting at least 12 months of lead time for nonprofit employers); Small Business Majority (180 days for small businesses with fewer than 50 employees). A few commenters linked the need for a longer effective date with what they asserted was uncertainty as to the final salary amount caused by the Department's projections in footnote 3 of the NPRM, with NRF asserting that ''[t]he brevity of the implementation period is particularly problematic given the Department's . . . lack of clarity about the dollar value of the proposed threshold.'' *See also* HR Policy Association; RILA.

Several commenters suggested phasing in any increase in the salary level, often in addition to an initial extension of the proposed effective date. Commenters advocating for a phase-in suggested a range of steps or timeframes. *See, e.g.,* ASTA (not less than 3 years); Chamber (3 years in even or incrementally larger steps); North Carolina Center for Nonprofits (''multiple years''); National Council of Nonprofits (two or more steps); PPWO (a period of years), Safe Journeys (6 years); Washington Farm Labor Association (''multi-year''); YMCA (proportional increases over 5 years).

Most commenters supporting the Department's proposal did not specifically address the effective date for the Department's proposed changes. Commenters including American Federation of Teachers (AFT), National

[109] *See* 5 U.S.C. 801(a)(3)(A); 5 U.S.C. 553(d).

[110] The January 1, 2025 applicability date is six months after the effective date of the rule.

[111] 88 FR 62180.

[112] *Id.* Commenters generally did not address the Department's suggestion that a delay in the effective date for the proposed standard salary level increase be combined with an initial update to the existing salary level to reflect wage growth. An individual commenter acknowledged the Department's suggestion but ''defer[ed] to the economists and statisticians to comment as to whether, if the effective date is later than 60 days, the Department should initially adjust the salary level to reflect recent wage growth, and if so, the methodology for doing so.'' *See also* Ho-Chunk, Inc., a subsidiary of the Winnebago Tribe of Nebraska.

Partnership for Women & Families (National Partnership), and National Women's Law Center (NWLC) urged the Department to finalize the rule ''without delay.'' American Federation of State, County, and Municipal Employees (AFSCME) specifically supported the 60-day effective date as proposed. A number of commenters in the home and community-based health services sector, that were generally supportive of the Department's intent but expressed concerns with its proposal, advocated for a longer effective date. ANCOR suggested a 2-year delayed effective date followed by a 3-to-5-year phase-in of the new salary level. *See also* Advancing States (18-month to 2-year effective date); National Association of State Directors of Developmental Disabilities Services (NASDDDS) (18- to 24-month effective date for providers of services to individuals with intellectual and developmental disabilities); United Cerebral Palsy (phase-in or transition period for the Department to work with the Centers for Medicare and Medicaid Services and the Administration for Community Living to minimize impact on access to services). BrightSpring Health Services urged the Department to delay the effective date for 2 years and to consider an enforcement delay for the sector as it did in 2016.

As discussed below, the Department believes it is important to update the standard salary level in part to account for substantial earnings growth since the Department last updated the salary level in the 2019 rule. It has been more than 4 years since the Department updated the salary level, and economic conditions have changed significantly since then as evidenced by the salary increase that would result by applying current data to the 2019 salary level methodology ($844 per week, an increase of $160 per week over the existing salary level). These economic conditions have also impacted employees subject to the HCE exemption. Applying current data to the 2019 HCE compensation methodology would result in an annual compensation threshold of $132,964 (an increase of $25,551 over the existing compensation threshold).

At the same time, the Department is also mindful of the desire expressed by multiple commenters to extend the effective date of the new standard salary and annual compensation methodologies from the proposed 60-day period to 6-to-12 months (or more). A longer effective date for the new standard salary level and HCE compensation methodologies would provide employers with more time to make adjustments after they are informed of the exact levels of the thresholds set in this final rule.

After considering the comments, the Department has determined that the final rule will be effective on July 1, 2024, but the new standard salary level methodology and the new HCE total annual compensation methodology will not be applicable until January 1, 2025. The Department is setting the effective date on July 1, 2024 rather than a set number of days after publication in the **Federal Register** because it will further administrability for employers to have the effective date coincide with the first of a month and some employers' budget years also begin on that date.[113] While the rule will be effective on July 1, 2024, the Department is extending by an additional 6 months the time for employers to comply with the new standard salary level methodology and the HCE total annual compensation methodology. Accordingly, the applicability date for § 541.600(a)(2), which sets out the new standard salary level of the 35th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region, and § 541.601(a)(2), which sets out the new HCE total annual compensation level of the annualized earnings amount of the 85th percentile of full-time nonhourly workers nationally, will be January 1, 2025. The Department decided to delay application of the new HCE total annual compensation methodology so that the new methodologies for both the standard salary level and the HCE compensation level take effect at the same time. The delayed applicability date will allow employers 6 additional months beyond the proposed 60-day effective date in which to evaluate employees who will be affected by the new standard salary level methodology and the new HCE compensation level methodology and make any adjustments.

New § 541.607, Regular updates to amounts of salary and compensation required, will be applicable on the effective date July 1, 2024. Because the current standard salary and HCE annual compensation levels have not been updated in more than 4 years, and economic conditions have changed markedly during that time, the first update will occur on that same date (§ 541.607(a)). Subsequent updates will occur every 3 years after this date starting on July 1, 2027 (§ 541.607(b)). As discussed in section V.A, regular updating of the standard salary and HCE annual compensation levels to reflect current wage data is imperative to ensure that they continue to work effectively in combination with the duties tests in defining bona fide EAP employees. In light of the approximately 8-month delay in applicability of the new standard salary and HCE total compensation methodologies, the initial update will use the current methodologies from the 2019 rule, which result in a salary level of $844 per week and an HCE total annual compensation threshold of $132,964. Accordingly, the requirement that an exempt employee be compensated on a salary basis at a salary level of at least $844 per week, set forth in § 541.600(a)(1), and that an employee receive total annual compensation of at least $132,964 per year to qualify for the HCE exemption, set forth in § 541.601(a)(1), will apply on July 1, 2024. The Department believes that this date for the initial update is appropriate because it will use methodologies that employers are familiar with. Subsequent triennial updates will apply the most recent four quarters of data to the standard salary and HCE total annual compensation levels in effect at the time of the updates. The Department anticipates that at the time of the first triennial update, the salary and compensation methodologies that are in effect will be the methodologies described in §§ 541.600(a)(2) and 541.601(a)(2) of this final rule. The Department notes that the standard salary and HCE compensation levels need to be updated regularly based on up-to-date earnings data to ensure that they continue to function effectively regardless of the methodology used to set the levels.

Except for the specific provisions discussed in this section that will become applicable on January 1, 2025, all other provisions of this final rule will be applicable on the effective date on July 1, 2024.

V. Discussion of Final Regulatory Revisions

Consistent with its statutory duty to define and delimit the EAP exemption, the Department is making several changes to the earnings thresholds provided in the part 541 regulations. As explained in greater detail below, the Department is setting the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South). The Department additionally is raising the HCE test's total annual compensation requirement to the annualized equivalent of the 85th percentile of weekly earnings of full-time salaried workers nationally. Finally, the

[113] Future updates will occur every three years on July 1.

Department is adopting a new mechanism to update the standard salary level and the HCE total annual compensation threshold, initially on July 1, 2024 and every 3 years thereafter to ensure that they remain effective tests for exemption. The Department is not making substantive changes to any provisions related to the salary basis or job duties tests.

The primary changes to the existing regulations are in §§ 541.5, 541.600, 541.601, and newly added § 541.607. In addition, the Department is making conforming changes throughout part 541 to update references to the applicable salary level requirements.[114] The discussion below begins with the new updating provision (§ 541.607), which will make an initial update to the salary and compensation thresholds on July 1, 2024, followed by discussion of changes to the standard salary level methodology (§ 541.600(a)(2)) and HCE total annual compensation threshold methodology (§ 541.601(a)(2)), which will become applicable on January 1, 2025. As noted in these sections, the Department intends for the changes in this final rule to be severable. Severability is addressed more fully at the end of the discussion of final revisions with a discussion of the new severability provision (§ 541.5).

A. Updating the Standard Salary Level and Total Annual Compensation Threshold

As the Department stated in the NPRM, it has long recognized the need to regularly update the earnings thresholds to ensure that they remain useful in helping differentiate between exempt and nonexempt white-collar employees. In each of its part 541 rulemakings since 2004, the Department has observed that a salary level that is not kept up to date becomes obsolete as wages for nonexempt workers increase over time.[115] Long intervals between rulemakings have resulted in eroded earnings thresholds based on outdated earnings data that were ill-equipped to help identify bona fide executive, administrative, and professional employees. This problem was most clearly illustrated by the stagnant salary levels in the regulations from 1975 to 2004, during which period increases in the federal minimum wage meant that by 1991, earnings of a worker paid the federal minimum wage exceeded the long test salary level for a 40-hour workweek and came close to equaling the short test salary level.[116]

The Department proposed in the NPRM a mechanism to regularly update the earnings thresholds to maintain their effectiveness. In a new § 541.607(a)(1) and (b)(1), the Department proposed to update the standard salary level and the HCE total annual compensation requirement every 3 years to reflect current earnings data. The Department proposed in § 541.607(a)(2) and (b)(2) to make the triennial updates using the methodologies proposed to set the thresholds in the NPRM—*i.e.,* the 35th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region (currently the South) for the standard salary level and the annualized weekly earnings of the 85th percentile of full-time nonhourly workers nationally for the HCE total annual compensation requirement.[117] The NPRM also outlined in proposed § 541.607(c) the manner in which the Department would publish advance notice of the updated thresholds and included a pause mechanism in proposed § 541.607(d) that could be triggered to delay a scheduled update under certain circumstances.

The Department proposed to make the first update under its proposed updating mechanism 3 years after the effective date of the final rule. The effective date of the final rule was in turn proposed to be 60 days after publication and to apply to all aspects of the proposed rule, including the proposed methodologies for the standard salary level and the HCE total annual compensation threshold. As discussed in section IV, the Department specifically sought comments on whether the effective date for the proposed change to the standard salary level methodology (to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region) should be 60 days after publication as proposed or if the change should be made effective at some later date, such as 6 months or 1 year after publication of the final rule.[118] If the effective date were longer than 60 days, the Department sought comments on ''whether it should initially adjust the salary level to reflect recent wage growth (for example, making an initial adjustment for wage growth 60 days after publication of a final rule and having the final rule standard salary level be effective 6 months or a year after publication).'' [119] The Department also sought comments on what methodology to use for the initial update, were it to follow such an approach. In particular, the Department invited comments on ''whether to implement an initial update to the standard salary level, effective 60 days after publication of a final rule, that uses the current salary level methodology (the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region and retail nationally) and applies it to the most recent data available ($822 per week based on current data).'' [120]

The Department received numerous comments on its proposed updating mechanism. Many organizations representing employee interests as well as some employers generally supported the updating mechanism, while most organizations representing employer interests opposed it. Many of the commenters opposing the proposed updating mechanism asserted that the Department lacked the authority to institute such a mechanism. After considering the comments received, the Department is finalizing the updating mechanism, with some modifications as discussed below, to keep the salary and compensation thresholds up to date with current data and maintain their effectiveness.

The first update under new § 541.607 will occur on July 1, 2024. As discussed in section IV, the new standard salary level and HCE total annual compensation threshold methodologies will not be applicable until January 1, 2025 (a total of approximately 8 months

[114] The Department is also revising §§ 541.100, 541.200, and 541.300 to reflect that an executive, administrative, or professional employee must be compensated on a salary or fee basis at not less than the level set forth in § 541.600 (rather than referencing a specific salary level amount). Similarly, it is revising § 541.204 and § 541.400 to reflect that an employee employed in a bona fide administrative capacity and a computer employee may qualify for the section 13(a)(1) exemption if they are compensated on a salary or fee basis at not less than the level set forth in § 541.600 (rather than referencing a specific salary level amount). The Department is also updating cross-references to § 541.600(a) in §§ 541.602 and 541.605 to reference § 541.600(a)–(c). Finally, the Department is revising § 541.604, which explains the circumstances under which an employer may provide an exempt employee with additional compensation without violating the salary basis requirement, and § 541.605, which sets forth the conditions under which an administrative or professional employee may be compensated on a fee basis, with examples that reflect the new standard salary level amount of $1,128 per week.

[115] 84 FR 51250–51; 81 FR 32430; 69 FR 22164. *See also,* 88 FR 62176.

[116] *See* section II.B.1.

[117] Observing that the proposed special salary level for American Samoa and the base rate for the motion picture industry are set in relation to the standard salary level, the Department also proposed that those earnings thresholds reset at the time the standard salary level was updated. The Department is not finalizing its proposal to apply the standard salary level to the U.S. territories subject to the federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry. *See supra* note 9. Therefore, the updating mechanism finalized in this rule will not apply to the special salary levels at this time.

[118] 88 FR 62180

[119] *Id.*

[120] *Id.*

after publication of this final rule). Accordingly, § 541.607(a) establishes an initial update on July 1, 2024 to the standard salary level and the HCE total annual compensation threshold using the methodologies in place at that time (*i.e.,* the 2019 rule methodologies), which results in a $844 per week standard salary level and a $132,964 HCE total annual compensation threshold. Section 541.607(b) further establishes future updates to the standard salary level and HCE total annual compensation threshold with current earnings data beginning 3 years after the date of the initial update, and every 3 years thereafter, using the methodologies in place at the time of the updates. The Department anticipates that by the time the first triennial update under the updating mechanism occurs on July 1, 2027, assuming the Department has not engaged in further rulemaking, the new methodologies for the standard salary level and HCE total annual compensation requirement established by this final rule will be effective and the triennial update would employ these new methodologies. In response to commenter concerns, the Department is also adding clarifying language from the NPRM preamble to the final regulatory text of the delay provision.

1. The Department's Authority To Adopt a Salary Level Test

The updating mechanism in new § 541.607 will maintain the effectiveness of the salary and compensation thresholds set in §§ 541.600 and 541.601 by adjusting them regularly to reflect current economic data. At the outset, a small number of commenters contended the Department lacked authority under section 13(a)(1) to even include a salary level test in the regulations, advocating for the Department to withdraw this rulemaking. *See, e.g.,* AFPI; Job Creators Network Foundation; NFIB; Pacific Legal Foundation. These commenters asserted that the express terms of section 13(a)(1) do not permit the Department to include any compensation-based requirements.

The Department maintains its longstanding position that the Secretary's express authority to ''define[ ]'' and ''delimit[ ]'' the terms of the EAP exemption includes the authority to use a salary level test as one criterion for identifying employees who are employed in a ''bona fide executive, administrative, or professional capacity.'' The Department has used a salary level test since the first part 541 regulations in 1938. From the FLSA's earliest days, stakeholders have generally favored the use of a salary test,[121] and the Department's authority to use a salary test has been repeatedly upheld,[122] including recently in *Mayfield* v. *U.S. Dept. of Labor.*[123] Despite numerous amendments to the FLSA over the past 85 years, Congress has not restricted the Department's use of the salary level tests in the regulations. Significant regulatory changes involving the salary requirements since 1938 include adding a separate salary level for professional employees in 1940, adopting a two-test system with separate short and long test salary levels in 1949, and creating a single standard salary level test and establishing a new HCE exemption test in 2004. These changes were all made through regulations issued pursuant to the Secretary's authority to define and delimit the exemption. Despite having amended the FLSA numerous times over the years, Congress has not amended section 13(a)(1) to alter these regulatory compensation requirements.

The FLSA gives the Secretary power to ''define[]'' and ''delimit[]'' the terms ''bona fide executive, administrative, or professional capacity'' through regulation. Congress thus ''provided that employees should be exempt who fell within certain general classifications''—those employed in a bona fide executive, administrative, or professional capacity—and authorized the Secretary ''to define and delimit those classifications by reasonable and rational specific criteria.'' [124] Therefore, the Department ''is responsible not only for determining which employees are entitled to the exemption, but also for drawing the line beyond which the exemption is not applicable.'' [125]

2. Initial Update to the Standard Salary Level and Total Annual Compensation Threshold To Reflect the Change in Earnings Since the 2019 Rule

The Department received many comments regarding its proposed regulatory mechanism for updating the standard salary level and the HCE total annual compensation requirement to maintain their effectiveness. While commenters disagreed on how and when the salary and total annual compensation thresholds should be updated, commenters generally did not dispute that the earnings thresholds need to be periodically updated to reflect current economic conditions. Many commenters that opposed the proposed updating mechanism nonetheless agreed that the thresholds in the regulations need to be periodically updated. *See, e.g.,* ASTA; FMI; SBA Advocacy; SHRM; TechServe Alliance; World Floor Covering Association (WFCA).

In the context of addressing the Department's proposed standard salary level methodology, several commenters generally expressed support for—or in opposing the salary level suggested in the alternative—an increase to the salary level using the 2019 methodology. *See, e.g.,* Bellevue University; Center for Workplace Compliance (CWC); RILA; YMCA. CWC noted that the 2019 methodology is well-established and already familiar to employees and employers, and Bellevue University similarly stated that this methodology ''has been previously field-tested on the U.S. economy[.]'' As noted in section IV, commenters generally did not address applying the 2019 methodology through the updating mechanism.

The Department remains convinced that effective salary and compensation thresholds must use up-to-date earnings data. This position is long-standing. When the Department updated its salary level tests in 1949, for example, it explained that the ''relative ineffectiveness of these tests in recent years is the result of changed economic conditions rather than any inherent weakness in the tests[,]'' and that the ''increase in wage rates and salary levels gradually weakened the effectiveness of the present salary tests as a dividing line between exempt and nonexempt employees.'' [126] The principle that effective tests for exemption must use

[121] *See* Stein Report at 5, 19. As discussed in section V.B.4.i, the vast majority of employer commenters in this rulemaking, whether favoring no increase or a smaller increase, presumed the salary level test's continued existence and utility, with some, such as the National Restaurant Association, expressly referencing their support for the 2019 rule's salary level increase. Many commenters acknowledged the salary level's longstanding function of screening obviously nonexempt employees from the exemption. *See* section V.B.4.ii. Other commenters that opposed the proposal nonetheless cited benefits of having a salary level test, including helping to ensure that the EAP exemption is not abused, *see, e.g.,* AASA/AESA/ASBO, Bellevue University, and ''sav[ing] investigators and employers time by giving them a quick, short-hand test[.]'' *See* National Restaurant Association.

[122] *See, e.g., Wirtz* v. *Miss. Publishers Corp.,* 364 F.2d 603, 608 (5th Cir. 1966); *Fanelli* v. *U.S. Gypsum Co.,* 141 F.2d 216, 218 (2d Cir. 1944); *Walling* v. *Yeakley,* 140 F.2d 830, 832–33 (10th Cir. 1944).

[123] 2023 WL 6168251 (W.D. Tex. Sept. 20, 2023), *appeal docketed,* No. 23–50724 (5th Cir. Oct. 11, 2023).

[124] *Walling,* 140 F.2d at 831–32; *see Ellis* v. *J.R.'s Country Stores, Inc.,* 779 F.3d 1184, 1199 (10th Cir. 2015) (approvingly quoting *Walling*); *see also Auer* v. *Robins,* 519 U.S. 452, 456 (1997) (''The FLSA grants the Secretary broad authority to 'defin[e] and delimi[t]' the scope of the exemption for executive, administrative, and professional employees.'').

[125] Stein Report at 2.

[126] Weiss Report at 8.

up-to-date earnings data remains as true today as it was 75 years ago.

The Department's need to update the standard salary level and HCE total annual compensation requirement for current data in this rulemaking is distinct from its decision to establish new methodologies for setting those thresholds. The current salary and compensation levels have been in place for more than 4 years and need to be updated to reflect current wage data to maintain their effectiveness.[127] Since the Department's last rulemaking in 2019, there has been significant change in salaried worker earnings.[128] The $684 standard salary level is far below what constitutes the 20th percentile of weekly earnings of full-time salaried workers in the South and/or in the retail industry nationally using current data, which greatly undermines the utility of the threshold as a means of helping distinguish exempt from nonexempt employees. The same is true for the HCE total annual compensation threshold. Updating the existing thresholds to reflect current earnings data is consistent with the intent the Department has expressed repeatedly in its past part 541 rulemakings, including in the 2019 rule, to periodically update the thresholds.

For these reasons, the Department is revising final § 541.607(a) to provide for an initial update to the standard salary level and HCE total annual compensation requirement with current earnings data on July 1, 2024. Specifically, the standard salary level will be updated to the 20th percentile of weekly earnings of full-time salaried workers in the South and/or in the retail industry nationally using the most recent data, resulting in a standard salary level of $844 per week. The HCE total annual compensation threshold will be updated to the 80th percentile of full-time salaried worker earnings nationwide using the most recent data, resulting in an annual compensation threshold of $132,964. The Department believes that the July 1, 2024 effective date provides sufficient time for employers to adjust to this initial update because the methodology used for the initial update to the standard salary level has been used since 2004 and is familiar to the regulated community. The size of the initial increase to the standard salary level, which is $160 per week, is also less (in nominal terms) than the $229 per week change that resulted from the 2019 rule.[129]

The initial update on July 1, 2024 and the change in the standard salary level and HCE total annual compensation methodologies on January 1, 2025 will result in two increases in the compensation thresholds within a 12-month period. The Department recognizes that for some employers both changes to the compensation thresholds may occur in the same budget year. Because both the amount of the initial update and the subsequent increase to the thresholds are set forth in this final rule, some employers may choose to make a single adjustment at the first date that encompasses both the initial update and the impending change to the standard salary level and the HCE total annual compensation threshold.[130]

The Department intends for the initial update of the standard salary level and the HCE total annual compensation requirement, using current earnings data applied to the 2019 rule methodologies, to be severable from future triennial updates to the thresholds under § 541.607(b), as well as from the revision to the methodologies for the standard salary level and the HCE total annual compensation threshold discussed in section V.B and section V.C. In implementing the initial update, the Department intends to account for changes in earnings since the 2019 rule. In changing the methodology for the standard salary level, the Department further intends to fully restore the salary level's historic screening function and account for the shift in the 2004 rule from a two-test to a one-test system for defining and delimiting the EAP exemption.[131] Lastly, in changing the methodology for the HCE total annual compensation threshold, the Department intends to ensure the HCE threshold's role as a streamlined alternative for those employees most likely to meet the standard duties test by excluding all but those employees ''at the very top of [the] economic ladder[.]'' [132] These are independent objectives of this rulemaking and the provisions implementing them can each stand alone. Therefore, the Department intends for the initial update to remain in force even if the methodologies for the standard salary level and/or the HCE total annual compensation threshold established by this final rule are stayed or do not take effect. Similarly, the Department intends for the initial update to remain in effect even if future triennial updates under § 541.607(b) are stayed or do not take effect.

The initial update will take effect approximately 60 days after the publication of the final rule, immediately coming out of this notice and comment rulemaking. As such, the notice procedures set forth in § 541.607(b)(3) will not apply. As discussed below, future triennial updates will be preceded by advance publication of a notice of the updated salary level and HCE total annual compensation threshold in the **Federal Register**. For the initial update, this final rule provides notice of the updated salary and compensation levels.[133]

3. Future Triennial Updates To Keep the Standard Salary Level and Total Annual Compensation Threshold Up to Date

As the Department previously explained, the earnings thresholds are only an effective indicator of exempt status if they are kept up to date. Left unchanged, the thresholds become substantially less effective in helping identify exempt EAP employees as wages for workers increase over time. To that end, the Department proposed to triennially update the standard salary level and HCE total annual compensation threshold by applying the most recent earnings data to the methodologies set forth in proposed § 541.600(a)(1) and § 541.601(a)(1), while any change to the methodologies used to set the standard salary level and HCE annual compensation threshold would be effectuated through future rulemaking.

The Department received many comments on its proposed triennial updating mechanism for keeping the thresholds up to date in the future, which are addressed below. The comments were sharply divided on this aspect of the NPRM. After considering the comments received, the Department concludes that establishing a mechanism for resetting the standard salary level and HCE total annual compensation requirement based on

[127] The standard salary level and HCE total annual compensation threshold in the 2019 rule were set using pooled data for July 2016 to June 2019, adjusted to reflect 2018/2019. 84 FR 51250.

[128] *See* section VII.

[129] Consistent with the 2019 rule, the Department used pooled data for the most recent 3 years (2021, 2022, 2023), adjusting them to reflect 2023, for the initial updates to both the standard salary level and HCE total annual compensation threshold. *See* 84 FR 51250.

[130] Although the Department's approach is not a phase-in, the effect of increasing the salary level twice in 8 months is, from a timing perspective, not altogether different from the request from some commenters to phase in the salary level in more than one step. *See, e.g.,* Argentum & ASHA; Associated General Contractors; SBA Advocacy.

[131] *See* section V.B.

[132] *See* section V.C.

[133] The NPRM included updating the 2019 rule standard salary level and HCE annual compensation threshold using 2022 data as a regulatory alternative, stating that applying the methodologies would result in a standard salary level of $822 per week and a HCE annual compensation threshold of $125,268. *See* 88 FR 62218.

current earnings data, and on a regular 3-year schedule, will ensure that the thresholds remain effective into the future and thus better serve to help define and delimit the EAP exemption.

i. The Department's Authority To Update the Standard Salary Level and Total Annual Compensation Threshold With Current Data in the Future

The Department received many comments regarding its authority to update the earnings thresholds through the proposed triennial updating mechanism. A majority of the commenters opposing the updating mechanism challenged the Department's authority to adopt such a provision. Most commenters that supported the updating mechanism did not specifically discuss the Department's authority to institute such a mechanism. As to commenters supporting the proposed triennial updating mechanism that addressed the issue, they supported the Department's authority.

Commenters favoring automatic updating, such as AFL–CIO and EPI, agreed with the Department that just as the Department has authority to set salary thresholds for the EAP exemption, it also has authority to provide for regular updates to ensure the thresholds do not erode over time. Some supportive commenters further emphasized that future updates would make no change to the standard (*i.e.,* methodology) by which the Department implements the FLSA, but rather merely ensure that the standard accounts for current economic conditions. *See, e.g.,* Administrative Law Professors; Democracy Forward Foundation; EPI. The Administrative Law Professors similarly asserted that automatic adjustments to the earnings thresholds fall within the Secretary's authority to define and delimit ''what it means to function in a 'bona fide executive, administrative, or professional capacity[.]' '' Observing that even a so-called ''static'' salary threshold expressed in ''non-indexed dollar terms'' is constantly changing as a matter of economic value, the Administrative Law Professors asserted that ''if a non-indexed salary threshold is lawful, as nobody seriously questions, so too is a standard pegged to income percentile.'' The Administrative Law Professors observed ''it is arguably more rational'' for the Department to ''proffer a regulation that expressly accounts for the inevitably dynamic nature of every salary threshold . . . rather than to permit arbitrarily fluid macroeconomic conditions to dictate the threshold's true economic worth.''

On the other hand, many commenters opposing the proposed updating mechanism asserted that the Department lacks statutory authority to update the thresholds in this manner. Some of these commenters contended that since the FLSA does not expressly authorize the Department to index the earnings thresholds unlike, for example, the Social Security Act or the Patient Protection and Affordable Care Act, it follows that the FLSA does not authorize the Department to automatically update the thresholds.[134] *See, e.g.,* CUPA–HR; International Dairy Foods Association (IDFA); PPWO; RILA; Seyfarth Shaw. Several commenters pointed out that Congress did not provide for automatic updating of any of the earnings requirements under the FLSA, such as the minimum wage under section 6, the tip credit wage under section 3(m), or the hourly wage for exempt computer employees under section 13(a)(17). *See, e.g.,* AFPI; FMI. Commenters including National Restaurant Association and PPWO further asserted that Congress never amended the FLSA to grant the Department explicit authority to index the salary level despite knowing that the Department has updated the salary level on an irregular schedule.

As the Department stated in the NPRM, the Department's authority to update the salary level tests for the EAP exemption by regularly resetting them based on existing methodologies is grounded in section 13(a)(1), which expressly gives the Secretary broad authority to define and delimit the scope of the exemption. Using this broad authority, the Department established the first salary level tests by regulation in 1938. Despite numerous amendments to the FLSA over the past 85 years, Congress has not restricted the Department's use of the salary level tests. As just discussed, significant changes involving the salary requirements made through regulations issued pursuant to the Secretary's authority to define and delimit the exemption include adding a separate salary level for professional employees in 1940, adopting the two-test system in 1949, and switching to the single standard test and adding the new HCE test in 2004. Despite having amended the FLSA numerous times over the years, Congress has not amended section 13(a)(1) to alter these regulatory salary requirements.

Unlike the statutes some of the commenters referenced explicitly providing for indexing, or the statutory FLSA wage rates—*i.e.,* the minimum wage under section 6, the tip credit wage under section 3(m), or the hourly wage for exempt computer employees under section 13(a)(17)—the part 541 earnings thresholds are established in the regulations. Therefore, it is not surprising that the FLSA contains no specific reference to the indexing or automatic adjustments of these thresholds. The Department agrees with the Administrative Law Professors and other commenters that stated that the Department has the authority to establish a mechanism to automatically adjust the earnings thresholds to ensure their continued effectiveness, using a process established through notice and comment rulemaking, just as it has the authority to initially set them. The Department believes the updating mechanism in this final rule fulfills its statutory obligation to define and delimit the EAP exemptions by preventing the thresholds from becoming obsolete and providing predictability and clarity for the regulated community.

Many of the commenters opposed to the updating mechanism also asserted that automatically updating the earnings thresholds would violate the APA's rulemaking requirements expressly incorporated by reference in section 13(a)(1). *See, e.g.,* AFPI; FMI; National Club Association; and Wage and Hour Defense Institute. These and other commenters claimed that the Department cannot lawfully update the salary level without engaging in notice and comment rulemaking for each update. *See, e.g.,* AASA/AESA/ASBO; Competitive Enterprise Institute; CWC; RILA. IFDA, for example, asserted that notice and comment rulemaking needs to precede each future update so that stakeholders have the opportunity to comment on and adequately prepare for any changes that will affect them. AHLA commented that the proposal to update the thresholds triennially without a preceding opportunity for comment is

[134] In contrast, the Administrative Law Professors highlighted that ''[a]utomatic updating is a common feature of regulations pegged to monetary values, even when the relevant authorizing statutes make no specific reference to indexing or automatic adjustment.'' Some of the examples cited by the Administrative Law Professors to illustrate this point include: 79 FR 63317 (2014) (establishing automatic inflationary adjustments to the minimum amount set by the regulation to define ''adverse credit history''); 76 FR 23110 (2011) (establishing automatic adjustments to the amount of ''Denied Boarding Compensation'' airlines must pay affected passengers); 88 FR 35150 (2023) (adopting once-every-five year inflation adjustments to the revenue threshold for defining a ''small business''); and *Amusement & Music Operators Ass'n* v. *Copyright Royalty Tribunal,* 676 F.2d 1144 (7th Cir. 1982), cert. denied, 103 S. Ct. 210 (1982) (upholding a rule promulgated by the Copyright Royalty Tribunal establishing a $50 compulsory royalty fee to be paid by jukebox operators, and which would be subject to future inflationary adjustments).

''drastic and troublesome'' and that ''notice and comment will help ensure that the knowledge, expertise, and vital input of interested stakeholders will be considered before moving forward with increases.''

Relatedly, AFPI, NRF, and SBA Advocacy asserted that automatic updating would violate the directive under section 13(a)(1) that the Department define and delimit the EAP exemption ''from time to time'' by regulations. NRF, for example, noted that Congress asked the Department to revisit the EAP exemptions from time to time ''expecting the Department to use its deep knowledge of the U.S. economy in general, and labor market in particular, to establish appropriate parameters for the exemptions'' and contended that by implementing automatic updates the Department evades that decision-making process. AFPI similarly asserted that the ''directive, 'from time to time,' does not allow the Department to set it and forget it.''

The Department disagrees with the assertion that triennial updates using the compensation methodologies adopted in the regulations improperly bypass the APA's—and section 13(a)(1) by reference—requirements for notice and comment rulemaking. The Department is adopting an updating mechanism in this rulemaking after publishing a notice of the proposed rule and providing opportunity for stakeholders to comment in accordance with the APA's notice and comment requirements. The Department has received and considered numerous comments on the proposed updating mechanism. Future updates under the triennial updating mechanism would simply reset the thresholds by applying current data to a standard already established by notice and comment regulation, providing clarity for the regulated community as to future changes in the thresholds. Therefore, the Department disagrees with commenters that claimed that notice and comment rulemaking must precede each future update made through the updating mechanism even where the methodology for setting the compensation levels and the mechanism for updating those levels would remain unchanged.[135] The updating mechanism will not alter the Department's ability to engage in future rulemaking to change the updating mechanism or any other aspect of the part 541 regulations at any point.

The Department also disagrees with commenters that claimed section 13(a)(1)'s ''time to time'' language precludes the Department from adopting an updating mechanism. The updating mechanism would only ensure the standard salary level and total annual compensation threshold remain at the percentiles established through rulemaking. This does not preclude the Department from engaging in future rulemaking ''from time to time'' if it determines that there is a need to change the underlying methodologies for setting the standard salary level or HCE total annual compensation threshold, the updating mechanism, or any other substantive change to part 541, as the Department did, for instance, in 1940, 1949, 1958 1975, 2004, 2016, and 2019.

Many commenters opposing the updating mechanism referenced the Department's prior statements to further support their assertion that the Department lacks authority to implement automatic updating. In particular, commenters pointed to the Department's decision not to institute an automatic updating mechanism in the 2004 rule and its statement that ''the Department finds nothing in the legislative or regulatory history that would support indexing or automatic increases.'' *See, e.g.,* NAM; NFIB; SBA Advocacy. Others, like PPWO, further asserted that automatic updates are contrary to the Department's statement in the 2004 rule that ''[t]he salary levels should be adjusted when wage survey data and other policy concerns support such a change.''

As stated in the NPRM, the Department's decision not to institute an automatic updating mechanism in the 2004 and 2019 rulemakings in no way suggests that it lacks the authority to do so. In its 2004 rule, the Department stated that it found nothing in the legislative or regulatory history that would support indexing or automatic increases.[136] As the Department elaborated in its 2016 rulemaking, there was likewise no such authority prohibiting automatic updating.[137] The 2004 rule did not discuss the Department's statutory authority to promulgate an updating mechanism through notice and comment rulemaking or explore in detail whether automatic updates to the salary levels posed a viable solution to problems created by lapses between rulemakings. As the Department explained in the 2016 rule, the Department's reference in the 2004 rule to automatic updating simply reflected the Department's conclusion at that time that an inflation-based updating mechanism, such as one based on changes in the prices of consumer goods, that unduly impacts low-wage regions and industries, would be inappropriate. Such concerns are not implicated here, where the mechanism will update the salary level to keep it at the same percentile of earnings of full-time salaried workers. As for concerns that the salary level should be updated only when wage data warrants it, the updating mechanism does just that—as the earnings thresholds will change only to the extent earnings data in the relevant data sets have changed, whether upward or downward as conditions dictate.

Similarly, the Department declined to adopt automatic updating in the 2019 rule because it ''believe[d] that it is important to preserve the Department's flexibility to adapt to different types of circumstances,'' [138] and not because it lacked authority to do so. While the Department decided not to institute an updating mechanism in its 2019 rule, it never said that it lacked the statutory authority to do so. Upon further consideration, the Department concludes that the best way to ensure the standard salary level and HCE total compensation threshold remain up to date is a triennial updating mechanism that maintains the Department's flexibility to adapt to different circumstances and change course as necessary.

ii. Rationale for Continuing To Update the Standard Salary Level and Total Annual Compensation Threshold With Current Data in the Future

The Department explained in the NPRM that its proposed updating

[135] Some commenters, such as Independent Electrical Contractors, RILA, and U-Haul, further asserted that automatic updates improperly bypass the requirements of the Regulatory Flexibility Act (''RFA'') and executive orders requiring the Department to undertake a detailed economic and cost analysis. The Department disagrees. Pursuant to the RFA, the Department has included in this final rule as well as in the NPRM detailed estimates for the future costs of updates under the updating mechanism. *See* section VII and VIII; 88 FR 62224. Similarly, as relevant here, Executive Order 13563 directs agencies to take certain steps when promulgating regulations, including using the ''best available techniques to quantify anticipated present and future benefits and costs as accurately as possible'' and adopting regulations ''through a process that involves public participation.'' 76 FR 3821 (Jan. 18, 2011). The current rulemaking fully satisfies all aspects of Executive Order 13563. *See* section VII; 88 FR 62182. The RFA and Executive Order 13563 do not require notice and comment rulemaking to precede future triennial updates made through the updating mechanism established in this rulemaking.

[136] 69 FR 22171.

[137] *See* 81 FR 32432–33 (noting that ''instituting an automatic updating mechanism . . . is an appropriate modernization and within the Department's authority.'').

[138] 84 FR 51252.

mechanism would allow for regular and more predictable updates to the earnings thresholds, which would benefit both employers and employees and would better fulfill the Department's statutory duty to define and delimit the EAP exemption by preventing the erosion of those levels over time. The Department noted that its regulatory history, marked in many instances by lengthy gaps between rulemakings, underscored the difficulty with updating the earnings thresholds as quickly and regularly as necessary to keep pace with changing employee earnings and to maintain the full effectiveness of the thresholds. Through the proposed updating mechanism, the Department explained it would be able to timely and efficiently update the standard salary level and the HCE total annual compensation requirement by using the same methodologies as initially proposed and adopted through notice and comment rulemaking to set the thresholds. The Department noted that updating the thresholds in this manner would prevent the more drastic and unpredictable increases associated with less frequent updates and ensure that future salary level increases occur at a known interval and in more gradual increments. The Department received many comments on the rationale for implementing the proposed triennial updating mechanism.

Several organizations representing employee interests as well as a handful of employers agreed with the Department that an updating mechanism would ensure the thresholds keep pace with wages and retain their usefulness. *See, e.g.,* Coalition of Gender Justice and Civil Rights Organizations; National Partnership; National Education Association (NEA); National Employment Lawyers Association (NELA); National Employment Law Project (NELP); Uncommon Goods; W.S. Badger Company. Nichols Kaster, PLLP (Nichols Kaster) noted the updating mechanism protects the thresholds from becoming outdated and irrelevant, although it believed that annual updates would better reflect the economy. NELA commented that ''indexing represents the only simple and accurate'' way to preserve the real value of the standard salary level and the HCE total compensation threshold through time, although they contended that the proposed methodologies should be higher earnings percentiles.

Many commenters supportive of the updating mechanism also asserted that regular updates would provide greater predictability for employers and employees alike. *See, e.g.,* AFL–CIO; Center for WorkLife Law at University of California Law and Partner Organizations (Family Caregiving Coalition); Justice at Work; NEA. Small Business Majority expressed support for the proposed updating mechanism noting that smaller, predictable increases that are known well in advance—as opposed to ''large and sudden'' increases—would allow small business owners to be better prepared for any staffing or compensation changes they need to make. Nineteen Democratic Senators commented that an updating mechanism is the most effective way to provide consistency and stability for both workers and businesses. *See also, e.g.,* EPI; Washington State Department of Labor and Industries. CLASP similarly noted the proposed updating provision would enable employers to know exactly what to expect and when to expect it.

In contrast, many organizations representing employer interests disagreed with the Department's rationale for the proposed updating mechanism. Several of these commenters criticized the Department for stating that the updating mechanism is a more ''viable and efficient'' means of updating the thresholds by asserting that the Department is trying to avoid its obligation to engage in notice and comment rulemaking simply because such rulemaking is resource-intensive. *See, e.g.,* IDFA; National Restaurant Association; PPWO. The Chamber similarly commented that the Department's history of long gaps in rulemaking is not an adequate justification for adopting what it characterized as ''a historically unprecedented change.''

Commenters including AHLA, FMI, the National Beer Wholesalers Association, and Seyfarth Shaw, asserted automatic updating would lead to uncertainty that would pose administrative and compliance burdens on employers. Some commenters, such as HR Policy Association and PPWO, asserted the proposed mechanism would make it difficult to ascertain exactly what the threshold will be every 3 years. Other commenters, including CUPA–HR, FMI, IDFA, and SHRM, asserted triennial updates would have a significant financial impact on employers as they would need to account for the cost of salaries or potential overtime as well as the cost of conducting reclassification analysis and implementing the necessary changes every 3 years. Some nonprofit organizations and providers of home and community-based health services expressed concern that future updates would be difficult for the nonprofit sector because of their funding sources. *See, e.g.,* Allegheny Children's Initiative; ANCOR.

Some commenters opposing the updating mechanism claimed automatic updates would hinder the Department from considering economic circumstances when making updates. Ten Republican Senators asserted automatic updates ''blind the administration to critical considerations about the state of the economy and the workforce, including the unemployment rate, inflation, job vacancies, or whether employers are in a position to adjust to the increases without shedding jobs.'' Some commenters, including Illinois College, ISSA, and the Society of Independent Gasoline Marketers of America, expressed concern that the proposed mechanism could lead to updates happening at a time of economic downturn or a recession and could further exacerbate those economic conditions. Others expressed concern that the updating mechanism would hinder future rulemaking to change the earnings thresholds. *See, e.g.,* Chamber; National Association of Convenience Stores.

The Department continues to believe that the updating mechanism will ensure the earnings thresholds keep pace with changes in earnings and remain useful in the future in helping to delineate EAP employees from non-EAP employees. Whereas a fixed salary level threshold becomes less effective over time as the data used to set it grows outdated, a fixed methodology remains relevant if applied to contemporaneous data. The Department agrees with the commenters that stated that the updating mechanism's triennial updates would provide greater certainty and predictability for the regulated community. Unlike irregular updates to the earnings thresholds, which may result in drastic changes to the thresholds, regular updates on a pre-determined interval and using an established methodology will produce more predictable and incremental changes. For this reason, the Department disagrees with the assertion by some commenters that regular updates will lead to unpredictable adjustments and ongoing uncertainty. The Department also disagrees with commenters like HR Policy Association that claimed the proposed mechanism will make it difficult to ascertain what exactly the threshold will be every 3 years. Through the updating mechanism, the Department will reset the standard salary level and total annual compensation threshold using the most recent, publicly available, U.S. Bureau of Labor Statistics (BLS) data on earnings for salaried workers. Therefore,

stakeholders will be able to track where the thresholds would fall on a quarterly basis by looking at the BLS data [139] and can estimate the changes in the thresholds even before the Department publishes the notice with the adjusted thresholds in the **Federal Register**. The Department believes that, compared to the irregular updates of the past, stakeholders will be better positioned to anticipate and prepare for future updates under the updating mechanism.

Moreover, the Department does not agree with the assertion that routine updates would lead to undue increases at a time of economic downturn or recession. If anything, the Department's new updating mechanism will ensure that the thresholds match the earnings data as they exist at the time of the update, whether by increasing or decreasing the earnings thresholds as warranted by the data. As discussed below, the Department's decision to deviate from the 2016 rule by adopting a mechanism for pausing future updates further guards against such concerns. Similarly, nothing about the updating mechanism precludes the Department from revisiting the standard salary level and HCE total annual compensation methodologies in the future when conditions warrant. Having considered the comments received, the Department remains convinced that an updating mechanism providing for regular updates on a triennial basis is the best means of ensuring that the salary and compensation tests continue to provide an effective means, in tandem with the duties tests, to distinguish between EAP and non-EAP employees.

iii. Specific Features of the Updating Mechanism

The Department received many comments regarding the various aspects of the proposed updating mechanism, including the updating frequency, methodology, notice period, and pause mechanism. The Department proposed in § 541.607(a) and (b) to update the earnings thresholds every 3 years by using the same methodology used in the regulations to set the thresholds. Specifically, proposed § 541.607(a)(2) and (b)(2) stated that the methodologies for setting the standard salary level and HCE annual compensation threshold in the NPRM would be used for future updates.

Many commenters that supported the proposed updating mechanism expressed a preference for more frequent updates. *See, e.g.,* Coalition of State AGs; Jobs to Move America; NEA; NELP. Commenters including AFL–CIO, National Partnership, and Nichols Kaster asserted annual updates, compared to triennial updates, offered better predictability and would ensure that the salary threshold keeps pace with the changes in wages. EPI similarly observed that annual updates would ensure that the salary threshold more closely adheres to the chosen percentile ''rather than slipping further and further behind in between triennial updates[.]''

Most commenters that opposed updating did not separately comment on the updating frequency, but some addressed it in the context of discussing the impact of the updating mechanism on employers. Many of these commenters claimed triennial updates would impose substantial financial and compliance burdens on employers as they would need to engage in reclassification analysis and implement necessary changes to adjust to the updated thresholds every 3 years. *See, e.g.,* ABC; CUPA–HR; HR Policy Association; NAM. Most of the commenters opposing the updating mechanism did not suggest an alternative updating frequency. Notwithstanding their objection to automatic updating, however, a few commenters, including AHLA, ASTA, WFCA, and YMCA, suggested a longer updating frequency ranging from 4 to 6 years.

The Department agrees with the commenters that stated annual updates would keep the salary level more up to date given that employee earnings are constantly changing. However, as stated in the NPRM, the Department is also mindful of the potential burden that possible changes to the tests for exemption on an annual basis would impose on employers, including costs associated with evaluating the exemption status of employees on an annual basis. Conversely, the Department is not convinced by commenter claims that triennial updates would impose an undue financial and compliance burden on employers. Many of these commenters did not address the fact that the alternative to automatic updating is not a permanent fixed earnings threshold, but instead larger changes to the threshold that could occur during irregular future updates. Since the updating mechanism will change the thresholds regularly and incrementally, and based on actual earnings of salaried workers, the Department predicts that employers will be in a better position to be able to adjust to the changes resulting from triennial updates. The Department remains persuaded that triennial updates are frequent enough to ensure that the part 541 earnings thresholds are kept up to date—and continue to serve the purpose of helping to identify exempt employees—while not being overly burdensome for employers. The final rule, therefore, adopts an updating frequency of 3 years as proposed.

The comments regarding the method through which the Department's proposed updating mechanism would reset the salary and compensation thresholds were also divided. Commenters favoring routine updates also supported the proposal to update the thresholds using the fixed percentile approach—to keep the thresholds at the same percentile of earnings of full-time salaried worker as established by the regulations. NELA, for example, asserted that updating the thresholds using a fixed percentile of earnings ''is the fairest way to maintain consistency in workers' FLSA eligibility in light of inevitable economic change.'' EPI similarly noted updating the thresholds through the proposed methodology ensures that the standard under the Department's rule ''is simply preserved—neither strengthened nor weakened.''

Commenters that opposed automatic updating opposed the proposed updating methodology. Several of these commenters reiterated an assertion from comments on the 2016 rulemaking that the proposed updating mechanism—tied to a fixed percentile—would result in the salary level being ''ratcheted'' upward over time due to the resulting actions of employers. *See, e.g.,* Chamber; NAM; NRF (including a report by Oxford Economics); SBA Advocacy. The commenters contended that in response to each automatic update, most employers would either reclassify employees earning below the new salary level to hourly status or raise the salaries of those employees to keep their exempt status. These responses, the commenters claimed, would skew the relevant data for future updates in favor of substantial increases because those employees who were reclassified as hourly would fall out of the data pool causing the data pool to be smaller and skew towards higher-paid workers. *See, e.g.,* Chamber; National Association of Convenience Stores; National Restaurant Association; NRF. While expressing a strong preference that automatic updates be abandoned altogether, some of the commenters concerned about this possible effect suggested that the Department adopt an updating mechanism tied to an inflation-related index. *See* Seyfarth Shaw; SHRM.

The Department notes that very similar comments concerning an alleged

[139] *See https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.*

''ratcheting'' effect were received during the 2016 rulemaking, which also proposed an updating mechanism based on earnings percentiles. In response to those comments, the Department examined historical data to determine the impact of its previous salary increase.[140] Specifically, the Department looked at the share of full-time white-collar workers paid on an hourly basis before and after the 2004 rule (January–March 2004; January–March 2005) both below and above the standard salary level. The Department found that following the 2004 rule, the share of full-time white-collar workers being paid hourly actually decreased marginally in the group below the standard salary level and increased slightly in the group above the standard salary level.[141]

The Department finds the claim that updating with a fixed percentile methodology would lead to the ''ratcheting'' upward of the thresholds to be unsubstantiated. The ''ratcheting'' claim is almost entirely based on the assumption that employers will respond to an automatically updated salary level by converting all or a large number of newly nonexempt workers to hourly status, thus removing them from the data set of full-time salaried workers. Yet none of the commenters advancing this claim presented any tangible data or evidence to support their assumption. Even those few commenters that provided economic analyses rested their views on the same unsubstantiated assumption that employers will generally reclassify newly nonexempt employees as hourly. *See, e.g.,* NRF (including a report by Oxford Economics); PPWO (quoting a study by Edgeworth Economics).[142] The results of the Department's close examination of the impact of the 2004 salary level increase provide no evidence that salary level increases due to regular triennial updating will result in employers converting significant numbers of affected EAP workers to hourly pay status and thus raising potential concerns about skewing future updates. Although many commenters made nearly identical ratcheting claims in this rulemaking, none of the commenters addressed the Department's analysis in response to those same claims in the 2016 rule.

Having found no merit in the ''ratcheting'' claim, the Department declines to adopt the alternative methodologies suggested such as an updating mechanism tied to an inflation-related index. As noted in the NPRM, the fixed percentile approach, as opposed to other methods such as indexing the thresholds for inflation, eliminates the risk that future levels will deviate from the underlying salary setting methodology established through rulemaking. During the 2016 rule, the Department extensively considered whether to update the thresholds based on changes in the Consumer Price Index for All Urban Consumers (CPI–U)—a commonly used economic indicator for measuring inflation.[143] The Department chose to update the thresholds using the same methodology used to initially set them in that rulemaking (*i.e.,* a fixed percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region), observing that the objectives that justify setting the salary level using a fixed percentile methodology also supported updating the thresholds using the same methodology.[144] The Department is persuaded that updating the earnings thresholds by applying the same methodology used to originally set the levels instead of indexing them for inflation best ensures that the earnings thresholds continue to fulfill their objective of helping effectively differentiate between bona fide EAP employees and those who are entitled to overtime pay and work appropriately with the duties test.

New § 541.607 therefore establishes triennial updates of the standard salary level and the HCE total compensation threshold using the same methodologies used to set those thresholds. Assuming the Department has not engaged in further rulemaking, the Department anticipates the second update under the updating mechanism—which will occur 3 years after the date of the initial update discussed in section V.A—will use the methodologies established by this final rule as those will become effective before the second update. Accordingly, the second update will reset the standard salary level to the 35th percentile of weekly earnings of full-time workers in the lowest-wage Census Region and will reset the HCE total annual compensation threshold to the annualized weekly earnings of the 85th percentile of full-time salaried workers nationally based on contemporaneous data at that time.

The Department further proposed to publish in the **Federal Register** a notice with the adjusted standard salary level and the HCE total annual compensation threshold at least 150 days before the date the adjusted thresholds are set to take effect and to publish the updated thresholds on WHD's website no later than their effective date. The Department proposed to update both thresholds using the most recent available 4 quarters of data, as published by BLS, preceding the publication of the Department's notice with the adjusted levels. The Department received fewer comments regarding these aspects of the proposal than on the updating mechanism itself.

Most commenters supporting the proposed updating mechanism did not separately comment on the 150-day notice period. Some commenters opposing automatic updates asserted that the 150-day notice period would not be adequate time to prepare for compliance with the new updated thresholds. *See, e.g.,* Association of Public and Land-grant Universities (APLU) (suggesting 180-day advance notice); Chamber (suggesting at least 1 year notice); National Association of Convenience Stores (same); The American Association of Advertising Agencies (The 4As) (same). Regarding the data set, EPI suggested the Department use the most recent quarter of data asserting that the salary threshold would be ''suppressed'' for 2 out of every 3 years if the Department adopts triennial updates. On the other hand, the National Association of Convenience Stores, while opposing automatic updating, recommended the Department use the most recent 6 quarters of data, or those quarters minus the 2 most recent, to account for changes it claimed employers may make preemptively to adjust to an upcoming update for budgetary reasons.

After considering the comments received, the Department is persuaded that a notice period of not less than 150 days provides sufficient time for employers to make the necessary adjustments to comply with the updated thresholds. This is especially true given that employers will be able to access the data set that will be used to make the adjustments as published by BLS and anticipate the extent of the adjustment even before the Department publishes the notice. A period substantially longer than 150 days would hinder the Department's ability to ensure that the thresholds that take effect are based on the most up-to-date data. Similarly, the Department believes that using the most recent available 4 quarters of data will account for the Department's goal that

[140] 81 FR 32441.

[141] *See id.* at 32441, 32507–08.

[142] The Edgeworth Economic study that was quoted by PPWO and a few other commenters seemed to assume, without any support, that all affected workers or newly nonexempt workers who earn between $684 and $1,059 per week will be reclassified as hourly employees.

[143] *See* 81 FR 32438–41.

[144] *See id.* at 32440.

the thresholds reflect prevailing economic conditions while balancing the concerns of commenters that wanted a longer or shorter period for the data set. Therefore, the final rule establishes that for future updates under the updating mechanism, the Department will publish in the **Federal Register** a notice with the adjusted thresholds not fewer than 150 days before the date the new adjusted thresholds are set to take effect and will publish the updated thresholds on the WHD website no later than their effective date. The updates will be based on the most recent available 4 quarters of data as published by BLS.

Lastly, the Department's proposal included a provision providing for the delay of a scheduled update under the updating mechanism while the Department engages in notice and comment rulemaking to change the earnings requirements and/or updating mechanism, where economic or other conditions merit. The Department explained that the delay would be triggered if the Department publishes an NPRM proposing to change the salary level methodology and/or modify the updating mechanism by the date on which it publishes the notice of the revised salary and compensation thresholds. In that instance, the notice with the adjusted thresholds must state that the scheduled update will be paused for 120 days from the day the update was set to occur while the Department engages in rulemaking, and that the pause will be lifted on the 121st day unless the Department finalizes a rule changing the salary level methodology and/or automatic updating mechanism by that time. In the event the Department does not issue a final rule by the prescribed deadline, the pause on the scheduled update will be lifted and the new thresholds will take effect on the 121st day after they were originally scheduled to take effect. The Department also explained the 120-day pause would not affect the date for the next scheduled triennial update given the relative shortness of the delay and so as not to disrupt the updating schedule. The next update, therefore, would occur 3 years from the date on which the delayed update would have originally been effective.

The Department received somewhat mixed comments regarding its proposed pausing mechanism. For example, notwithstanding their objection to automatic updating (and in some cases, certain aspects of the pause mechanism), some employer organizations such as CUNA, AHLA, and the National Association of Professional Insurance Agents commended the Department for recognizing that there may be circumstances that may require temporarily delaying a scheduled update. Some commenters that supported the updating proposal agreed. For example, the Coalition of State AGs described the delay provision as ''a fail-safe mechanism'' that would provide the Department flexibility to adjust to changed circumstances as necessary. On the other hand, Sanford Heisler Sharp, while otherwise favoring the updating mechanism, objected to the pause feature asserting that it would ''inject uncertainty into the administration of the threshold, undermining the stated purpose of the NPRM to simplify enforcement of overtime and minimum wage protections.''

Some commenters took issue with the phrase ''unforeseen economic or other conditions'' in the NPRM's preamble which generally described the circumstances in which the Department may trigger the pause mechanism. AHLA, CUNA, and NAIS/NBOA asserted it is not clear what circumstances would constitute ''unforeseen economic or other conditions.'' AFPI similarly pointed out the phrase was found only in the preamble and not in the proposed § 541.607. American Council of Engineering Companies expressed concern that the proposed pause mechanism does not provide sufficient flexibility for the Department to respond to unexpected economic conditions and recommended that the provision be modified to allow the Secretary ''to suspend automatic updates if economic conditions warrant.'' RILA asserted the pause feature is an inflexible process asserting that if a catastrophic event were to occur within 150 days of the date of a scheduled update, the Department would have no flexibility or ability to delay or stop the update. A few commenters claimed that the 120-day pause period is not sufficient time to provide the Department the flexibility it needs to adjust to unforeseen circumstances or complete a rulemaking. *See, e.g.,* National Association of Convenience Stores; NRF.

Most of the comments objecting to or otherwise criticizing the pause mechanism seem to assume the only way the Department can alter a scheduled update or change any other aspect of the rule is through the updating mechanism's pause provision. That is not correct. Nothing in the proposed updating mechanism limits the Department's ability to engage in future rulemaking to change any aspect of the part 541 regulations at any time. The pause mechanism offers the Department added flexibility—in addition to its ability to engage in rulemaking at any time to change the rule—by allowing it the ability to delay a scheduled update as it engages in rulemaking. As the Department noted in the NPRM, the pause mechanism offers the Department 270 days—150 days before, and 120 days after, the effective date for the scheduled update—to complete the rulemaking process. The Department can still engage in rulemaking outside of this period and through that rulemaking can stop or delay a scheduled update or change any other aspect of the part 541 regulations. This is true regardless of whether the Department adopts the delay provision. The Department believes that the pause provision will provide additional flexibility in the context of the triennial updates and will not impact the Department's normal rulemaking powers.

The Department recognizes that the phrase ''unforeseen economic or other conditions'' was not in proposed § 541.607 and agrees that the lack of this language in the regulatory text creates ambiguity about the standard for pausing a triennial update. Therefore, the Department is revising § 541.607(d) to include similar language. The Department believes this revision clarifies the standard for when the pause mechanism may be triggered but does not impinge on the Department's normal authority to engage in rulemaking for other reasons. The Department is disinclined to further define what circumstances would trigger the pause mechanism, as some commenters suggested. In proposing the pause mechanism, the Department was mindful of previous statements from stakeholders, and the Department's own prior statements, about the need to preserve flexibility to adapt to unanticipated circumstances. As an example, the Department referenced the COVID pandemic and its widespread impact on workplaces. However, it is not feasible for the Department to outline every possible circumstance that could warrant a delay of a scheduled update. Doing so would unduly limit the Department's flexibility to adjust to truly unanticipated circumstances.

For these reasons, the Department has concluded that the proposed pause mechanism, with the modification noted above, provides the Department sufficient flexibility to adopt to unforeseen circumstances where necessary. Therefore, the new § 541.607(b)(4) establishes that the Department can trigger the pause, where unforeseen economic or other

conditions warrant, by issuing an NPRM proposing to change the salary level methodology and/or modify the updating mechanism by the date on which it publishes the notice with the adjusted salary and compensation thresholds. Section 541.607(b)(4) further clarifies that the notice with the adjusted thresholds must state that the scheduled update will be paused for 120 days from the day the update was set to occur while the Department engages in rulemaking, and that the pause will be lifted on the 121st day unless the Department finalizes a rule changing the salary level methodology and/or automatic updating mechanism by that time.

Lastly, as discussed in more detail in section V.D, the Department intends for the triennial updates of the standard salary level and the HCE total annual compensation threshold using current earnings data to be severable from the revision to those methodologies discussed in section V.B and section V.C. In implementing routine triennial updates, the Department intends to ensure that the salary and compensation thresholds set in the regulations reflect changes in earnings data and continue to function effectively in helping identify exempt white-collar employees. As already noted, the Department has different objectives for changing the methodologies for setting the standard salary level and HCE total annual compensation threshold. Specifically, in changing the methodology for the standard salary level, the Department intends to fully restore the salary level's historic screening function and account for the shift in the 2004 rule from a two-test to a one-test system for defining and delimiting the EAP exemption.[145] In changing the methodology for the HCE total annual compensation threshold, the Department intends to ensure the HCE threshold's role as a streamlined alternative for those employees most likely to meet the standard duties test by excluding all but those employees ''at the very top of [the] economic ladder[.]'' [146] These are independent objectives of this rulemaking and the provisions implementing them can each stand alone. Therefore, the Department intends for the triennial updates to remain in force even if the methodologies for the standard salary level and the HCE total annual compensation threshold established by this final rule are stayed or do not take effect. Similarly, the Department intends for the triennial updates under § 541.607(b) to remain in force even if the initial update for wage growth in § 541.607(a) is stayed or does not take effect.

[145] *See* section V.B.

[146] *See* section V.C.

B. Standard Salary Level

In its NPRM, the Department proposed to update the salary level by setting it equal to the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census Region (the South), resulting in a proposed salary level of $1,059 per week ($55,068 for a full-year worker). The proposed salary level methodology built on lessons learned in the Department's most recent rulemakings to more effectively define and delimit employees employed in a bona fide EAP capacity. Specifically, the Department's intent in the NPRM was to fully restore the salary level's screening function and account for the switch in the 2004 rule from a two-test system to a one-test system for defining the EAP exemption, while also updating the standard salary level for earnings growth since the 2019 rule.

The Department is finalizing the proposed standard salary level methodology and applying it to the most recent available earnings data, resulting in a salary level of $1,128 per week ($58,656 for a full-year worker). Setting the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region will, in combination with the standard duties test, better define and delimit which employees are employed in a bona fide EAP capacity in a one-test system. Because the salary level is above the equivalent of the long test salary level, the final rule will (unlike the 2004 and 2019 rules) ensure that lower-paid white-collar employees who perform significant amounts of nonexempt work, and were historically considered by the Department not to be employed in a bona fide EAP capacity because they failed the long duties test, are not all included in the exemption. At the same time, by setting the salary level well below the equivalent of the short test salary level, the final rule will address potential concerns that the salary level test should not be determinative of EAP exemption status for too many white-collar employees. The combined result will be a more effective test for exemption. The final salary level will also reasonably distribute between employees and their employers what the Department now understands to be the impact of the 2004 shift from a two-test to a one-test system on employees earning between the long and short test salary levels.

1. History of the Salary Level

The FLSA became law in 1938 and the first version of the part 541 regulations, issued later that year, set a minimum compensation requirement of $30 per week for executive and administrative employees.[147] Since then, the Department has increased the salary levels eight times—in 1940, 1949, 1958, 1963, 1970, 1975, 2004, and 2019.

In 1940, the Department maintained the $30 per week salary level for executive employees but established a higher $200 per month salary level test for administrative and professional employees. In selecting these thresholds, the Department used salary surveys from Federal and state government agencies, experience gained under the National Industrial Recovery Act, and Federal government salaries to determine the salary level that was a reasonable ''dividing line'' between employees performing exempt and nonexempt work.[148]

In 1949, recognizing that the ''increase in wage rates and salary levels'' since 1940 had ''gradually weakened the effectiveness of the present salary tests as a dividing line between exempt and nonexempt employees,'' the Department calculated the percentage increase in weekly earnings from 1940 to 1949, and then adopted new salary levels at a ''figure slightly lower than might be indicated by the data'' to protect small businesses.[149] In 1949, the Department also established a short test for exemption, which paired a higher salary level with a less rigorous duties test. The justification for this short test was that employees who met the higher salary level were more likely to meet all the requirements of the exemption (including the 20 percent limit on nonexempt work), and thus a ''short-cut test of exemption . . . would facilitate the administration of the regulations without defeating the purposes of section 13(a)(1).'' [150] Employees who met only the lower long test salary level, and not the higher short test salary level, were required to satisfy the long duties test, which included a limit on the amount of nonexempt work that an exempt employee could perform. The two-test system remained part of the Department's regulations until 2004. In 1958, the Department reiterated that salary is a ''mark of [the] status'' of an exempt employee and reinforced the importance of salary as an enforcement tool, adding that the Department had

[147] 3 FR 2518.

[148] *See* Stein Report at 20–21, 31–32.

[149] Weiss Report at 8, 14.

[150] *Id.* at 22–23.

''found no satisfactory substitute for the salary tests.'' [151] To set the salary levels, the Department considered data collected during 1955 WHD investigations on the ''actual salaries paid'' to employees who ''qualified for exemption'' (*i.e.,* met the applicable salary and duties tests in place at the time) and set the salary levels at $80 per week for executives and $95 per week for administrative and professional employees.[152] The Department set the long test salary levels so that only a limited number of employees performing EAP duties (about 10 percent) in the lowest-wage regions and industries would fail to meet the new salary level and therefore become entitled to overtime pay.[153] In laying out this methodology, often referred to as the ''Kantor'' methodology and generally referenced in this rule as the ''long test'' methodology, the Department echoed its prior comments stating that the salary tests ''simplify enforcement by providing a ready method of screening out the obviously nonexempt employees.'' [154]

The Department followed a similar methodology when determining the appropriate long test salary level in 1963, using data regarding salaries paid to exempt workers collected in a 1961 WHD survey.[155] The salary level for executive and administrative employees was increased to $100 per week, and the professional exemption salary level was increased to $115 per week.[156] The Department noted that these salary levels approximated the methodology used in 1958 to set the long test salary levels.[157]

The Department continued to use a similar methodology when it updated the salary levels in 1970. After examining data from 1968 WHD investigations, 1969 BLS wage data, and information provided in a report issued by the Department in 1969 that included salary data for executive, administrative, and professional employees,[158] the Department increased the long test salary level for executive and administrative employees to $125 per week and increased the long test salary level for professional employees to $140 per week.[159]

In 1975, instead of following the previous long test methodology, the Department set the long test salary levels ''slightly below'' the amount suggested by adjusting the 1970 salary levels for inflation based on increases in the Consumer Price Index.[160] The long test salary level for executive and administrative employees was set at $155, while the professional level was set at $170. The salary levels adopted were intended to be interim levels ''pending the completion and analysis of a study by [BLS] covering a six-month period in 1975[,]'' and were not meant to set a precedent for future salary level increases.[161] The envisioned process was never completed, however, and the ''interim'' salary levels remained unchanged for the next 29 years.

The short test salary level increased in tandem with the long test level throughout the various rulemakings between 1949 and 2004. Because the short test was designed to capture only those white-collar employees whose salary was high enough to indicate a stronger likelihood of being employed in a bona fide EAP capacity and thus warrant a less stringent duties requirement, the short test salary level was always set significantly higher than the long test salary level (approximately 130 percent to 180 percent of the long test level).

When the Department updated the part 541 regulations in 2004, it created a single standard test for exemption instead of retaining the two-test system from prior rulemakings. The Department set the new standard salary level at $455 per week and paired it with a duties test that was substantially equivalent to the less rigorous short duties test. The Department set a salary level that would exclude from exemption roughly the bottom 20 percent of full-time salaried employees in each of two subpopulations: (1) the South and (2) the retail industry nationally. In setting the salary level the Department looked to earnings data for all white-collar workers—exempt and nonexempt—and looked to a higher percentile than the long test methodology (10th percentile of exempt workers in low-wage industries and areas). The Department acknowledged, however, that the salary arrived at by this method was, at the time, equivalent to the salary derived from the long test method using contemporaneous data.[162]

In the 2016 rule, the Department set the standard salary level equal to the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South). This resulted in a standard salary level of $913 per week, which was at the low end of the historic range of short test salary levels. The Department explained that the increase in the standard salary level was needed because, in moving from a two-test to a one-test system, the 2004 rule exempted lower-salaried employees performing large amounts of nonexempt work who had historically been, and should continue to be, covered by the overtime compensation requirement.[163] Since the standard duties test was equivalent to the short duties test, the Department asserted that a salary level in the short test salary range—traditionally 130 to 180 percent of the long test salary level—was necessary to address this effect of the 2004 rule. As explained earlier, the U.S. District Court for the Eastern District of Texas held the 2016 rule invalid.

In the 2019 rule, the Department reapplied the methodology for setting the standard salary threshold from the 2004 rule, setting the salary level equal to the 20th percentile of weekly earnings of full-time salaried workers in the South and/or in the retail sector nationwide.[164] This methodology addressed concerns that had been raised that the 2016 methodology excluded too many employees from the exemption based on their salary alone and produced the current standard salary level of $684 per week (equivalent to $35,568 per year).[165] Unlike in 2004, however, where the 20th percentile of weekly earnings of full-time salaried workers in the South and retail nationally was essentially the same as the long test, in 2019 this methodology now produced a salary level amount that was lower than the equivalent of the long test salary level using contemporaneous data ($724 per week, $37,648 per year). Put another way, the salary level set in the 2019 rule was $40 per week below the long test level (used to validate the salary level in the 2004 rule) and $292 per week below the low end of the short test range (used to set the salary level in the 2016 rule).

2. Standard Salary Level Proposal

In its NPRM, the Department proposed to update the salary level by setting it equal to the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census Region (the

[151] Kantor Report at 2–3.
[152] *Id.* at 6, 9.
[153] *Id.* at 6–7.
[154] *Id.* at 2–3; *see* Weiss Report at 8.
[155] 28 FR 7002 (July 9, 1963).
[156] *Id.* at 7004.
[157] *Id.*
[158] *See* 34 FR 9934, 9935 (June 24, 1969).
[159] 35 FR 885.
[160] 40 FR 7091.
[161] *Id.* at 7091–92.
[162] *See* 69 FR 22168. The 2004 rule looked to the 20th percentile of a data set of all full-time salaried workers and the long test methodology looked to the lowest paid 10 percent of exempt salaried workers. The two methodologies resulted in equivalent salary levels because exempt salaried workers generally have higher earnings than nonexempt salaried workers.
[163] 81 FR 32405.
[164] *See* 84 FR 51260 (Table 4).
[165] *Id.* at 51238.

South), resulting in a proposed salary level of $1,059 per week ($55,068 for a full-year worker). The Department's proposal explained that fully restoring the salary level's screening function required setting a salary level at least equal to the long test salary level. The Department elaborated that prior to the 2019 rule (when the Department set the salary level $40 per week below the long test level), employees who earned below the long test salary level were screened from the EAP exemption by virtue of their pay—either by the long test salary level itself or, in the case of the 2004 rule, a standard salary level set equal to the long test salary level. The Department stated that the long test salary level provided what it believed should be the lowest boundary of the new salary level methodology because it would ensure the salary level's historic screening function was restored.

In selecting the proposed salary level methodology, the Department also considered the impact of its switch in 2004 to a one-test system for determining exemption status. The Department explained that a single-test system cannot fully replicate both the two-test system's heightened protection for employees performing substantial amounts of nonexempt work and its increased efficiency for determining exemption status for employees who are highly likely to perform EAP duties. Rather than reinstate the long duties test with its limitation on nonexempt work, the Department examined earnings ventiles that would produce a salary level between the long and short test salary levels (which were, respectively, equivalent to between the 26th and 27th percentiles, and the 53rd percentile, of full-time salaried worker earnings in the lowest-wage Census Region). The Department explained that the long and short tests had served as the foundation for nearly all the Department's prior rulemakings, either directly under the two-test system, or indirectly as a means of evaluating the Department's salary level methodology under the one-test system, and therefore were useful parameters. The Department concluded that setting the salary level equal to the 35th percentile would, in combination with the standard duties test, more effectively identify in a one-test system who is employed in a bona fide EAP capacity in a manner that reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move to a one-test system.

After reviewing the comments received, the Department is finalizing its proposal to set the standard salary level equal to the 35th percentile of full-time salaried worker earnings in the lowest-wage Census Region (the South), which is below the midpoint of the long and short test salary levels. Applying this methodology to data for calendar year 2023 results in a salary level of $1,128 per week ($58,656 annually for a full-year worker). This approach will fully restore the salary level's function of screening obviously nonexempt workers from the EAP exemption, and account for the switch in the 2004 rule to a one-test system in a way that reasonably distributes the impact of this shift among employees earning between the long and short test salary levels and their employers. The resulting salary level will work effectively with the standard duties test to better define who is employed in a bona fide EAP capacity.

3. Salary Level Test Function and Effects

For 85 years, the Department's regulations have consistently looked at both the duties performed by the employee and the salary paid by the employer in defining and delimiting who is a bona fide executive, administrative, or professional employee exempt from the FLSA's minimum wage and overtime protections. From 1949 to 2004, the Department determined EAP exemption status using a two-test system comprised of a long test (a lower salary level paired with a more rigorous duties test that limited performance of nonexempt work to no more than 20 percent for most employees) and a short test (a higher salary level paired with a less rigorous duties test that looked to the employee's primary duty and did not have a numerical limit on the amount of nonexempt work). The two-test system facilitated the determination of whether white-collar workers across the income spectrum were employed in a bona fide EAP capacity, and employees who met either test could be classified as EAP exempt.

In a two-test system, the long test salary level screens from the exemption the lowest-paid white-collar employees, thereby ensuring their right to overtime compensation. The Department has often referred to many of the employees who are screened from the exemption by virtue of their earning below the lower long test salary level as "'obviously nonexempt employees[.]' " [166] The long test salary level helped distinguish employees who were not employed in a bona fide EAP capacity because the Department found that employees who were screened from exemption by the long test salary level generally did not meet the other requirements for exemption.[167] Since 1958, the long test salary level was generally set to exclude from exemption approximately the lowest-paid 10 percent of salaried white-collar employees who performed EAP duties in the lowest-wage regions and industries.[168] The long test salary level also served as a line delimiting the population of white-collar employees for whom the duties test determined their exemption status. In the two-test system, this duties analysis included an examination of the amount of nonexempt work performed by lower-salaried employees, which ensured that these employees were employed in an EAP capacity by limiting the amount of time they could spend on nonexempt work. The duties and salary level tests worked in tandem to properly define and delimit the exemption: lower-paid workers had to satisfy a more rigorous duties test with strict limits on nonexempt work, and higher-paid employees were subject to a less rigorous duties test because they were more likely to satisfy all the requirements of the exemption (including the limit on nonexempt work).[169]

Because employees who met the short test salary level were paid well above the long test salary level, the short test salary level did not perform the same function as the long test salary level of screening obviously nonexempt employees. Instead, the short test salary level was used to determine whether the full duties test or the short-cut duties test would be applied to determine EAP exemption status. The exemption status of employees paid more than the long and less than the short test salary levels was determined by applying the more rigorous long duties test that ensured overtime protections for employees who performed substantial amounts of nonexempt work. The exemption status of employees paid at or above the higher short test salary level was determined by the less rigorous short duties test that looked to the employee's primary duty and did not cap the amount of nonexempt work an employee could perform. The short test thus provided a faster and more efficient duties test based on the Department's experience

[166] *See id.* at 51237 (quoting Kantor Report at 2–3).

[167] *See* Kantor Report at 2–3; Weiss Report at 8 ("In an overwhelming majority of cases, it has been found by careful inspection that personnel who did not meet the salary requirements would also not qualify under other sections of the regulations[.]").

[168] *See* 84 FR 51236.

[169] Weiss Report at 22–23.

that employees paid at the higher short test salary level ''almost invariably'' met the more rigorous long duties test, including its 20 percent limit on nonexempt work, and therefore a shortened analysis of duties was a more efficient test for exemption status.[170]

In 2004, rather than updating the two-test system, the Department chose to establish a new, single-test system for determining exemption status. The new single standard test for exemption used a duties test that was substantially equivalent to the less rigorous short duties test in the two-test system.[171] Since the creation of the standard test, the Department has taken two different approaches to set the standard salary level that pairs with the standard duties test.

In 2004, as noted above, the Department set the new salary level roughly equivalent to the 20th percentile of weekly earnings of full-time salaried workers in the South and in the retail industry nationwide.[172] The Department acknowledged that the salary level ($455 per week) was, in fact, equivalent to the lower long test salary level amount under the two-test system using contemporaneous data.[173] Because it was equivalent to the long test salary level, the standard salary test continued to perform the same initial screening function as the long test salary level: employees who historically were entitled to overtime compensation because they earned below the long test salary level remained nonexempt under the new standard test.

Without a higher salary short test, however, all employees who met the standard salary level were subject to the same duties test. Since the single standard duties test was equivalent to the short duties test, some employees who previously did not meet the long duties test met the standard duties test. As a result, the shift from a two-test to a one-test system significantly broadened the EAP exemption because employees who historically had not been considered bona fide EAP employees were now defined as falling within the exemption and would not be eligible for overtime compensation. This broadening specifically impacted lower-paid, salaried white-collar employees who earned between the long and short test salary levels and performed substantial amounts of nonexempt work. Under the two-test system, these employees had been entitled to overtime compensation if their nonexempt duties exceeded the long test's strict 20 percent limit on such work. Under the 2004 standard test, these employees became exempt because they met both the low standard salary level and the less rigorous standard duties test, which does not have a numerical limit on the amount of nonexempt work.

The Department's discussion of the elimination of the long duties test in the 2004 rule focused primarily on the minimal role played by the long test at that time due to the erosion of the long salary level, and on the difficulties employers would face if they were again required to track time spent on nonexempt work when the dormancy of the long duties test meant that they had generally not been performing such tracking for many years.[174] While asserting that employees who were then subject to the long test would be better protected under the higher salary level of the new standard test, the Department in the 2004 rule did not compare the protection lower salaried employees would receive under the standard test with the protection they would have received under an updated long test with a salary level based on contemporaneous data and the existing long duties test.

To address the concern that lower-salaried employees performing large amounts of nonexempt work historically were not considered bona fide EAP employees and thus should be entitled to overtime compensation, in 2016 the Department set the standard salary level at the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (the South). This methodology produced a salary level ($913 per week) that was at the low end of the historical range of short test salary levels, which had traditionally been paired with the short duties test, and above the midpoint between the long and short test salary levels.[175] This approach restored overtime protection for employees performing substantial amounts of nonexempt work who earned between the long and short test salary levels, as they failed the new salary level test. However, this approach generated potential concerns that the salary level test should not be determinative of exemption status for too many individuals. Specifically, the 2016 rule's narrowing of the exemption prevented employers from using the exemption for employees who earned between the long test salary level and the low end of the short test salary range and would have met the more rigorous long duties test. Prior to 2004, employers could use the long test to exempt these employees, and under the 2004 rule these employees remained exempt under the one-test system. Thus, while the 2016 rule accounted for the absence of the long duties test by restoring overtime protections to employees earning between the long test salary level and the low end of the short test salary range who perform significant amounts of nonexempt work, it also made a group of employees who had been exempt under the two-test system newly nonexempt under the one-test system: employees earning between the long test level and the short test salary range who perform only limited nonexempt work.

In its 2019 rule, the Department determined that the 2016 rule had not sufficiently considered the impact of the increased standard salary level on employers' ability to use the exemption for this group of lower-paid employees who performed only limited amounts of nonexempt work.[176] The Department emphasized that ''[f]or most . . . employees the exemption should turn on an analysis of their actual functions, not their salaries,'' and that the 2016 rule's effect of making nonexempt lower-paid, white-collar employees who traditionally were exempt under the long test ''deviated from the Department's longstanding policy of setting a salary level that does not 'disqualify[] any substantial number of' bona fide executive, administrative, and professional employees from exemption.'' [177] To address these concerns, the Department simply returned to the 2004 rule's methodology for setting the salary threshold. Applying the 2004 method to the earnings data available in 2019 produced a standard salary level of $684 per week, which was below the equivalent of what the long test salary level would have been using contemporaneous data ($724 per week).[178] The 2019 rule was the first time the Department paired the standard duties test with a salary level that was not at least equivalent to the long test level.

The 2019 rule, like the 2004 rule, exempted all employees who earned between the long and short test salary levels and performed too much nonexempt work to meet the long duties test, but passed the standard duties test (equivalent to the short duties test). The 2019 rule also for the first time permitted the exemption of a group of low-paid white-collar employees (those

[170] *Id.*

[171] 69 FR 22214.

[172] *See id.* at 22168–69.

[173] *See id.*

[174] *See* 69 FR 22126–27.

[175] 81 FR 32405, 32467.

[176] 84 FR 10908.

[177] *Id.* (quoting Kantor Report at 5).

[178] 84 FR 51260.

earning between $684 and $724 per week) who had always been protected by the salary level test's initial screening function—either under the long test or under the 2004 rule salary level that was equivalent to the long test salary level. The Department stated that the standard salary level's ''fairly small difference'' from the long test level did not justify using the long test methodology to set the salary level and emphasized that its approach preserved the salary level's principal function as a tool for screening from exemption obviously nonexempt employees.[179] In response to commenter concerns about the 2019 rule exempting employees who traditionally earned between the long and short test salary levels and received overtime compensation because they did not meet the long duties test, the Department cited the legal risks posed by the 2016 methodology (drawing on the district court's decisions as evidence) and explained that such employees were already exempt in the years leading up to 2004 because the Department's outdated salary levels had rendered the long test with its more rigorous duties requirement largely dormant.[180] As in the 2004 rule, the Department did not address the protection such lower salaried employees would have received had the Department updated the long test using contemporary data.

As explained in the NPRM, the Department's experience with a one-test system shows that it is less nuanced than the two-test system, which allowed for finer calibration in defining and delimiting the EAP exemption. In a two-test system, there are four variables (two salary levels and two duties tests) that can be adjusted to define and delimit the exemption. In a one-test system, there are only two variables (one salary level and one duties test) that can be adjusted, necessarily yielding less nuanced results. The loss in precision does not impact the lowest-paid white-collar employees, who were screened from exemption by the long test salary level, because they maintain their right to overtime pay so long as the standard salary level is set at least equivalent to the lower long test salary level—a condition that was met by the 2004 rule's salary level but not by the 2019 rule's salary level. Instead, the Department's experience shows that the shift from a two-test system to a one-test system impacts employees earning between the long and short test salary levels and, in turn, employers' ability to use the exemption for these employees.

In the two-test system, employees who earned between the long and short test salary levels and performed large amounts of nonexempt work were protected by the long duties test, while bona fide EAP employees in that earnings range who performed only limited amounts of nonexempt work were exempt. Meanwhile, the short test provided a time-saving short-cut test for higher-earning employees who would almost invariably pass the more rigorous, and thus more time consuming, long duties test. But the more rigorous long duties test, with its limitation on the amount of nonexempt work that could be performed, was always core to the two-test system, with the higher short test salary level and less rigorous short duties test serving as a time-saving mechanism for employees who would likely have met the more rigorous long duties test.[181]

As explained in the NPRM, one way in a one-test system to ensure appropriate overtime protection to lower-salaried employees earning between the long and short test salary levels who were historically entitled to overtime compensation under the long test would be to reinstate the long duties test with its limitation on nonexempt work. A one-test system with a more rigorous duties test would appropriately emphasize the important role of duties in determining exemption status. However, the Department did not propose in this rulemaking to replace the standard duties test with the long duties test or to return to a two-test system with the long duties test. The Department has not had a one-test system with a limit on nonexempt work other than from 1940 to 1949,[182] when the Department replaced this approach with its two-test system, and the two-test system was replaced 20 years ago. Returning to the two-test system would eliminate the benefits of the current duties test, including having a single test with which employers and employees are familiar.

In light of these considerations, the Department's goal in this rulemaking is not only to update the single standard salary level to account for earnings growth since the 2019 rule through the use of the updating mechanism, but also to build on the lessons learned in its most recent rulemakings to more effectively define and delimit employees employed in a bona fide EAP capacity. Consistent with its broad authority under section 13(a)(1), the Department's aim is to have a single salary level test that will work effectively with the standard duties test to better define who is employed in a bona fide EAP capacity and will both fully perform the salary level's initial screening function and account for the change to a single-test system.

4. Discussion of Comments and Final Standard Salary Level

i. Overall Commenter Feedback

The Department received a significant number of comments in response to its proposal to set the standard salary level equal to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region. Numerous commenters supported the Department's proposed salary level. Supporters included thousands of individual employees, writing separately or as part of comment campaigns, and many groups representing employees or employee interests. *See, e.g.,* American Association of Retired Persons (AARP); AFSCME; AFT; NEA; Restaurant Opportunities Center United; United Auto Workers Region 6; United Steelworkers; WorkMoney. Many other commenters, including advocacy groups, academics, and State officials also supported the Department's proposal. *See, e.g.,* Administrative Law Professors; CLASP; Coalition of Gender Justice and Civil Rights Organizations; Coalition of State AGs; Common Good Iowa; EPI; The Leadership Conference on Civil and Human Rights; National Partnership; NWLC. A number of supportive commenters urged the Department to set a higher salary level than the one it proposed. *See, e.g.,* AFL–CIO; Demos; Nichols Kaster; Sanford Heisler Sharp; SEIU; Winebrake & Santillo, LLC (Winebrake & Santillo). A minority of employers, including most notably a campaign of small business commenters, also supported the proposed salary level. *See, e.g.,* Business for a Fair Minimum Wage; Dr. Bronners; Firespring; Small Business Majority. Some members of Congress also commented in support of the proposed salary level. *See* 19 Democratic Senators; 10 Democratic Representatives; U.S. Representative Maxwell Frost (D–FL).

Commenters that supported increasing the salary level often emphasized that the FLSA's minimum wage and overtime requirements are fundamental employee protections, intended to spread employment to more workers and provide extra

[179] *Id.* at 51244.

[180] *Id.* at 51243.

[181] Numerous employer organizations supported the Department's decision in 2004 to move to a one-test system. *See* 69 FR 22126–27. Commenters likewise opposed returning to the two-test structure in the 2016 and 2019 rulemakings. *See* 84 FR 10905; 81 FR 32444.

[182] *See* 5 FR 4077.

compensation (above the statutory minimum) to employees who work more than 40 hours in a week. *See, e.g.,* AARP; AFL–CIO; Coalition of State AGs; NELA; NELP; Nichols Kaster; United Steelworkers. Some supportive commenters, including Sanford Heisler Sharp, Texas RioGrande Legal Aid, and Washington State Department of Labor and Industries, stressed that the EAP exemption was premised in part on the expectation that exempt employees received high salaries and other privileges to compensate for their long hours of work and lack of FLSA protections. Other commenters similarly stressed that the exemption is intended for employees who, based on the nature of their work and their compensation, have sufficient bargaining power not to need the Act's protections. *See, e.g.,* Business for a Fair Minimum Wage; CLASP; NELP; NWLC.

Supportive commenters often also emphasized that the salary level test has an important and longstanding role in helping define which employees are employed in a bona fide executive, administrative, or professional capacity. Some commenters, including AARP and NELA, stressed that the salary level provides an important ''bright line'' test for helping determine exemption status, and NWLC similarly stated that the salary level provides a ''clear, objective, and straightforward'' test that is ''easy for employers to apply and for employees to understand[.]'' NELP, quoting testimony from EPI at a 2015 Congressional hearing on this issue, stated that salary level tests have been used since the Department's earliest part 541 regulations because the '' 'final and most effective check on the validity of the claim for exemption is the payment of a salary commensurate with the importance supposedly accorded the duties in question.' '' The Coalition of State AGs stated that a salary level that is too low ''no longer accurately delimits the boundaries of who is an EAP'' employee.

The vast majority of employers and commenters supporting employer interests opposed the proposed salary level. As discussed in section III, many employer representatives opposed any salary level increase and urged the Department to withdraw its proposal. *See, e.g.,* AHLA; Americans for Prosperity; Chamber; CUPA–HR; FMI; NAM; National Restaurant Association; Oregon Restaurant and Lodging Association; PPWO; Wisconsin Bankers Association. Some Members of Congress also opposed the proposed salary level and urged that the proposal be withdrawn. *See* 10 Republican Senators; 16 Republican Representatives; U.S. Senator Mike Braun (R–IN). Some commenters opposed to the proposal, writing separately or as part of comment campaigns, expressed general opposition to the rule but did not specifically address what, if any, salary level increase they would support in a final rule. *See, e.g.,* American Dental Association; Humane Society of Manatee County; National Sporting Goods Association. Others that opposed or questioned any salary level change stated, in the alternative, what method they preferred if the Department updated the salary level in the final rule. Most such commenters favored applying the methodology that the Department used to set the salary level in its 2004 and 2019 rulemakings (the 20th percentile of earnings of full-time salaried workers in the South and in the retail industry nationally) or updating for inflation the current salary level, which was set using that methodology. *See, e.g.,* ABC; CWC; NAM; National Restaurant Association. A handful of employer commenters supported, or stated that they did not oppose, an increase based on the 2004/2019 methodology (resulting in a salary level of $822 per week based on data used in the NPRM), citing, for example, that this approach promoted predictability, *see* RILA, and accounted for regional and industry-specific differences, *see* YMCA. *See also, e.g.,* SHRM; WFCA. Others supported or suggested a salary level that was higher, but below the Department's proposed level. *See, e.g.,* American Society of Association Executives; Ho-Chunk, Inc.; University System of Maryland.

Commenters that opposed the Department's proposal almost always objected to the size and/or timing of the proposed salary level increase rather than to the existence of the salary test itself. Most employer commenters, whether favoring no increase or a smaller increase, presumed the salary level test's continued existence and lawfulness, with some, such as National Restaurant Association, expressly referencing their support for the 2019 rule's salary level increase. As discussed in detail below, many commenters acknowledged the salary level's longstanding function of screening obviously nonexempt employees from the exemption. *See* section V.B.4.ii. Other commenters that opposed the proposal nonetheless cited benefits of having a salary level test, including helping to ensure that the EAP exemption is not abused, *see, e.g.,* AASA/AESA/ASBO, Bellevue University, and ''sav[ing] investigators and employers time by giving them a quick, short-hand test[.]'' *See* National Restaurant Association. APLU recognized ''DOL's mission and responsibility to update the Fair Labor Standards Act overtime regulations and ensure a baseline of protections for our nation's workers, including periodic updates to the minimum salary threshold for overtime exemptions.'' In rather stark contrast, AFPI asserted that employee ''[c]ompensation is no more helpful than would be a dress code test'' in determining exemption status. AFPI was one of only a small number of commenters, as previously discussed in section V.A.1, that asserted the Department lacks authority under section 13(a)(1) to adopt a salary level test. *See, e.g.,* Job Creators Network Foundation; NFIB; Pacific Legal Foundation.

As the Department stated in its 2019 rule, an employee's salary level ''is a helpful indicator of the capacity in which an employee is employed, especially among lower-paid employees.'' [183] The amount an employee is paid is also a ''valuable and easily applied index to the 'bona fide' character of employment for which exemption is claimed,'' as well as the principal ''delimiting requirement . . . prevent[ing] abuse'' of the exemption.[184] As the Department has explained, if an employee ''is of sufficient importance . . . to be classified'' as a bona fide executive employee, for example, and ''thereby exempt from the protection of the [A]ct, the best single test of the employer's good faith in attributing importance to the employee's services is the amount [it] pays for them.'' [185] Employee compensation is a relevant indicator of exemption status given that, as many commenters observed, the EAP exemption is premised on the understanding that individuals who are employed in a bona fide executive, administrative, or professional capacity typically earn higher salaries and enjoy other privileges to compensate them for their long hours of work, setting them apart from nonexempt employees entitled to overtime pay.[186]

[183] 84 FR 51239 (internal quotation marks omitted).

[184] Stein Report at 19, 24; *see also* 81 FR 32422.

[185] Stein Report at 19; *see also id.* at 26 (''[A] salary criterion constitutes the best and most easily applied test of the employer's good faith in claiming that the person whose exemption is desired is actually of such importance to the firm that he is properly describable as an employee employed in a bona fide administrative capacity.'').

[186] *See* Report of the Minimum Wage Study Commission, Vol. IV, at 236, 240; *see also, e.g.,* Stein Report at 19 (explaining that the ''term 'executive' implies a certain prestige, status, and importance'' denoted by pay ''substantially higher than'' the federal minimum wage).

Accordingly, the Department agrees with the overwhelming majority of commenters that, explicitly or implicitly, supported the salary level continuing to have a role in helping determine whether employees are employed in a bona fide executive, administrative, or professional capacity.[187]

The Department nonetheless recognizes that commenters had a wide range of views about the salary level test and that no salary level methodology can satisfy all stakeholders. As discussed below, competing commenter views were often grounded in differing opinions about the salary level test's role in defining the EAP exemption. Broadly speaking, commenters that opposed the proposal generally favored a far more limited role for the salary level test and emphasized perceived negative effects on employers of the proposed increase, while commenters that supported the proposal or urged the Department to set a higher salary level often deemed the proposal modest by historical standards and emphasized perceived positive effects on employees of the proposed increase. Against this backdrop, the Department has reviewed the comments received on its proposed methodology, with particular focus on feedback on the NPRM's rationale that the proposed methodology will better define and delimit the EAP exemption by fully restoring the salary level's screening function and accounting for the switch from a two-test to a one-test system.

ii. Fully Restoring the Salary Level's Screening Function

Some employer advocates that opposed the Department's proposal emphasized the salary level's limited function of screening obviously nonexempt employees from the EAP exemption. *See, e.g.,* Independent Community Bankers of America; IFDA; National Council of Farmer Cooperatives (NCFC); SHRM. Many employer representatives stated that the proposed salary level exceeded this purpose by excluding from the exemption too many employees who pass the duties test, particularly in low-wage regions and industries. *See, e.g.,* Chamber; NAW; PPWO; RILA; Seyfarth Shaw. AFPI quoted the statement in the Department's 2019 rule that any salary level increase must ''have as its primary objective the drawing of a line separating exempt from nonexempt'' employees, and the Chamber asserted that to the extent employee ''protection or fairness'' concerns motivated the proposed increase, such considerations exceed the Department's statutory authority.

Employer representatives that focused on the salary level's screening function often contrasted the Department's proposal with prior rules that they stated met this objective. CWC referenced the Department's 1958 and 2004 rules as such examples, while AHLA stated more broadly that the Department historically set a salary level that was ''intentionally low'' to screen out nonexempt employees, and that the Department's proposed methodology ''is objectively not the low end of the salary range as that has been understood since 2004[.]'' Other commenters similarly cited the 2004 and 2019 rules as fulfilling the salary level test's screening function, with National Restaurant Association, for example, emphasizing the salary level's screening function when explaining that the ''2004 methodology's chief virtue is its consistency with historical practice.'' *See also, e.g.,* Bellevue University. Some commenters, including NCFC and PPWO, stated that the proposed salary level would change the salary level from a ''screening device'' to a ''de facto sole test'' for exemption, while others cautioned that the salary level set in the 2016 rule was declared invalid for exceeding this screening function. *See also, e.g.,* Argentum & ASHA; NAM.

Though some employee representatives addressed the salary level's screening function, they generally emphasized other considerations that they believed justified setting a salary level equal to or higher than what the Department proposed. A number of commenters stated that, along with the duties test, the salary level ''is intended to set a guardrail so that employers do not incorrectly classify lower-paid salaried employees as'' exempt. *See, e.g.,* AFSCME; Family Values @ Work; North Carolina Justice Center; United Steelworkers; Yezbak Law Offices. Similarly alluding to the salary level's screening function, AFL–CIO emphasized that until 2019 the Department had never set the salary level below the long test level and that as a result more than half of the employees affected by the proposed salary level would have been nonexempt under every prior rule (because they earned below the long test or long test-equivalent salary level). EPI similarly stated that the 2019 rule set a salary level ''that was even lower than what the long-test methodology would have yielded.'' *See also* Coalition of State AGs (referencing the salary level's screening function).

The Department has considered commenter feedback about the salary level test's screening function. The Department agrees with all commenters that emphasized the salary level test's function of screening obviously nonexempt employees from the exemption, a principle that, as the Department observed in the 2019 rule and in the NPRM, ''has been at the heart of the Department's interpretation of the EAP exemption for over 75 years.'' [188] Fully effectuating the salary level's screening function is a key part of ensuring that the salary level sets an appropriate dividing line separating exempt and nonexempt employees. In response to the Chamber's concern about the motivations underlying the proposed salary level, the Department notes that while its proposal protects employees and promotes fairness (by helping ensure that only employees employed in a bona fide executive, administrative, or professional capacity are deprived of the FLSA's minimum wage and overtime protections), these beneficial effects are a byproduct of any higher salary level, not a basis for the proposed salary level.

As the Department explained in its NPRM, the concept of the salary level's screening function dates back to the two-test system, when the lower long test salary level provided ''a ready method of screening out the obviously nonexempt employees, making an analysis of duties in such cases unnecessary.'' [189] When the Department updated the long test in 1958, it reaffirmed the long test salary's function as a screening tool.[190] When the Department moved to a one-test system in 2004, the standard salary test had to perform the initial screening function that the long test salary level performed in the two-test system. In the 2004 rule, the Department reaffirmed its historical statements emphasizing the salary level's critical screening function and, most significantly, used the long test salary level methodology to validate its new salary level of $455 per week.[191] The Department stressed in its final rule that both the 2004 rule standard salary level methodology and the long test salary level methodology ''are capable of

[187] Consistent with its longstanding practice, the Department declines requests from commenters, including Defiance College, International Bancshares Corporation, Rachel Greszler, and WFCA, that suggested the Department adopt multiple salary level tests for different regions, industries, and/or small businesses, rather than a single salary level that applies to all entities nationwide. *See* 84 FR 51239; 81 FR 32411; 69 FR 22171.

[188] 88 FR 62165 (citing 84 FR 51241).

[189] Weiss Report at 8.

[190] Kantor Report at 2–3.

[191] 69 FR 22165–22166.

reaching exactly the same endpoint'' and demonstrated that the two methods, in fact, produced equivalent salary levels using contemporaneous data.[192] By setting a salary level equivalent to the long test level, the Department ensured that employees earning at levels that would have entitled them to overtime compensation under the two-test system because they earned below the long test salary level remained screened from the exemption by the new standard salary test, regardless of whether they met the less rigorous standard duties test. The Department rejected requests from commenters that supported a salary level that was $30 to $95 lower than the level the Department ultimately adopted,[193] thus maintaining the historic screening function by declining to set a salary level lower than the long test level.

In its 2019 rule, the Department reemphasized the salary level's screening function.[194] The Department distinguished the 2016 rule, which was invalidated because it '' 'untethered the salary level test from its historical justification' of '[s]etting a dividing line between nonexempt and potentially exempt employees' by screening out only those employees who, based on their compensation level, are unlikely to be bona fide executive, administrative, or professional employees.'' [195] In contrast, the Department explained, reapplying the 2004 methodology to contemporaneous data was likely to pass muster because the district court that invalidated the 2016 rule ''endorsed the Department's historical approach to setting the salary level'' and ''explained that setting 'the minimum salary level as a floor to screen[ ] out the obviously nonexempt employees' is 'consistent with Congress's intent.' '' [196]

In its NPRM, the Department explained that it needed to set a salary level at least equal to the long test—$925 per week, equating to between the 26th and 27th percentiles of weekly earnings of full-time salaried workers in the South—to fully restore the salary level's screening function. As noted above, employer commenters that emphasized the salary level's screening function generally viewed this function (which they often construed narrowly) as a justification for limiting the size of any potential salary increase. However, such commenters did not directly address the NPRM's explanation of the long test salary level's key role in the salary level's screening function or the relationship between the 2004/2019 methodology and the long test. Other commenters that endorsed the screening function as embodied in the 2004 rule did not grapple with the fact that in the 2019 rule, that methodology did not fully fulfill that function because it no longer arrived at the same endpoint as prior rules (*i.e.,* a long test or long-test equivalent salary level).

The Department's position remains that a core function of the salary level test is to screen from the EAP exemption employees who, based on their low pay, should receive the FLSA's overtime protections. For decades under the Department's two-test system, the long test salary level performed this screening function. In the 2004 rule, the Department used a different approach to reach the same outcome—setting a single salary level test that was equivalent to, and thus set the same line of demarcation as, the long test salary level. The Department deviated from this approach in 2019, setting a salary level that was $40 per week below the level produced using the long test methodology.[197] In doing so, the Department for the first time expanded the exemption to include employees who were paid below the equivalent of the long test salary level.

The Department reaffirms its position stated in the NPRM that the salary level test must equal at least the long test salary level in order to fulfill its historical screening function. From 1938 to 2019, all salaried white-collar employees paid below the long test salary level were entitled to the FLSA's protections, regardless of the duties they performed. This was true from 1938 to 1949 under the salary level test that became the long test; [198] from 1949 to 2004 under the long test; and from 2004 to 2019 under the standard salary level test that was set equivalent to the long test level—a key fact that commenters that opposed the Department's proposal generally did not address. Setting the salary level below the long test level as was done in the 2019 rule—because the 2004 methodology no longer matched the long test salary level based on contemporaneous data—departed from this history by enlarging the exemption to newly include employees who earned less than the long test salary level. As an initial step, the new salary level methodology must fully restore the salary level's screening function by ensuring that employees who were nonexempt because they earned less than the long test or long test-equivalent salary level are also nonexempt under the standard test. Achieving this objective requires a standard salary level amount at least equal to the long test level ($942 per week using current data, which equates to approximately the 25th percentile of full-time salaried worker earnings in the South).

As discussed in section V.B.5.iii, fully restoring the salary level's screening function would affect 1.8 million employees. These are currently exempt employees who earn between $684 (the current salary level) and $942 per week (the long test level calculated using current data) and would become nonexempt absent intervening action by their employers. In every rule prior to 2019, employees who earned below the long test or long-test equivalent salary level have always been excluded from the exemption based on their salary alone—even if they passed the standard duties test or (prior to 2004) the more rigorous long duties test. The Department's approach does not, as commenters asserted, create an impermissible ''de facto'' salary-only test or make nonexempt too many employees who pass the duties test, and is compatible with the district court decision's emphasis on the salary level test's historic screening function.[199]

iii. Accounting for the Shift to a One-Test System

In addition to fully restoring the salary level test's screening function, the Department's proposed salary level methodology also accounted for the shift from a two-test to a one-test system for determining who is employed in a bona fide executive, administrative, or professional capacity. Commenters that supported the proposed salary level and specifically addressed this rationale agreed with it. A group of Administrative Law Professors stated that the Department's move to a one-test system in 2004 ''significantly expanded the number of relatively low-income

[192] *See id.* at 22167–71 (showing that for all full-time salaried employees, $455 in weekly earnings corresponded to just over the 20th percentile in the South and the 20th percentile in retail, and that for employees performing EAP duties, $455 in weekly earnings corresponded to just over the 8th percentile in the South and the 10th percentile in retail). AFPI commented that in the 2003 NPRM the Department ''acknowledged that 'equivalency to either the current long or short test salary levels is not appropriate' *because of* the switch to a one-test system.'' (quoting 68 FR 15560, 11570 (Mar. 31, 2003)). However, the Department shifted in its final rule and validated its chosen methodology using the long test salary level.

[193] *See* 69 FR 22164.

[194] 84 FR 51237.

[195] *Id.* at 51231 (quoting 84 FR 10901).

[196] *Id.* at 51241 (quoting 275 F. Supp.3d at 806).

[197] *Id.* at 51244.

[198] During this period the Department used a one-test system that paired a lower salary level with a more rigorous duties test. *See, e.g.,* 5 FR 4077.

[199] The district court was principally concerned with the 2016 rule exceeding the salary level's screening function and making too many employees nonexempt based on salary alone. *See Nevada* 275 F.Supp.3d at 806 & n.6.

workers who might fall within the exemption . . . despite engaging in substantial nonexempt work[,]'' and concluded that the Department's proposal was ''reasonably geared'' to restoring nonexempt status to this class of workers. The Coalition of State AGs similarly stated that the proposal ''does more to take into account the shift to a one-test system in 2004 and establishes more of a middle ground between . . . the previous short- and long-test methodologies.'' They elaborated that ''the balance struck is a more appropriate one'' because most salaried white-collar employees paid less than the proposed standard salary level do not meet the duties test, whereas a substantial majority of salaried white-collar employees earning above the proposed standard salary level meet the duties test. Some commenters asserted that this aspect of the Department's rationale supported setting a salary level higher than proposed. For example, AFL–CIO stated that the proposed salary level captures only ''a portion of workers who have been wrongly excluded from nonexempt status since the 2004 elimination of the long and short test in favor of a single test,'' and Sanford Heisler Sharp stated that the proposal ''does not go far enough towards meeting [the] goal'' of '''ensur[ing] that fewer white-collar employees who perform significant amounts of nonexempt work and earn between the long and short test salary levels are included in the exemption.' '' [200] NELA similarly urged the Department to adopt its 2016 methodology to more fully account for the shift to a one-test system.

Employer commenters that directly addressed the shift to a one-test system generally rejected the premise that any adjustment for this change was warranted or appropriate. Some commenters emphasized that the long test's limit on nonexempt work became inoperative in 1991 and/or that the Department fully accounted for the move to the standard duties test in its 2004 rule. *See* Bellevue University; Chamber; NAM; RILA. The National Association of Convenience Stores, which likewise emphasized that the short and long tests have not existed since 2004, stated that to ''the extent the two-test system still has any limited relevancy to the current inquiry, it is that the salary level should be closer to what the pre-2004 long test would have produced'' rather than ''to what the pre-2004 'short' test would have produced'' today. AFPI asserted that ''[a]ny salary level that excludes employees who are not 'obviously nonexempt' is invalid[,]'' that the long test salary level is a ''made-up concept[,]'' and that the '' 'long test' and the 'short test' are terms [that have not been] considered since the Department's regulatory changes in 2004 . . . [and] should have no place in determining an appropriate increase to the minimum salary level for exemption today.'' [201]

The Department agrees with commenters that supported the NPRM's objective of updating the salary level in part to account for the move to a one-test system. As previously explained in detail in the NPRM and in section V.B.3 of this preamble, the Department traditionally considered employees earning between the long and short test salary levels to be employed in a bona fide EAP capacity only if they were not performing substantial amounts of nonexempt work. With the adoption of a duties test based on the less rigorous short duties test, the shift to a single-test system significantly decreased the examination of the amount of nonexempt work employees performed. Following this shift, the Department has taken two approaches to setting the salary level to pair with the standard duties test. The approach taken in the 2004 rule permitted the exemption of all employees earning above the long test salary level who met the standard duties test—including many employees who performed substantial amounts of nonexempt work and traditionally were protected by the long duties test. The approach taken in the 2016 rule was challenged and criticized as making employees earning between the long test salary level and the low end of the short test salary range nonexempt—including employees who performed very little nonexempt work and would have been exempt under the long duties test.

The Department recognizes that a single-test system cannot fully replicate both the two-test system's heightened protection for employees performing substantial amounts of nonexempt work and its increased efficiency for determining exemption status for employees who are highly likely to perform EAP duties. Inevitably, any attempt to pair a single salary level with the current duties test will result in some employees who perform substantial amounts of nonexempt work being exempt, and some employees who perform almost exclusively exempt work being nonexempt.[202] But such a result is inherent in setting any salary level. The Department continues to believe that it can better identify which employees are employed in a bona fide EAP capacity by, in combination with the current duties test, using a salary level methodology that accounts for the shift to a one-test system, and that doing so will both restore overtime eligibility for many individuals who perform substantial amounts of nonexempt work and historically would have been protected by the long duties test, and address potential concerns that the salary level test should not be determinative of exemption status for too many individuals. Such a salary level will also more reasonably distribute between employees and their employers what the Department now understands to be the impact of the shift to a one-test system on employees earning between the long and short test salary levels.

The Department disagrees with commenters that disputed this aspect of the NPRM based on their view that the only valid salary level function is to screen from exemption obviously nonexempt employees. Section 13(a)(1)'s broad grant of statutory authority for the Department to define and delimit the EAP exemption provides the Department a degree of latitude in determining an appropriate salary level for identifying individuals who are employed in a bona fide EAP capacity. As discussed in section V.B.3, for decades, the short test salary level did not perform a screening function, but rather was used to determine whether the full duties test or the short-cut duties test would be applied to determine EAP exemption status. In a one-test system, the Department can change the duties test, the salary level, or both, to ensure that the test for exemption appropriately distinguishes bona fide EAP employees from nonexempt workers. As discussed at length in the NPRM,[203] while acknowledging that it could lessen the salary level test's role by returning to a duties test that explicitly limited the amount of nonexempt work that could be performed, the Department ultimately declined to propose changes

[200] Quoting 88 FR at 62158.

[201] NRF included an Oxford Economics report that questioned the Department's long test figure ($925 per week), and, observing that the long test methodology varied over time, stated that a ''more reasonable'' approach for replicating the long test would be to adjust the 1975 long test level for inflation (which it concluded would result in a salary level of $843 per week in 2022 dollars).

[202] *See* Stein Report at 6 (''In some instances the rate selected will inevitably deny exemption to a few employees who might not unreasonably be exempted, but, conversely, in other instances it will undoubtedly permit the exemption of some persons who should properly be entitled to benefits of the act.'').

[203] 88 FR 62164–65. Although some commenters addressed changes to the duties test, *see, e.g.,* AFL–CIO, AHLA, NELA, FMI, such changes are beyond the scope of the current rulemaking.

to the duties test in this rulemaking. Given that decision, it is appropriate for the Department to choose to better define the EAP exemption by accounting for the shift to a one-test system, and to select a salary level methodology that excludes from exemption some employees who historically were nonexempt because of the more rigorous long duties test. The 2004 and 2019 rules' significant broadening of the statutory exemption (a fact employer commenters generally did not address) to permit all salaried employees earning between the long and short tests who passed the standard duties test to be exempt was not unlawful, but it leaves room for refinement. Section 13(a)(1) does not require the Department to forever maintain the regulatory choice it made 20 years ago to pair the current duties test with a salary level that places the entire burden of the move to a one-test system on employees who historically were entitled to the FLSA's overtime protection because they performed substantial amounts of nonexempt work and earned between the long and short test salary levels.

The Department continues to believe that the long and short tests provide useful parameters for determining the new salary level test methodology in this rulemaking. The Department disagrees with AFPI that variations in the long test methodology render it a ''made-up concept'' or that the long and short tests have ''no place'' in determining the new salary level. The long test salary level has played a crucial role in defining the EAP exemption for the better part of a century, either directly under the two-test system or indirectly under the one-test system. As the Department explained in detail in its 2004 rule, the long test salary level ''regulatory history reveals a common methodology used, with some variations, to determine appropriate salary levels[,]'' and (with the exception of the 1975 rule) beginning in 1958 ''the Department set the [long test] salary levels to exclude approximately the lowest-paid 10 percent of exempt salaried employees'' in low-wage areas and industries.[204] The Department ''[u]se[d] this regulatory history as guidance'' in its 2003 NPRM and, most importantly, validated its chosen methodology in the 2004 rule by showing that it produced the same salary level as the long test methodology—a critical fact employer representatives generally did not address in their comments.[205] While the Department agrees with AFPI and the Oxford Economics report that the data set used to set the long test salary level was not exactly the same in each regulatory update, just as in 2004, minor historical variations do not deprive the long test of its usefulness in helping determine an appropriate salary level now. The Oxford Economics report's suggestion to calculate the long test by updating the 1975 long test salary level for inflation would not faithfully replicate the long test because it would produce a salary level below the 10th percentile of exempt workers in low-wage regions and industries and would conflict with the Department's historical practice of avoiding the use of inflation indicators in updating the salary level.[206]

The Department also disagrees with commenters who asserted that no adjustment is needed to account for the shift to a one-test system because the long test became largely dormant in 1991. In the 2004 rule, the Department acknowledged this dormancy resulting from its outdated salary levels and asserted that employees who were then subject to the long test would be better protected under the higher salary level of the new standard test.[207] But as previously explained, section V.B.3, in the 2004 rule the Department did not compare the overtime protection lower-salaried employees would receive under the standard test with the protection they would have received had the Department updated the long test with a salary level based on contemporaneous data and kept the existing long duties test. Instead, the Department's discussion of the elimination of the long duties test in the 2004 rule focused primarily on the minimal role played by the long test at that time due to the erosion of the long salary level, and on the difficulties employers would face if they were again required to track time spent on nonexempt work when the dormancy of the long duties test meant that they had generally not been performing such tracking for many years.[208]

The Department also disagrees with commenters that asserted that the 2004 rule fully accounted for the move to the standard duties test. Because the 2004 rule did not fully account for the lessened overtime protection for employees who would have been nonexempt under an updated long test (as just described), it created a group of employees with lessened protection under the standard test—those who earned between the long and short test salary levels. These employees were traditionally nonexempt because they failed the long duties test, but were exempt under the 2004 rule because they passed the more lenient standard duties test.[209] By setting the standard salary level equivalent to the long test salary, the 2004 rule in effect created a group of employees who bore the impact of the change from the two-test to the one-test system.

iv. Selecting the Salary Level Methodology

In its NPRM, the Department explained that fully restoring the salary level's screening function and accounting for the move to a one-test system supported setting the salary level at the 35th percentile of full-time salaried worker earnings in the lowest-wage Census Region (the South)—resulting in a proposed salary level of $1,059 per week. Commenters provided competing views on this proposed increase. Employers and employer representatives that opposed the proposed salary level often characterized it as ''too much, too soon''—stating that an increase of 54.8 percent (or 69.3 percent, based on the $60,209 projected salary level figure included in footnote 3 of the NPRM) [210] less than 4 years after the most recent increase was unnecessary and unprecedented. *See, e.g.,* Air Conditioning Contractors of America; Americans for Prosperity; Joint Comment from Argentum and American Seniors Housing Association; CUPA–HR; International Sign Association; NRF. Some commenters, including American Association of Community Colleges and Associated Builders and Contractors, observed that, by contrast, prior salary level updates have ranged from 5 to 50 percent, and others commented that the proposed increase greatly exceeded the rate of inflation since the 2019 rule, *see* Independent Community Bankers of America, Ohio

[204] 69 FR 22166.

[205] *See id.* at 22166–70; *see also* section V.B.3.

[206] *See, e.g.,* 84 FR 51245; 69 FR 22167.

[207] *See* 69 FR 22126.

[208] *See id.* at 22126–27.

[209] The Chamber asserted that the Department's decision to adjust the salary level to account for the shift to a one-test system ''fails to appreciate the continued importance of the 'primary duty' principles, the application of which includes an analysis of non-exempt work performed and its relation to the employee's exempt work.'' Although the Chamber is correct that the standard duties test accounts for nonexempt work, it does so in a less rigorous manner than the long duties test, resulting in some lower-paid white-collar employees who pass the standard duties test but (due to their nonexempt work) would have failed the long duties test.

[210] Several commenters criticized the Department for providing projected salary level figures in footnote 3. *See, e.g.,* PPWO; NRF. NAM stated that footnote 3 was ''inconsistent'' with the Administrative Procedure Act.

Township Association. Many employer organizations asserted that the Department was trying to resurrect a methodology akin to the invalidated 2016 rule and that, like that rule, the proposed salary level (which many stressed is a higher dollar figure than the level set in the 2016 rule) would unlawfully supplant the duties test. *See, e.g.,* Americans for Prosperity; National Restaurant Association; PPWO.

Commenters that opposed the proposed salary level were particularly concerned about the impact of this change on specific industries and on businesses in low-wage regions. Some commenters, such as the American Outdoors Association, CUPA–HR, NAHB, and SHRM, provided information from internal surveys to support how the proposal would negatively affect their members. SBA Advocacy similarly summarized concerns received from small businesses. *See also, e.g.,* NFIB. Some commenters emphasized the proposal's impact on particular occupations in their industries, including first-line supervisors, *see, e.g.,* AHLA, NAHB, and entry-level managers, *see, e.g.,* NAM, NRF. Emphasizing the proposed salary level's geographic impact, National Restaurant Association and PPWO warned that the proposal would exclude from exemption a high percentage of employees who pass the duties test in lower-wage regions, and could result in employees in the same job classification being treated differently based on where they live. A number of educational institutions opposed the proposed increase due to cost-related concerns specific to the educational sector. *See, e.g.,* American Association of Community Colleges; Association of Independent Colleges and Universities of Ohio; National Association of Independent Colleges and Universities. The National Association of Counties raised similar concerns about the impact of the increased salary level on local governments. Nonprofit sector feedback was more mixed, with the National Council of Nonprofits characterizing the industry response as one of ''moral support'' and ''operational anxiety.'' Some nonprofit organizations opposed the proposal, *see, e.g.,* Children's Alliance of Kentucky, U.S. Public Interest Research Group (U.S. PIRG), some supported it, *see, e.g.,* CLASP, Justice at Work, and some agreed with the Department's intent but raised cost and other concerns, *see, e.g.,* Catholic Charities, Open Roads Bike Program.

Commenters had different suggestions for how the Department should account for such regional and industry-specific differences. For example, RILA urged the Department to include the retail industry in its data set, AFPI suggested setting the salary level equal to the 20th percentile of non-hourly employee earnings in the ten lowest-wage states, and Seyfarth Shaw recommended using the East South Central Census Division. The Chamber asked the Department to focus on data from the lowest-wage types of entities (such as small businesses, small nonprofits or small public employers), in the lowest-wage industries, in rural areas, in the lowest-wage Census Region. The Chamber and National Association of Convenience Stores favored excluding nonexempt workers from the data set (and using a lower earnings percentile) and questioned the Department's use of Current Population Survey (CPS) Merged Outgoing Rotation Group (MORG) data for nonhourly earnings for full-time workers as a proxy for salaried worker earnings.

Commenters that supported increasing the salary level viewed the Department's proposal very differently than employer representatives. Whereas many employer representatives focused on specific regions or industries to assert that the proposed salary level was too high, supportive commenters focused on the national impact to assert that the salary level was appropriate or too low. Many supportive commenters considered it ''modest.'' *See, e.g.,* AFSCME; CLASP; Family Caregiving Coalition; National Partnership. Others stated that the salary level ''could have reasonably been significantly higher and still within historical precedent.'' *See, e.g.,* Common Good Iowa; Jobs to Move America; Louisiana Budget Project; Maine Center for Economic Policy; North Carolina Justice Center. The statistic most often cited to support that the proposal was conservative by historical standards was that whereas 62.8 percent of full-time salaried workers earned less than the short test salary level in 1975, 28.2 percent of full-time salaried workers earned less than the proposed standard salary level (and several of these commenters noted that only approximately 9 percent earned less than the current salary level). *See, e.g.,* EPI; National Center for Law and Economic Justice; Worker Justice Center of New York; Workplace Justice Project. AFL–CIO and others highlighted that the proposed salary level was 19 percent lower than the inflation-adjusted value of the 1975 short test salary level, and EPI stated that, on average, the proposed salary level was 16 percent lower than inflation-adjusted short test salary levels set from 1949 and 1975. Some supportive commenters stressed that a significant salary level increase was needed in part to account for the 2004 rule's elimination of the long duties test, *see, e.g.,* EPI, NELP, while NWLC stated that the proposed methodology would ''not eclipse the role of the duties test'' and instead would ''restore[] a reasonable balance between the strength of the duties test and the height of the salary threshold.''

Some commenters advocated for a much higher salary level than the Department proposed, and a number of commenters specifically proposed alternate methodologies for the Department to adopt in the final rule. For example, NELA stated that the proposed level was ''too low from a historical perspective'' and, favoring ''[b]older federal action[,]'' asked the Department to (like in the 2016 rule) set the salary level equal to the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (which would produce a salary level of $1,196 per week based on the data used in this final rule). Winebrake & Santillo similarly favored a return to that methodology. AFL–CIO supported setting the salary level higher—at the historical average short test salary level (which would result in a salary level of $1,404 per week based on current data). Other commenters sought a salary level that they stated would exclude from exemption the same proportion of full-time salaried workers as under the 1975 salary level test. For example, Demos urged the Department to set the salary level at the 55th percentile of weekly earnings of full-time salaried workers nationwide to meet this ''high-water'' mark, and Nick Hanauer supported a salary level of at least $83,000 to ''restore the overtime threshold'' to a time ''when the American middle class was strongest[.]'' Commenters that sought a higher salary level than the Department proposed often expressed their disagreement with the district court's decision invalidating the 2016 rule. *See, e.g.,* NELA; Sanford Heisler Sharp; Winebrake & Santillo.

After considering the comments received, the Department is finalizing the salary level methodology as proposed, setting it equal to the 35th percentile of full-time salaried worker earnings in the lowest-wage Census Region (the South)—which produces a salary level of $1,128 per week using calendar year 2023 data. Consistent with the Department's responsibility to ''not only . . . determin[e] which employees are entitled to the exemption, but also [to] draw[] the line beyond which the

exemption is not applicable[,]'' [211] this salary level will, in combination with the standard duties test, effectively calibrate the scope of the exemption for bona fide EAP employees and do so in a way that distributes across the population of white-collar employees earning between the long and short test salary levels the impact of the shift to a one-test system. As previously discussed, updating the salary level for wage growth since the 2019 rule produces a salary level of $844 per week, and fully restoring the salary level's historic screening function would result in a salary level of $942 per week, equivalent to the 25th percentile of full-time salaried worker earning in the South (*i.e.,* the long test level). Accordingly, the increase from the 25th percentile to the 35th percentile is to account for the shift to a one-test system.[212] The Department set the standard salary level at (or below) the long test level in the 2004 and 2019 rules and set it at the low end of the historic range of short test salary levels in the 2016 rule. Setting the salary level at either the long test salary level or equivalent to a short test salary level in a one-test system with the standard duties test, however, results in either denying overtime protection to lower-paid employees who are performing large amounts of nonexempt work, and thus, would have been exempt under the Department's historical view of the EAP exemption, or in raising concerns that the salary level is determining the exemption status of too many employees. In contrast, an appropriately calibrated salary level between the long and short test salary levels better defines and delimits which employees are employed in a bona fide EAP capacity, and thus better fulfills the Department's duty to define and delimit the EAP exemption.

The Department's methodology established in this final rule uses the second-to-lowest of the earnings ventiles between the long test salary level (the 25th percentile of full-time salaried worker earnings in the lowest-wage Census Region) and the short test salary level (approximately the 51stth percentile of this data set). These ventiles are the 30th, 35th, 40th, 45th, and 50th percentiles of full-time salaried worker earnings in the lowest-wage Census Region. The Department continues to believe that its methodology produces a salary level high enough above the long test salary level to ensure overtime protection for some lower-paid employees who were traditionally entitled to overtime compensation under the two-test system by virtue of their performing large amounts of nonexempt work, and also low enough, as compared with higher salary levels, to significantly shrink the group of employees performing EAP duties who are excluded from the exemption by virtue of their salary alone. Whereas the 2004 and 2019 rules permitted the exemption of employees earning between the long and short test salary levels even if they performed significant amounts of nonexempt work, and the 2016 rule prevented employers from using the exemption for such employees earning below the short test salary range even if they performed EAP duties, the methodology adopted in this final rule falls between these two methodologies and thus, as commenters including the Administrative Law Professors and Coalition of State AGs agreed, reasonably balances the effect of the switch to a one-test system in a way that better differentiates between those who are and are not employed in a bona fide EAP capacity. Of the 10.8 million salaried white-collar employees earning between the equivalent of the long and short test salary levels, approximately 40 percent earn between $942 (the equivalent of the long test salary level) and $1,128 (the new salary level) and would receive overtime protection by virtue of their salary, while approximately 60 percent earn between $1,128 and $1,404 (the equivalent of the short test salary level) and would have their exemption status turn on whether they meet the duties test. These and other statistics, discussed in section V.B.5.iii, demonstrate that the salary level will not ''essentially eliminate[ ] the role of the duties test'' as National Restaurant Association and others contended. *See also, e.g.,* AHLA; CWC.

Even though the Department's decision to select a salary level below the midpoint between the long and short tests means that the effect of the salary level on employees earning within this range and their employers is not exactly equal, a higher salary level could disrupt the reliance interests of employers who (due in part to the Department's failure to update the salary level tests between 1975 and 2004), have been able to use a lower salary level and more lenient duties test to determine exemption status since 1991. However, a significantly lower salary level akin to the long test salary level would avoid disrupting such reliance interests only by continuing to place the burden of the move to a one-test system entirely on employees who historically were entitled to the FLSA's overtime protections because they perform substantial amounts of nonexempt work. The Department believes that employer reliance interests should inform where the salary level is set between the long and short test levels, and that its approach appropriately balances the impact of the move to a one-test system between employees' right to receive overtime compensation and employers' ability to use the exemption. Such balancing is fully in line with the Department's authority under the FLSA to ''mak[e] certain by specific definition and delimitation'' the ''general phrases'' ''bona fide executive, administrative, or professional capacity.'' [213] This grant of authority confers discretion upon the Department to determine the boundaries of these general categories; any such line-drawing, as courts have recognized, will ''necessarily'' leave out some employees ''who might fall within'' these categories.[214]

The Department recognizes the tension between the methodology adopted in this final rule and some statements made in its 2016 and 2019 rules. The Department stated in its 2016 rule that the current duties test could not be effectively paired with a salary level below the short test salary range, and for this reason expressly rejected setting the salary level at the 35th percentile of weekly earnings of full-time salaried workers in the South.[215] But that rule, which would have prevented employers from using the EAP exemption for some employees who were considered exempt under the prior two-test system, was challenged in court, and a return to it would result in significant legal uncertainty for both workers and the regulated community. In the 2019 rule, the Department expressly rejected setting the salary level equal to the long test or higher.[216] However, as noted above, the Department did not fully address in that rule the implications of the switch from a two-test to a single-test system. Having now grappled with those implications, the Department concludes that not only can it pair the current duties test with a salary between the long and short test salary levels, but that doing so

[211] Stein Report at 2.

[212] AFPI mistakenly asserts that the increase from the 20th percentile to the 35th percentile ''is based entirely on the switch to a one-test system in 2004.'' The majority of the salary level increase (from $684 to $942) is to update the salary level for wage growth and fully restore the salary level's historic screening function, with less than half (the increase from the $942 to $1,128) made to account for the shift from the two-test system.

[213] *See Walling,* 140 F.2d at 831–32.

[214] *Id.* at 832.

[215] 81 FR 32410.

[216] *See* 84 FR 51244.

appropriately recalibrates the salary level in a one-test system to ensure that it effectively identifies bona fide EAP employees.

In setting the salary level, the Department continues to believe that it is important to use a methodology that is transparent and easily understood. As in its prior rulemakings, the Department is setting the salary level using earnings data from a lower-salary regional data set (as opposed to nationwide data) to accommodate businesses for which salaries generally are lower due to geographic or industry-specific reasons.[217] Specifically, the Department is setting the salary level using the data set of full-time nonhourly [218] workers in the lowest-wage Census Region (the South). This approach promotes transparency because BLS routinely compiles this data. It also promotes regulatory simplification because the data set is not limited to exempt EAP employees and thus does not require the Department to model which employees pass the duties test.[219] In keeping with the Department's past practice, it is relying on up-to-date data to determine the salary level.[220] In the NPRM, the Department used 2022 salary data for estimating the salary level resulting from the proposed methodology, which was current at the time the Department developed its proposal. In this final rule, the Department is relying on calendar year 2023 salary data, as published by BLS, to set the salary level.[221]

Given the strong views expressed by commenters, including those opposing the proposal or favoring a higher salary level, the Department did not arrive lightly at its decision to finalize the salary level methodology as proposed. Commenter feedback often reflected competing vantage points for assessing the Department's proposal. Commenters that supported the Department's proposal or a higher salary level (most often, the 2016 rule methodology) often compared the proposed salary to short test salary levels, while commenters that opposed the proposed increase often stressed the size of the change from the current salary level. The Department agrees with supportive commenters that past salary levels should inform the current update, and agrees that statistics such as the percentage of salaried white-collar workers who earn below the salary level or statistics comparing the new salary level to inflation-adjusted prior levels, reinforce the reasonableness of the Department's approach. However, the Department is wary of comments urging a return to the 2016 rule methodology that do not account for subsequent court decisions and the Department's 2019 rulemaking. The Department also recognizes concerns from some commenters about the size of the salary level increase. But this metric is influenced by many factors and thus does not, in and of itself, establish whether a salary level sets an appropriate dividing line for determining whether an employee is employed in a bona fide EAP capacity. For example, the size of the current increase is influenced by factors including significant wage growth since the 2019 rule (simply adjusting the current salary level methodology for wage growth would result in a roughly 23 percent increase); the Department for the first time updating a salary level that was set below the long test; and the Department adjusting the salary level to account for the move to a one-test system. While the 65 percent increase is greater in percentage terms than most prior updates, the Department does not consider this factor dispositive.[222]

The salary level methodology adopted in this final rule ($1,128 per week; $58,656 annually) produces a salary level that is lower than the two salary level estimates provided in footnote 3 of the NPRM ($59,284 and $60,209), which were based on a quarter of data. The Department disagrees with commenters that criticized the Department for providing projected salary level figures in its NPRM. These comments overlook that the NPRM proposed a methodology for updating the salary level test, not just a salary level figure. Providing commenters an estimate of the salary level that the proposed methodology could produce in a final rule based on updated data promoted rulemaking transparency and the opportunity for fully informed commenter feedback. That many commenters used the figures in footnote 3 in their comments, and the final salary level based on calendar year 2023 data is between the proposed salary level and the two estimates in the footnote, reinforces that footnote 3 in no way deprived commenters of the opportunity to meaningfully comment on the NPRM.

As previously discussed, most employer commenters that opposed the proposed salary level opposed any increase or at most supported a return to the 2004/2019 methodology, and so they did not address the NPRM's analysis examining where to set the salary level between the long and short test salary levels. The Department does not find these comments persuasive because they in effect sought a salary level below the long test level, which would not even fully restore the salary level's screening function, let alone account at all for the move to a one-test system. As for commenter concerns about the salary level's impact on low-wage regions and industries, the Department accounts for these concerns by setting the salary level using the lowest-wage Census Region. This aspect of the rulemaking differs from the 2016 rulemaking, where the Department proposed to set the salary level using a national data set and then, in response to commenters concerns, shifted to the lowest-wage Census Region in the final rule to account for low-wage regions and industries.[223] The Department used this past experience to account for the impact on low-wage regions and industries in developing the NPRM and, having done so, is again basing the salary level on the earnings of workers in the lowest-wage Census Region in this final rule.

The Department declines requests from some commenters to change the data set it used to set the salary level. Some asked the Department to add earnings data from a specific industry to the CPS earnings data. The Department is not altering the data set in this way because it believes that using earnings data from the lowest-wage Census Region produces a salary level that accounts for differences across industries and regional labor markets. The Department also is not altering the Census region data set so that it excludes all states with higher earnings, nor is the Department creating a new data set that includes only States with the lowest earnings. The Department's chosen approach is consistent with its practice since the 2004 rule of using the South, rather than a narrower geographic region, when setting the salary level. Restricting the data set to the ten lowest-wage states or to the East South Central Region (made up of just four states, Alabama, Kentucky, Mississippi, and Tennessee) would give undue weight to low-wage areas and

[217] *See id.* at 51238; 81 FR 32404.

[218] Consistent with recent rulemakings and the NPRM, *see* 88 FR 62188, 84 FR 51258, in determining earnings percentiles the Department looked at nonhourly earnings for full-time workers from the CPS MORG data collected by BLS.

[219] As discussed in the economic analysis, *see* section VII, this modeling is done using the Department's probability codes. *See* 84 FR 51244; 69 FR 22167.

[220] *See* 84 FR 51245; 81 FR 32405; 69 FR 22168.

[221] BLS currently publishes this data at *https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.*

[222] As discussed in section IV, in part to provide employers more time to adjust, the new methodology will not be applicable until January 1, 2025.

[223] *See* 81 FR 32408.

skew the salary level. The Chamber's suggestion to restrict the data set even further (by focusing on low-wage entities within low-wage industries within rural areas within the South) would even further compound this concern.

The purpose of the data set is not simply to produce the lowest possible salary level. The Department's approach directly accounts for low-wage areas while producing a salary level that is appropriate to apply nationwide. The Department also declines requests to limit its data set to exempt workers, instead continuing to set the salary level using earnings data for exempt and nonexempt workers—as it has done in every one of its rulemakings under the one-test system. As explained in the 2004 rule, the Department's chosen approach is preferable in part because restricting the data set to exempt employees requires ''uncertain assumptions regarding which employees are actually exempt[.]'' [224] The Department is also continuing to use data on nonhourly worker earnings as a proxy for compensation paid to salaried workers. Although some commenters challenged this approach, the Department is not aware of, and commenters did not provide, any statistically robust data source that more closely reflects salary as defined in the Department's regulations. Also, as discussed in section VII, the Department believes that relatively few nonhourly workers were paid by methods other than salaried.

In response to commenter opposition to the proposed salary level and the concerns described above, the Department considered setting the salary level equal to the 30th percentile of earnings of full-time salaried workers in the lowest-wage Census Region. The Department ultimately decided not to adopt this approach, however, because it would less effectively account for the shift to a one-test system. This methodology would set the salary level based on the lowest earnings ventile between the short and long test salary levels and produce a salary level that is only $77 above the long test level. As a result, for the population of white-collar workers earning between the long and short tests, only 18 percent would earn below the salary level (whereas 40 percent of this population earn below the new salary level). This approach thus would not sufficiently address the problem inherent in the 2004 methodology of including in the exemption employees who perform significant amounts of nonexempt work, including those earning salaries close to the long test salary level—where the Department would expect a higher proportion of workers to perform more nonexempt work.[225] In contrast, the Department's approach addresses these concerns in a manner that more reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move to a one-test system.

The Department disagrees with commenters that stated that the chosen methodology simply resurrects the 2016 methodology—which set the salary level equal to the 40th percentile of full-time salaried worker earnings in the lowest-wage Census Region. The fact that the new salary level is higher in nominal dollars than the level set in the 2016 rule ($913 per week) is irrelevant because that level was calculated using 2015 data.[226] Applying the 2016 methodology to current data produces a salary level of $1,196 per week. Whereas under this rule an employee's salary level will be determinative of exemption status for 40 percent of the 10.8 million employees earning between the long and short test levels, under the 2016 methodology salary would be determinative for 55 percent of such employees. A salary level equivalent to the 40th percentile in the South would also result in 5.0 million affected workers. Although some of these workers earn below the long test level and would be nonexempt under either approach, this alternative approach would result in 949,000 more affected workers than the Department's chosen methodology. The Department's decision to deviate from the 2016 methodology is significant, as underscored by the fact that (as discussed in more detail below) a number of employee representatives urged the Department to adopt that methodology or a higher percentile.

The Department recognizes that many commenters found the proposed methodology conservative, or overly conservative, with some commenters urging the Department to select a methodology that produces a higher salary level. Repeating the 2016 rule methodology, as some commenters requested, by setting the salary level at the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region would further reduce the impact of the move to a one-test system on lower-paid white-collar employees who perform significant amounts of nonexempt work. As discussed above, commenters that supported the 2016 rule methodology provided statistics demonstrating that this approach yields a salary level within historical norms. The 40th percentile would produce a salary level ($1,196 per week) that is above the midpoint between the long and short test salary levels. As noted above, of the approximately 10.8 million salaried white-collar employees who earn between the long and short test salary levels, approximately 55 percent earn between the long test salary level and $1,196 and would receive overtime protection by virtue of their salary, while approximately 45 percent earn between $1,196 and the short test salary level and would have their exemption status turn on whether they meet the duties test.

The Department believes this rule appropriately distributes the burden of the change from a two-test to one-test system between employees and employers. By contrast, the Department remains concerned that courts could find that adopting the 2016 rule methodology would make the salary level test determinative of overtime eligibility for too many employees. Setting the salary level equal to a higher percentile of weekly earnings (such as the 55th percentile as Demos recommended), would further amplify this concern. Setting the salary level based on a lower percentile of earnings will (compared to such higher levels) increase the number of employees for whom duties is determinative of exemption status, and in turn increase the ability of employers to use the exemption for more lower-paid employees who meet the EAP duties requirements. This outcome is consistent with the important role of the duties test in identifying bona fide EAP employees. EPI did not find the number of workers affected by a salary level increase to be an informative metric for assessing whether a threshold is appropriate and the Department agrees that this statistic has significant limitations. In particular, it is notable that although the standard salary level changes will result in 4.0 million affected workers (1.0 million from the initial update and 3.0 million from applying the new standard salary

[224] 69 FR 22167.

[225] The Department has repeatedly recognized that increasing salary level tends to correlate with the performance of bona fide EAP duties. *See* section V.B.1 (discussing role of long test and short test salary levels); section V.C (discussing the role of the HCE total annual compensation threshold). Thus, increasing overtime protection specifically for workers earning at the lower end of the range between the long test salary level and short test salary level—but not those earning at the higher end of that range—is an especially appropriate approach to balancing these concerns.

[226] *See* 81 FR 32393.

level),[227] only 2.2 million of these workers are due to the increase from the long test to the new methodology, while 1.8 million affected workers (or 45 percent) are a result of restoring the historic screening function of the long test salary level. By comparison, updating the salary level using the 2016 methodology and current data would result in 5.0 million affected workers. Although the number of affected workers for this rule is above the number of affected workers in the 2019 rule, the difference is necessary to fully restore the salary level's screening function and account for the shift to a one-test system, and the overall impact of this change on the workforce is relatively small (*see* section V.B), such that the new salary level is a proper exercise of the Department's authority to define and delimit the scope of the EAP exemption.

In declining to adopt the 2016 rule methodology, the Department is also responding to concerns that setting the salary level equal to the 40th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region would foreclose employers from exempting any white-collar employees who earn less than that amount ($1,196 per week based on the data used in this final rule) and perform EAP duties, including those who were exempt under the long test and remained exempt when the Department established the one-test system in 2004 and set the salary level equivalent to the long test level.[228] Litigants challenging the 2016 rule emphasized this consequence of setting a salary level above the long test in a one-test system, and those arguments have contributed to the Department more fully attempting to account for the impact of the shift to a one-test system. Although some commenters favored a salary level equivalent to the short test level, such an approach would result in employers being unable to use the exemption for any employees who earn between the long and short test and have previously been exempt, either under the long test, or under the standard test set equal to the long test. In contrast, the methodology in this final rule produces a salary level that is not only below any short test level, but also lower than the midpoint between the long and short test salary levels. This approach appropriately balances the goal of ensuring that employees earning above the long test salary level who perform substantial amounts of nonexempt work are not exempt with the goal of enabling employers to use the exemption for employees who do not perform substantial amounts of nonexempt work.

v. Salary Level Effects

In selecting the salary level methodology, the Department also considered commenter views that the proposed salary level would generate a range of repercussions. Many commenters that opposed the proposed salary level stated that it would cause widespread reclassification of currently exempt employees to nonexempt status and a corresponding decrease in flexible work arrangements, including remote work opportunities. *See, e.g.,* FMI; IFDA; National Lumber and Building Material Dealers Association; NRF. Others stated that employers would convert newly nonexempt employees from salaried to hourly status, which they contended would harm employee morale, *see, e.g.,* Independent Electrical Contractors, National Small Business Association, and create an undesirable ''punch the clock'' mentality, *see, e.g.,* North Carolina Center for Nonprofits, The 4A's. Some commenters that opposed the proposal stated that the rule would ''harm the very workers the Department says it is trying to benefit,'' asserting, for example, that the proposal would result in reduced employee benefits and career advancement opportunities, and increased turnover. *See* Americans for Prosperity; *see also* PPWO. Other commenters expressed concern that the proposed increase would decrease employee productivity, *see, e.g.,* John. C. Campbell Folk School, decrease social services, *see, e.g.,* Social Current, increase employer costs, prices, and inflation, *see, e.g.,* Chamber, and/or cause salary compression issues, *see, e.g.,* Seyfarth Shaw.

Commenters that supported the Department's proposed salary level or a higher salary level than proposed often highlighted what they viewed as positive effects of the proposed increase. Many emphasized that the updated salary level would make it more difficult to exempt lower-paid employees who they believed should be nonexempt, particularly low-level managers with many duties equivalent to non-managerial employees. *See, e.g.,* Coalition of Gender Justice and Civil Rights Organizations; NELP; Winebrake & Santillo. Restaurant Opportunities Center United stated that the current ''low salary threshold discourages restaurant employees from taking managerial and supervisory positions, thereby gaining skills and experience that would enable them to advance their careers[.]'' Sanford Heisler Sharp stated that the ''need for monitoring and protecting white-collar workers' hours is critical today'' because the significant increase in telework since 2020 has meant that employers are ''no longer constrained by the practical limitation of the worker leaving the workplace.'' Other employee representatives explained that the rule would produce positive societal benefits such as increased economic security, *see, e.g.,* NELP, improved worker health due to decreased work hours, *see, e.g.,* SEIU, decreased poverty, *see, e.g.,* NEA, and disproportionate benefits for women, people of color, and workers with disabilities, *see, e.g.,* National Partnership.

Taken together, the above comments do not provide a compelling justification for deviating from the Department's proposed salary level methodology. The Department agrees that the salary level increase will result in some currently exempt employees becoming nonexempt and therefore receiving minimum wage and overtime protections. Employee reclassification is a consequence of any salary level increase, and the number of reclassified employees will depend on how employers choose to respond to this rule for their employees who earn between the current and new salary levels. Moreover, there is no prohibition on paying nonexempt employees a salary as long as any overtime hours are appropriately compensated, and employers may therefore choose to continue to pay a salary to affected workers. Employers likewise have latitude to determine what flexible work arrangements to provide employees and, more broadly, need not structure their pay plans in a manner that results in the potentially adverse effects (such as decreased employee benefits) that some employers identified. Significantly, employees and employee representatives did not share employer commenter concerns about potential adverse consequences of the proposed salary level, let alone view them as a justification for deviating from the proposed salary level. This includes comments from individual employees. For example, an exempt manager for a small nonprofit organization stated that they ''would love the opportunity to be reclassified to nonexempt and be compensated for time worked beyond 40 hours, or alternatively be given a raise if that level of flexibility is deemed necessary by my employer.'' As to potential consequences of the updated salary level on the economy more broadly, such implications are speculative and in dispute (as discussed

[227] *See* Table 25.

[228] *See* 84 FR 51242.

in some detail in section VII), and do not provide a basis for a different salary level methodology.

iv. Other Issues

The Department also addresses some other issues stakeholders raised in their comments.

Many nonprofit organizations worried that the proposed salary level would disproportionately affect them, raising concerns related to, for example, their reliance on government grants, *see, e.g.,* Asclepius Initiative, Catholic Charities, National Council of Nonprofits, and their inability to raise prices, *see, e.g.,* Advancing States, Independent Sector, YMCA. Some commenters asked the Department to exempt at least certain nonprofit organizations from the salary level test. *See, e.g.,* Oklahoma Wesleyan University; U.S. PIRG. Many nonprofit organization commenters opposed this idea. *See, e.g.,* A Second Chance; Delaware Alliance for Nonprofit Advancement; National Council for Nonprofits; North Carolina Center for Nonprofits. The Department recognizes and values the enormous contributions that nonprofit organizations make to the country. Nonprofit organizations provide services and programs that benefit many vulnerable individuals in a variety of facets of life, including services that benefit the vulnerable workers who the Department also works to protect by ensuring that their workplaces are fair, safe, and secure. However, the Department's EAP exemption regulations have never had special rules for nonprofit organizations; the employees of nonprofits have been subject to the EAP exemption if they satisfied the same salary level, salary basis, and duties tests as other employees.[229] Consistent with this history, the Department declines to exempt nonprofit organizations from the salary level test. As with other industries, as discussed above, the Department accounts for nonprofit industry concerns by setting the salary level using the lowest-wage Census Region.

A number of community-based service providers for people with intellectual and developmental disabilities urged the Department to work closely with other government agencies, including the Centers for Medicare and Medicaid Services (CMS) and the Administration for Community Living (ACL), to implement the Department's proposed changes in the context of Medicaid home and community-based services (HCBS). *See, e.g.,* ANCOR; BrightSpring Health Services; NASDDDS; United Cerebral Palsy Association. Some commenters specifically referenced a policy that was adopted by the Department related to the enforcement of the 2016 regulation for providers of Medicaid-funded services for individual with intellectual or developmental disabilities in residential homes or facilities with 15 or fewer beds.[230] *See, e.g.,* Chimes; The Arc of the United States. Consistent with its approach in the 2019 rule, the Department is not adopting a similar policy in this rulemaking. The Department believes following this approach is appropriate given that the initial update (to $844 per week) is less than salary level increase in the 2019 rule, and service providers will have approximately 8 months from publication of this rule to comply with the new salary level ($1,128 per week). Additionally, the Department intends (as many commenters requested) to issue technical assistance to help employers comply with the FLSA and will continue to coordinate (as other commenters requested) with ACL and CMS on supporting Medicaid-funded service providers impacted by this rule.

Some commenters asked the Department to permit employers to prorate the salary level for part-time employees. *See, e.g.,* NCFC; PPWO; Seyfarth Shaw; University System of Maryland. The Department has never prorated the salary level for part-time positions; considered and rejected similar requests in its 2004, 2016, and 2019 rules; and declines to establish a prorated salary level for part-time positions in this rule.[231] As the Department has previously explained, employees hired to work part time generally do not work in excess of 40 hours in a workweek, and overtime pay is not at issue for these employees. An employer may pay a nonexempt employee a salary to work part time without violating the FLSA, so long as the salary equals at least the minimum wage when divided by the actual number of hours (40 or fewer) the employee worked.[232]

The Chamber objected to the Department's proposed change to the example provided in § 541.604(b), a salary basis test regulation establishing that an exempt employee may be paid on an hourly, daily, or shift basis if the employment arrangement ''includes a guarantee of at least the minimum weekly required amount paid on a salary basis regardless of the number of hours, days or shifts worked, and a reasonable relationship exists between the guaranteed amount and the amount actually earned.'' The Department did not propose any substantive change to this regulation and only proposed to update the dollar amounts in light of the proposed increase in the standard salary level. The Department has again updated the figures in the regulation to account for the salary level change from the NPRM to the final rule. The updated numbers in this final rule produce the same ratios between actual and guaranteed earnings as example in the current regulations. The Department declines the Chamber's suggestion to change the numbers, which would change the ratio.

Some commenters urged the Department to increase the percentage of the salary level that employers could satisfy using nondiscretionary bonuses and incentive payments (including commissions). *See, e.g.,* FMI; National Automobile Dealers Association; National Golf Course Owners Association; TechServe Alliance. The Department did not propose any changes to how bonuses are counted toward the salary level requirement,[233] and declines to make any such changes in this final rule. Consistent with the current regulations, employers can satisfy up to 10 percent of the new salary level ($112.80 per week under this final rule) through the payment of nondiscretionary bonuses and incentive payments (including commissions) paid annually or more frequently.

5. Assessing the Impact of the Salary Level

i. The Department's Assessment of the Impact of the Proposed Salary Level

As stated in the NPRM, the Department sought to achieve three objectives in proposing to set the standard salary level at the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region: preserve the primary role that the duties test plays in determining EAP exemption status; fully restore the initial screening function of the salary level; and more effectively identify in a one-test system who is employed in a bona fide EAP capacity in a manner that reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move from a two-test to a one-test system.

In assessing whether the proposal met these objectives, the Department first considered the impact of its proposed

[229] *See* 81 FR 32398, 32421; *see also* 84 FR 51234.

[230] *See* 81 FR 32390 (May 23, 2016).

[231] 84 FR 51239; 81 FR 32422; 69 FR 22171.

[232] *See* FLSA2008–1NA (Feb. 14, 2008).

[233] *See* 88 FR 62169.

salary level on salaried white-collar workers across the income spectrum. The Department noted that almost three-quarters of salaried white-collar workers earned above the proposed salary level, and therefore duties, rather than salary, would remain determinative of exemption status for a significant majority of white-collar workers. The Department also concluded that a minority of the smaller share of salaried white-collar workers who earn less than the proposed standard salary level would meet the duties test, whereas approximately three-quarters of the far-larger share of salaried white-collar workers who earn at least the proposed standard salary level would meet the duties test. The Department noted that this supported that the proposed salary level would be an effective indicator of the capacity in which salaried white-collar workers are employed. The Department also examined the impact of the proposed salary level on currently exempt EAP workers—salaried white-collar employees who meet the standard duties test and earn at least $684 per week. The Department found that 1.8 million of the workers who would be affected by the proposed salary level earned less than the long test salary level and therefore would have been screened from the exemption under every prior rule issued by the Department except for the 2019 rule, thus confirming that the proposed standard salary level would play a relatively modest role in determining EAP exemption status.

ii. Comments Received

The Department received relatively few comments directly addressing its estimates of the impact of the proposed salary level or the metrics it identified to assess those impacts. As previously discussed, some commenters representing employer interests stated that the proposal would exclude too many workers from the exemption based on their earnings. *See, e.g.,* Chamber; PPWO; Seyfarth Shaw. However, commenters that expressed such views generally did not challenge the Department's analysis of the impact of its proposed salary level on all salaried white-collar workers,[234] nor did they generally address the Department's conclusion that under the proposed standard salary level, duties would be determinative of exemption status for a large majority of full-time salaried white-collar workers.[235] As noted in section V.B, employer advocates that opposed the Department's proposed salary level instead often emphasized the salary level's function of screening obviously nonexempt employees from the exemption, albeit asserting that the proposed salary level would exceed its screening function, *see, e.g.,* PPWO, RILA, SHRM, whereas worker advocates often favored a greater role for the salary level than employer representatives, *see, e.g.,* AFSCME, EPI, Family Values @ Work.

AFPI challenged the Department's estimate of the number of workers who earn between the proposed salary level and the long test salary level, which it claimed is a ''made-up number.'' [236] Some commenters representing employer interests stated that the Department underestimated the number of currently exempt workers who would be impacted by its proposed salary level. *See, e.g.,* AFPI; NAM; NRF (including a report by Oxford Economics); Rachel Greszler; Seyfarth Shaw. The Oxford Economics report claimed that up to 7.2 million workers could be affected by the proposed salary level; AFPI asserted that approximately ''7.5 million employees would be non-exempt for the first time based on salary alone''; and Rachel Greszler stated that the correct figure is as high as 12.3 million workers. NAM stated that the Department ''underestimated the impact,'' though it did not elaborate. Some of these commenters also challenged the probability codes the Department used to estimate the number of workers who meet the duties test. *See, e.g.,* AFPI; Rachel Greszler.

On the other hand, AFL–CIO, the Coalition of State AGs, and EPI relied on the Department's estimates in their comments. For instance, the Coalition of State AGs observed that '' 'most salaried white-collar employees paid less than the proposed standard salary level do not meet the duties test, whereas a substantial majority of salaried white-collar employees earning above the proposed standard salary level meet the duties test,' '' quoting the NPRM, in opining that the proposed salary level struck a more appropriate balance between the long and short test salary levels than the 2004 and 2019 rules. In asserting that the proposed salary level, although ''too low[,]'' would restore overtime protections to lower-paid workers ''who were wrongly classified as exempt[,]'' AFL–CIO referenced the Department's estimate that the proposed salary level would be ''restorative for more than half of the workers it affects'' since ''these employees would have been entitled to overtime in every rule prior to the 2019 rule.'' EPI noted that the 3.4 million workers that the Department estimated would be affected by the proposed salary level, plus the approximately 248,000 workers who would be affected by the proposed change in the total compensation threshold for the HCE test, discussed below, together constituted ''just 2.6% of workers subject to [the] FLSA . . . and just 2.3% of all workers.'' As discussed in section V.B, numerous commenters representing workers also pointed to additional data points which, they stated, show that the Department's proposed salary level would fulfill a relatively limited role in determining exemption status, particularly by historical standards. For instance, multiple commenters stated that approximately 28.2 percent of all full-time salaried workers earn below the proposed salary level, whereas in 1975 approximately 62.8 percent of full-time salaried workers earned below the short test salary level. *See, e.g.,* AFL–CIO; EPI; NELP; NWLC.

iii. Assessing the Impact of the New Salary Level

As discussed in section V.B, the Department is finalizing its proposal to set the standard salary level equal to the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census Region, which, based on the most recent earnings data, produces a salary level of $1,128 per week. The Department has analyzed the impact of the new salary level, applying generally the same metrics that it applied in the

[234] Some commenters asserted that the proposed salary level would make nonexempt too many workers in lower-wage regions and industries. *See, e.g.,* AHLA; CUPA–HR; NAHB; National Restaurant Association. As discussed above, the Department has accounted for low-wage industries and regions by using earnings data from the lowest-wage Census Region to set the salary level.

[235] AFPI objected to the Department's use of nonhourly workers' earnings to estimate the impact of the proposed salary level on salaried workers. *See also* Chamber; National Association of Convenience Stores. The Department disagrees with the suggestion that data on compensation paid to full-time nonhourly workers is not representative of the earnings of full-time salaried workers. The Department used the same approach in the 2004, 2016, and 2019 rules. *See* 84 FR 51258; 81 FR 32414; 69 FR 22197. As explained in greater detail below, *see* section VII, while the CPS MORG data on full-time nonhourly workers on which the Department has relied includes workers paid on a salary basis along with workers paid on other bases, such as on a piece-rate or day-rate basis, the Department's analysis of data from the Panel Study of Income Dynamics (PSID) shows that relatively few nonhourly workers were paid by methods other than salaried.

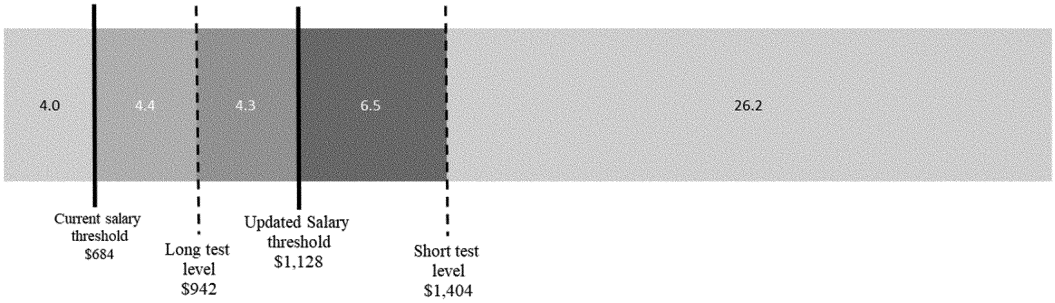
[236] NRF included a report from Oxford Economics which stated that a more reasonable methodology for modeling the long test salary level would be to update the 1975 long test level for inflation. As discussed in section V.B, the Department disagrees with Oxford Economics' suggestion, which would conflict with the Department's historical practice of avoiding the use of inflation indicators in updating the salary level.

NPRM. Upon consideration of the comments received, the Department concludes that this salary level meets the objectives it sought to achieve in undertaking this rulemaking: preserving the primary role of an analysis of employee duties in determining EAP exemption status; fully restoring the initial screening function of the salary level; and more effectively identifying in a one-test system who is employed in a bona fide EAP capacity in a manner that reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move from a two-test to a one-test system.

The Department intentionally chose a salary level methodology that will ensure that EAP exemption status for the great majority of white-collar employees will continue to depend on their duties. Consistent with the NPRM, the Department thus began by analyzing the impact of the new salary level on all full-time white-collar salaried workers. The Department continues to believe that an analysis of how the new salary level will impact all full-time salaried white-collar workers is necessary to put the salary level and its relation to an examination of duties in the appropriate context, as this is the universe of workers who could potentially be impacted by an increase in the standard salary level. As noted above, commenters representing employers did not directly challenge this aspect of the Department's analysis. And many commenters representing workers effectively endorsed this approach in stating that the proportion of full-time salaried workers who earn less than the proposed salary level shows the relatively modest impact of the proposed salary level in determining EAP exempt status, in comparison to an examination of duties. *See, e.g.,* AFL–CIO; EPI; NELP; NWLC.[237]

The Department's analysis confirms that the number of full-time salaried white-collar workers who will be excluded from the EAP exemption due to the Department's salary level is greatly exceeded by the far-larger population of full-time salaried white-collar workers for whom duties will continue to determine their exemption status. As illustrated in Figure A below, of the approximately 45.4 million full-time salaried white-collar workers in the United States subject to the FLSA,[238] about 12.7 million earn below the new salary level of $1,128 per week, and about 32.7 million earn above the salary level.[239] Thus, approximately 28 percent of full-time salaried white-collar workers (most of whom, as discussed below, do not perform EAP duties) earn below the new salary level, whereas approximately 72 percent of full-time salaried white-collar workers earn above the salary level and would have their exemption status turn on their job duties.

Figure A—Distribution of Full-Time Salaried White-Collar Workers by Weekly Earnings



Note: Numbers are in millions of workers.

Scrutinizing these figures more closely reinforces the continued importance of the duties test under the final rule. Of the approximately 12.7 million full-time salaried white-collar workers who earn below the new salary level of $1,128 per week, about 8.3 million earn below the long test salary level of $942 per week. With the exception of the 2019 rule when the Department set the salary level slightly lower, the Department has always set salary levels that screened from exemption workers earning below the long test salary level. As discussed in section V.B, the long test salary level is a key parameter for determining an appropriate salary level.[240] The number of full-time salaried white-collar workers for whom salary would be determinative of their nonexempt status and who earn at least the long test salary level—4.3 million—is over seven times smaller than the number of full-time salaried white-collar workers for whom job duties would continue to be determinative of their exemption status because they earn at least the new salary level—32.7 million.

In analyzing how the Department's new salary level will impact all salaried white-collar workers, the Department also considered the extent to which full-time salaried white-collar workers across the income distribution perform EAP duties. As the Department stated in

[237] As discussed further below, the Department does not believe, as some commenters representing workers suggested, that the proportion of full-time salaried workers who earned below the short test salary level in 1975 is the most appropriate comparator for the population of workers who earn below the new salary level.

[238] Excluded from this number are workers in named occupations and those exempt under another non-EAP overtime exemption. The exemption status of these groups will not be impacted by a change in the standard salary level. Commenters did not address the Department's exclusion of these workers from its analysis of the impact of the proposed salary level.

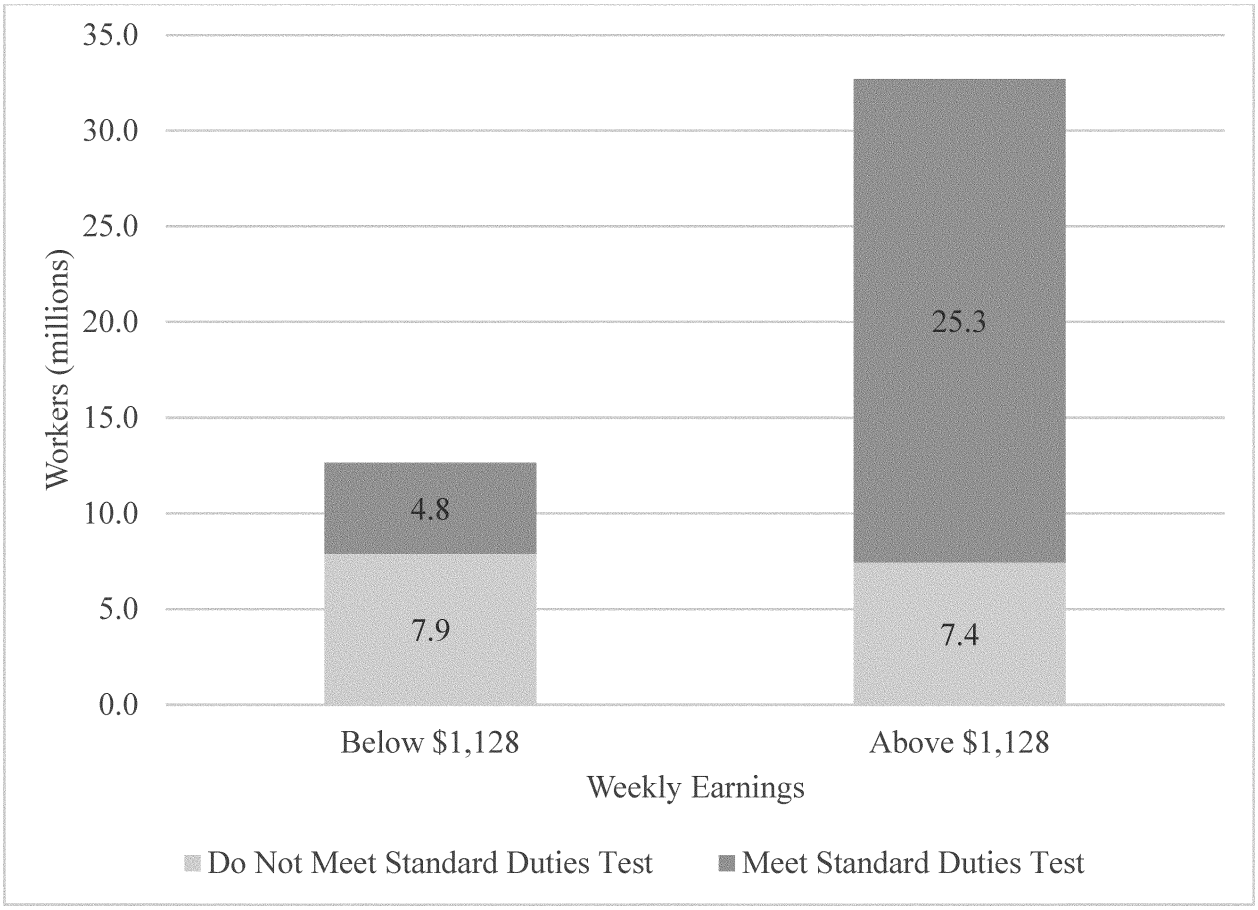
[239] This estimate is conservative, as it excludes 8.1 million white-collar workers employed as teachers, attorneys, and physicians, for whom there is no salary level requirement under the part 541 regulations and whose exemption status is therefore always determined by their duties. If these workers in ''named occupations'' are included, the percentage of salaried full-time white-collar employees for whom exemption status would depend on duties, rather than salary, increases to 76 percent. *See* §§ 541.303–304.

[240] The Department calculated the value of the long test salary level using the same methodology it used in the NPRM, updated for current earnings data: the 10th percentile of earnings of likely exempt workers in low-wage industries and regions. As explained in section V.B, any minor historical variations in the long test methodology do not deprive it of its usefulness in helping determine an appropriate salary level now.

the NPRM and the 2019 rule, the salary level has historically served as ''a helpful indicator of the capacity in which an employee is employed, especially among lower-paid employees; however, the salary level should not eclipse the duties test.[241] In considering the extent to which full-time salaried white-collar workers perform EAP duties, the Department uses probability estimates of passing the standard duties test, as it did in the NPRM.[242]

The Department's analysis shows that the new salary level is a helpful indicator of whether salaried workers perform EAP duties, since a minority of full-time salaried white-collar workers who earn less than the salary level meet the standard duties test, whereas a large majority of such workers who earn more than the salary level meet the standard duties test. As illustrated in Figure B, of the 12.7 million full-time salaried white-collar workers who earn less than $1,128 per week, the Department estimates that only 38 percent—about 4.8 million workers—meet the standard duties test. In contrast, of the 32.7 million full-time salaried white-collar workers who earn at least $1,128 per week, a large majority—77 percent, or about 25.3 million workers—meet the standard duties test.[243] The number of full-time salaried white-collar workers who meet the standard duties test and earn below the salary level is thus over five times smaller than the number of full-time salaried white-collar workers who meet the standard duties test and earn at least the salary level amount.[244] And 84 percent of all full-time salaried white-collar workers who meet the standard duties test—25.3 million out of a total of approximately 30.0 million—earn at least the new salary level.[245]

Figure B—Salaried White-Collar Workers Earning Above and Below the Standard Salary Level Who Meet or Do Not Meet the Standard Duties Test



The Department disagrees with commenters that challenged its use of its probability codes to determine whether a worker meets the duties test in light of changes in occupational codes and the duties test since the

[241] 88 FR 62171;84 FR 51239, 51237.

[242] *See* section VII.

[243] While a significant majority of full-time salaried white-collar workers who earn above the new salary level meet the duties test, helping confirm its appropriateness as an indicator of the capacity in which individuals are employed, a large number of full-time salaried white-collar workers who earn above the salary level—7.4 million—do not meet the duties test. A comparable number of salaried white-collar workers who earned above the proposed salary level did not meet the duties test, as EPI and AFI–CIO noted in their comments. PPWO's statement that ''[t]he Department seem[ed] to be setting the salary level at a point at which all employees above the line would be exempt'' is thus incorrect. The Department agrees with EPI that the fact that a large number of salaried white-collar workers who earn above the salary level will be nonexempt because they do not meet the duties test underscores the importance of an examination of duties under this rule. These 7.4 million workers will continue to be entitled to overtime because of their duties, not their salaries. Notably, this population is significantly larger than the population of workers who will become nonexempt under the new salary level. Rather than indicating that the salary level must be set higher, as AFL–CIO suggested, this fact indicates that this rule meets the Department's objective of preserving a primary role for an examination of duties.

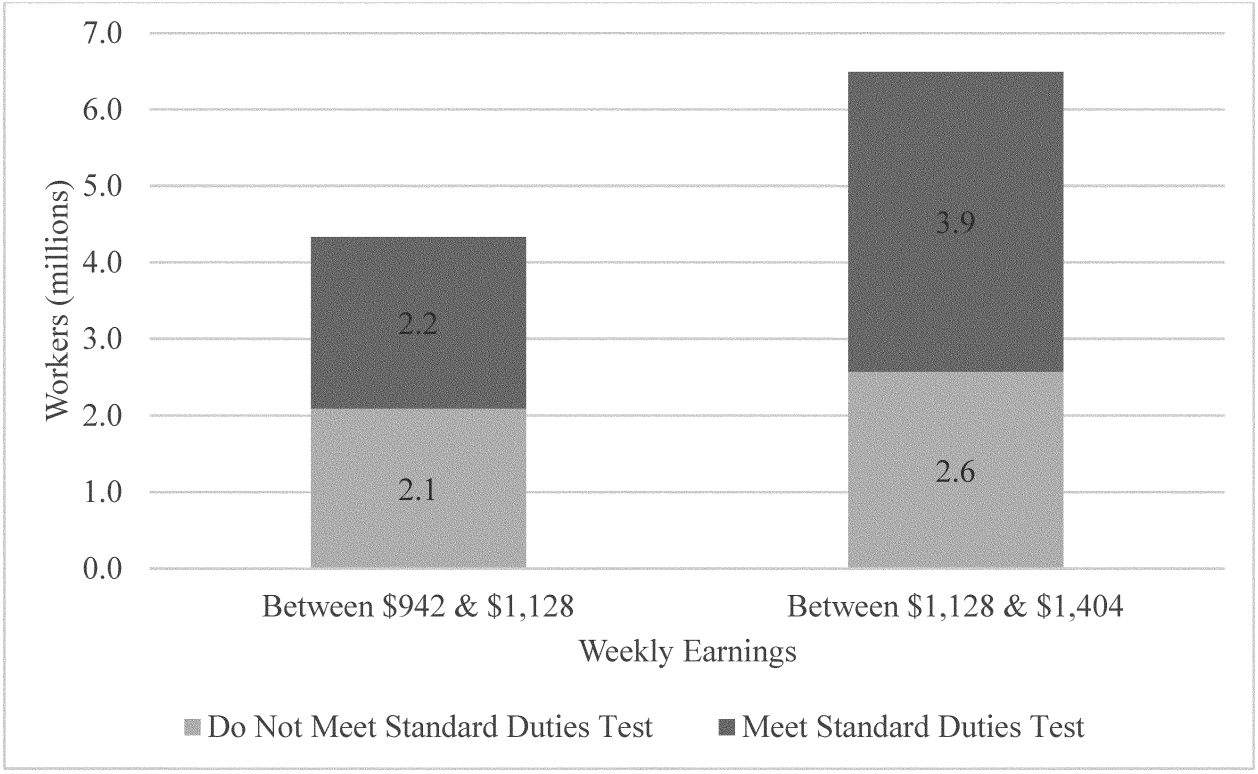
[244] As noted above, *see supra* note 239, these figures exclude salaried white-collar workers who are not subject to the part 541 salary criteria.

[245] Note that these numbers refer only to salaried white-collar workers at all salary levels who meet the standard duties test, including workers who are nonexempt because they earn below the current standard salary level.

probability codes were first developed. The Department has used the probability codes to estimate the number of workers who meet the duties test in its last three EAP rules.[246] As noted in section VII, although the probability codes were developed 25 years ago, the standard duties test is not substantively different from the former short duties tests reflected in the probability codes,[247] and the Department used occupational crosswalks to map the occupational codes on which the probability codes were originally based onto the 2018 Census occupational codes, which are used in the most recent CPS MORG data.[248] Additionally, the Department verified the continued appropriateness of the probability codes in 2016 through a review of the O*NET database,[249] which confirmed that the probability codes reflected current occupational duties.[250] The Department's probability codes remain reliable and appropriate indicators for evaluating whether workers meet the standard duties test.

Consistent with the NRPM, the Department next examined how the new salary level will impact salaried white-collar workers earning between the historic long and short test thresholds. As discussed in section V.B, the long and short test salary levels are important parameters for assessing the appropriateness of the salary level. Under the final rule, duties will continue to be determinative of exemption status for a majority of white-collar workers earning between these thresholds. As illustrated in Figure C, of the approximately 10.8 million salaried white-collar workers who earn between the long test salary level of $942 per week and the short test salary level of $1,404 per week, about 40 percent (4.3 million) earn below the new salary level, and about 60 percent (6.5 million) earn at or above the new salary level. Moreover, of the 4.3 million workers earning between the long test and the new standard salary level, almost half do not meet the standard duties test.[251]

Figure C—Salaried White-Collar Workers Between the Long and Short Test Salary Levels Who Meet or Do Not Meet the Standard Duties Test



Commenters representing workers pointed to the proportion of full-time salaried workers who earned below the short test salary level in 1975, as compared to the proportion of full-time salaried workers who earned below the proposed salary level, in stating that the Department could or should set the salary level higher than the proposed salary level. *See, e.g.,* AFL–CIO; EPI; NELP; NWLC. As emphasized above, the Department agrees that the short test and long test salary levels are key parameters for assessing the appropriateness of a salary level in a one-test system. It is also useful to put any salary level in historical context.

However, the Department notes that under the two-test system, employers could also use the long test, which paired a lower salary level with a more rigorous duties test. Accordingly, a segment of the workers who earned below the short test salary level in 1975—those who earned between the short and long test salary levels and

[246] *See* 84 FR 51258–59; 81 FR 32458; 69 FR 22198.

[247] *See* 69 FR 22214.

[248] *See* section VII.

[249] The O*NET database contains hundreds of standardized and occupation-specific descriptors. *See https://www.onetcenter.org.*

[250] *See* 81 FR 32459.

[251] As discussed further below, about 2.1 million of the approximately 4.3 million salaried white-collar workers who earn between the long test salary threshold and the Department's new salary level (about 48 percent of these workers) do not meet the standard duties test. Thus, in effect, only 21 percent of salaried white-collar workers who earn between the long and short test salary levels—2.2 million out of a total of 10.8 million—have their exemption status determined solely by the new standard salary level.

performed limited amounts of nonexempt work—were still exempt from overtime under the long test even though they earned below the short test salary level. As explained in section V.B.4, the Department has elected to set the salary level well below the short test salary level in part because setting it in the short test salary range would prevent employers from using the EAP exemption for this entire population of historically exempt workers.

Lastly, the Department also looked at the impact of the new salary level on currently exempt employees—those salaried white-collar workers who meet the standard duties test and earn at least $684 per week. As with every prior rulemaking to increase the part 541 salary levels, a relatively small percentage of currently exempt workers will become nonexempt. Of the approximately 45.4 million salaried white-collar workers in the United States, approximately 29.3 million currently qualify for the EAP exemption.[252] Of these 29.3 million presently exempt workers, just 4.0 million earn at or above the current $684 per week standard salary level but less than $1,128 per week and will, without some intervening action by their employers, become entitled to overtime protection as a result of the combined effect of the initial update and the subsequent application of the new standard salary level in this rule. A test for exemption that includes a salary level component will necessarily result in a number of workers who earned at or above the prior salary level and pass the duties test becoming nonexempt when the salary level is increased. As the Department has consistently found since 1938, salary is an important indicator of whether an individual is employed in a bona fide EAP capacity and therefore a key element in defining the exemption.

As the Department explained in its analysis of the impact of the proposed salary level, the new salary level will impact the exemption status of two distinct and important, but relatively small, groups of lower-paid EAP workers. First, the new salary level will restore overtime protections to 1.8 million currently exempt workers who meet the standard duties test but earn less than the equivalent of the long test salary level ($942 per week). Such employees were excluded from the EAP exemption under every rule prior to 2019, either by the long test salary level itself, or under the 2004 rule standard salary level, which was set equivalent to the long test salary level. Fully restoring the salary level's initial screening function requires a salary level that will ensure all employees who earn below the long test level are excluded from the exemption.

Second, the new salary level will result in overtime protections for an additional 2.2 million currently exempt workers who meet the standard duties test and earn between the long test salary level ($942 per week) and the final salary level. As explained earlier, the Department is setting the standard salary level above the long test level to account for the shift to a one-test system in a manner that reasonably distributes the impact of this switch. The final rule will limit the number of affected workers by setting a standard salary level below the midpoint between the long and short test salary levels and by using earnings data from the lowest-wage Census Region (the South).

Even among the 4.0 million workers affected by the combination of the initial update and the subsequent application of the new standard salary level in this rule, the fact that a large share of these workers earn below the long test level underscores the modest role of the final salary level. Beyond the 1.8 million workers earning less than the long test salary level—to whom the final rule will simply restore overtime protections that they had under every rule prior to 2019—the increase in the salary level will affect the exemption status of 2.2 million workers. This group makes up about 8 percent of all currently exempt, salaried white-collar workers and just under 5 percent of all salaried white-collar workers.[253] The salary level methodology adopted in this rule will thus maintain the ''useful, but limited, role'' of the salary level in defining and delimiting the EAP exemption.[254]

Finally, the Department does not agree with commenters that stated that it underestimated the number of affected workers in the NPRM. Commenters that asserted the number of affected workers could be much higher generally referenced estimates of the number of workers earning between the current salary level and the proposed salary level, regardless of whether they passed the duties test, and then posited that up to that many workers (*e.g.,* 7.2 million, 7.5 million, or 12.3 million) could be affected. *See* AFPI; NRF; Rachel Greszler. The position that all workers earning below the new salary level, regardless of their duties, will be affected by the new salary level fails to account for the fact that that millions of these workers are already nonexempt because they fail the duties test. The exemption status of workers who fail the duties test will not be affected by this rule.

Determining the workers who will be affected by a change in the salary level requires an examination of workers' earnings and their duties. Consistent with the NPRM, the Department determined the populations of currently exempt workers who will be affected by the salary level by applying its probability codes. For the reasons discussed earlier in this section and in section VII below, the Department's probability codes are reliable and appropriate indicators of whether an employee meets the standard duties test. The Department has consistently applied this methodology in all its recent part 541 rules.[255] Though some commenters criticized the Department's method for calculating the affected worker figure, they did not offer an alternate methodology for determining which workers pass the current duties test, let alone one as robust and proven as the Department's probability codes.

C. Highly Compensated Employees

In the 2004 rule, the Department created the HCE test for certain highly compensated employees. Combining a much higher compensation requirement with a minimal duties test, the HCE test is based on the rationale that employees who earn at least a certain amount annually—an amount substantially higher than the annual equivalent of the weekly standard salary level—will almost invariably pass the standard duties test.[256] The HCE test's primary purpose is therefore to serve as a streamlined alternative for very highly compensated employees because a very high level of compensation is a strong indicator of an employee's exempt status, thus eliminating the need for a detailed duties analysis.[257]

[252] Note that the 29.3 million worker figure only refers to workers who meet the standard EAP exemption and thus differs from the population of potentially affected EAP workers identified in the economic analysis (29.7 million), which includes workers who qualify only for the HCE exemption. As noted above, this is a conservative estimate because there are also 8.1 million workers in the ''named occupations'' who, under the Department's regulations, are exempt based on their duties alone.

[253] The 4.0 million workers affected by the new salary level represent only 13.8 percent of the 29.3 million salaried white-collar workers who currently qualify for the standard EAP exemption.

[254] *See* 88 FR 62173; 84 FR 51238.

[255] *See* 84 FR 51258–59; 81 FR 32458; 69 FR 22198.

[256] 84 FR 51249; *see also* § 541.601(c) (''A high level of compensation is a strong indicator of an employee's exempt status, thus eliminating the need for a detailed analysis of the employee's job duties.'').

[257] *See* 69 FR 22173–74.

As outlined in § 541.601, to be exempt under the HCE test, an employee must earn at least the amount specified in the regulations in total annual compensation—presently $107,432 per year.[258] Of this HCE threshold amount, no less than the full standard salary level amount must be paid on a salary or fee basis.[259] Finally, the employee must ''customarily and regularly perform[ ] any one or more of the exempt duties or responsibilities of an executive, administrative, or professional employee[.]'' [260] The HCE test applies only to employees whose primary duty includes performing office or non-manual work.[261]

Employees qualifying for exemption under the HCE test must receive at least the standard salary level per week on a salary or fee basis, while the remainder of the employee's total annual compensation may include commissions, nondiscretionary bonuses, and other nondiscretionary compensation.[262] Total annual compensation does not include board, lodging, or other facilities, and does not include payments for medical insurance, life insurance, retirement plans, or other fringe benefits. An employer is permitted to make a final ''catch-up'' payment during the last pay period or within 1 month after the end of the 52-week period to bring an employee's compensation up to the required level.

As stated in the NPRM, the Department continues to believe that the HCE test is a useful alternative to the standard salary level and duties tests for highly compensated employees. However, as with the standard salary level, the HCE total annual compensation level must be updated to ensure that it remains a meaningful and appropriate standard to pair with the minimal HCE duties test. To maintain the HCE test's role as a streamlined alternative for those employees most likely to meet the standard duties test, the HCE total annual compensation level must be high enough to exclude all but those employees ''at the very top of [the] economic ladder[.]'' [263] The proposal noted that when it was created in 2004, the HCE test featured a $100,000 threshold that exceeded the annual earnings of approximately 93.7 percent of salaried workers nationwide.[264] More recently in the 2019 rule, the Department set the HCE test threshold so it would be equivalent to the annual earnings of the 80th percentile of full-time salaried workers nationwide. At the time of the NPRM, however, the $107,432 per year HCE threshold covered only 72 percent of full-time salaried workers nationwide.[265]

The Department proposed to update the HCE test by setting the total compensation amount equal to the annualized weekly earnings of the 85th percentile of full-time salaried workers nationwide. Based on earnings data used in the NPRM, this proposed methodology resulted in a proposed HCE threshold of $143,988, of which at least $1,059 per week (the proposed standard salary level) would have to be paid on a salary or fee basis.[266] The Department noted that its proposed methodology would produce an HCE threshold that was higher than under the methodology adopted in the 2019 final rule (which set the HCE threshold equal to the annualized weekly earnings of the 80th percentile of full-time salaried workers nationwide),[267] but lower than under the 2004 rule (which covered 93.7 percent of salaried workers nationwide) and the method adopted in the 2016 rule (which would have covered 90 percent of salaried workers nationwide).[268] In justifying the proposed HCE threshold, the Department explained in the NPRM that it was concerned that repeating the 2019 rule's methodology now would not produce a threshold high enough to reserve the HCE test for employees at the top of today's economic ladder and could risk the unintended exemption of large numbers of employees in high-wage regions.[269]

The Department is finalizing its proposal to increase the HCE total compensation threshold to the 85th percentile of annualized weekly earnings of full-time salaried workers nationwide. Applying this methodology to calendar year 2023 earnings data results in a total compensation threshold of $151,164 per year. This approach will guard against the unintended exemption of workers who are not bona fide executive, administrative, or professional employees, including those in higher-income regions and industries.

As in prior rulemakings, the Department received significantly less feedback from commenters on the proposed increase to the HCE threshold than on the proposed increase to the standard salary level. Most commenters did not address the issue. Among the comments that addressed the proposed HCE threshold, stakeholder sentiment was split; employee representatives generally supported the proposed increase or asked for a higher increase, while most employer representatives favored a smaller increase or no increase at all.

A number of commenters expressed support for the proposed increase to the HCE threshold. *See, e.g.,* AFT; AFL–CIO; Coalition of State AGs. For example, the Coalition of State AGs asserted that ''[s]ignificant inflation since the 2019 rule became effective in January 2020 has eroded the purchasing power of the HCE salary level'' and remarked that the HCE threshold ''could arguably be made even higher than the proposed level, particularly for high-cost, high-wage states[.]'' The National Partnership described the proposed HCE threshold as ''in line with historic and economic precedent,'' while the AFT commented that the proposed HCE threshold ''will ensure [that] workers in the health care sector, and workers who provide a wide range of services and expertise for state and local governments, are not completely excluded from possibly qualifying for overtime.''

A handful of commenters advocated for the adoption of a higher HCE threshold than proposed. Noting that the HCE threshold originally exceeded the earnings of 93.7 percent of all salaried employees nationwide when it was introduced in 2004, Sanford Heisler Sharp asserted that the Department's proposal to set the HCE threshold at the 85th percentile ''introduces a substantial risk of harming employees who truly need overtime protections.'' NELA and Nichols Kaster urged the Department to repeat the approach it took in the 2016 rule, which set the HCE threshold equal to the 90th percentile of salaried earnings nationwide. Invoking

[258] § 541.601(a)(1).

[259] § 541.601(b)(1). Although § 541.602(a)(3) allows employers to use nondiscretionary bonuses, incentives, and commissions to satisfy up to 10 percent of the weekly standard salary level when applying the standard salary and duties tests, the Department's regulation at § 541.601(b)(1) does not permit employers to use such payments to satisfy the weekly standard salary level requirement for HCE workers. *See* 84 FR 51249.

[260] § 541.601(c).

[261] § 541.601(d).

[262] § 541.601(b)(1). The criteria for determining if an employee is paid on a ''salary basis'' are identical under the standard exemption criteria and the HCE test. *See Helix Energy Solutions,* 143 S.Ct. at 683.

[263] 69 FR 22174.

[264] *See* 88 FR 62159.

[265] *Id.*

[266] It is the Department's intent that the increase in the HCE total annual compensation threshold is independent of, and severable from, the increase in the standard salary level to the 35th percentile of weekly earnings of full-time salaried employees in the lowest-wage Census Region (the South) and the updating provision, pursuant to which the HCE total annual compensation threshold will be regularly updated to reflect current earnings.

[267] *See* 84 FR 51250.

[268] *See* 69 FR 22169–70 (Tables 3 and 4); 81 FR 32429.

[269] 88 FR 62176.

the FLSA's policy goal of spreading employment, NELA also opined that ''an overly permissive HCE [test] will result in fewer 'highly compensated' jobs available for workers aspiring to climb the economic ladder to benefit themselves and their families.''

Employer stakeholders that addressed the HCE threshold opposed the Department's proposed increase, with many commenters disputing that the current HCE threshold should be increased at all. *See, e.g.,* ABC; AHLA; Argentum & ASHA; NAW; Visiting Angels. A number of commenters that opposed the proposed HCE threshold asserted that it would be administratively burdensome to reevaluate the exemption status of employees who earn between the current and proposed HCE thresholds. *See, e.g.,* HR Policy Association; NAM; NCFC. PPWO commented that ''[e]mployers will be faced with the task of reviewing the basis on which each employee was accorded exempt status, including employees for whom the exempt status decision was made a decade ago and who may be among the most highly paid employees in the company.''

Other employer-side stakeholders opposed the proposed HCE threshold but indicated (either in the alternative or outright) that they would be open to a smaller increase. Several commenters stated an increase to the HCE threshold using the 80th percentile methodology applied in the 2019 rule would be preferable. *See, e.g.,* CWC; LeadingAge; RILA; *see also* Chamber (asserting that the NPRM ''does not address whatsoever why the 80th percentile [methodology] would be insufficient''). National Restaurant Association asserted that if the Department changes the HCE threshold, it ''should calculate any new HCE highly compensated level by using data from the South Census Region, rather than on a nationwide basis, to ensure that the HCE exemption is at least within reach of some employers in the lowest-wage regions in the country.'' WFCA similarly recommended that the Department set the HCE threshold at the 85th percentile of salaried earnings in lowest-wage Census Region or, alternatively, use the 80th percentile of national data for full-time salaried workers (*i.e.,* the 2019 rule's approach).

Having considered the comments received, the Department is finalizing its proposal to increase the HCE threshold to the 85th percentile of annualized weekly earnings of full-time salaried earnings nationwide. This results in a new HCE threshold of $151,164 per year, using calendar year 2023 earnings data, of which at least $1,128 per week (the standard salary level) must be paid on a salary or fee basis.[270]

As an initial matter, the Department maintains that the current HCE threshold must be increased. In nominal terms, the current $107,432 HCE threshold is only 7 percent higher than the $100,000 HCE threshold that was introduced in 2004 and, as multiple commenters noted, it has failed to keep up with wage growth over the last 20 years. According to 2023 earnings data, the current HCE threshold ($107,432) now covers just 70 percent of full-time salaried workers nationwide, less than the 80 percent of such workers that it covered when it was set in 2019. This coverage would continue to decrease in the absence of an increase, which is needed to reserve the HCE test for employees ''at the very top of today's economic ladder,'' [271] as the Department originally intended. Inaction could risk the unintended exemption of employees in higher-income regions and industries who clearly are outside of the scope of the exemption.[272]

The Department concludes that increasing the HCE threshold to the 85th percentile of annualized weekly earnings of full-time salaried workers nationwide will ensure that the threshold is sufficiently high to provide a meaningful and appropriate complement to the minimal HCE duties test, and that nearly all of the highly paid white-collar workers earning above this threshold ''would satisfy any duties test.'' [273] The Department considered keeping the 2019 rule's methodology for the HCE threshold (*i.e.,* the 80th percentile of earnings of full-time salaried employees nationwide) and applying it to current earnings data. However, the Department reaffirms its determination from the NPRM that this methodology is not appropriate because it does not produce a threshold high enough to reserve the HCE test for employees who would almost invariably pass the standard duties test. The Department agrees with commenters that stated that setting the HCE threshold at the annualized weekly earnings of the 85th percentile of full-time salaried workers nationwide will guard against the unintended exemption of workers who are not bona fide executive, administrative, or professional employees, including those in higher-income regions and industries.

The Department disagrees that the new HCE threshold is too high. Adjusting for wage growth, the proposed HCE threshold is significantly lower than the original HCE threshold that was introduced in 2004 (which surpassed the earnings of 93.7 percent of full-time salaried workers). Going forward, employers with employees affected by the increased HCE threshold can still use the standard exemption criteria to take advantage of the EAP exemption. The HCE test is a streamlined alternative to the standard exemption criteria for a select class of employees who are so highly paid that they will almost invariably pass the standard duties test.[274] By design, the HCE test is reserved for employees ''at the very top of today's economic ladder'' who would satisfy ''any duties test'' in ''virtually every'' case.[275] This exclusivity is necessary because of the risk that the HCE test poses to salaried employees in high-income regions and industries who are not bona fide EAP employees, which the Department acknowledged when the HCE test was created in 2004.[276]

Although the Department has previously acknowledged that the HCE test may exempt some employees who fail the standard duties test and would otherwise be entitled to overtime pay, such outcomes should be ''rare,'' involving employees whose pay is high enough that their exemption ''would not defeat the objectives of section 13(a)(1) of the Act.'' [277] The only way to ensure that the HCE test serves its intended purpose—*i.e.,* serving as an efficient, streamlined test for employees who would ''almost invariably'' meet the standard duties test—is for the test to include an earnings threshold high enough to exclude nearly all employees whose EAP status may be questionable. The exemption status of such employees should be determined by the standard exemption criteria.

The Department acknowledges that some commenters requested the adoption of a higher HCE threshold, closer in magnitude to the original $100,000 HCE threshold that was

[270] As discussed in section IV, the increase in the HCE threshold and the standard salary level using the new methodologies will be applicable on January 1, 2025.

[271] 69 FR 22174.

[272] *Id.*

[273] 84 FR 51250 (internal citation omitted).

[274] *See* § 541.601(c) (''A high level of compensation is a strong indicator of an employee's exempt status, thus eliminating the need for a detailed analysis of the employee's job duties.''); *see also* 84 FR 51249.

[275] 69 FR 22174.

[276] *See id.* (explaining the need to avoid the unintended exemption of employees ''such as secretaries in New York City or Los Angeles . . . who clearly are outside the scope of the exemptions and are entitled to the FLSA's minimum wage and overtime pay protections.'').

[277] *See* 84 FR 51249.

adopted in 2004. As noted above, the original HCE threshold exceeded the earnings of over 93 percent of salaried white-collar workers when it was adopted. Germane to these comments, the Department considered repeating the approach it took in the 2016 final rule and proposed in the 2019 NPRM of setting the HCE threshold at the annualized weekly earnings of the 90th percentile of full-time salaried workers nationwide, which would result in a threshold of $179,972 per year. As noted in the NPRM, however, the Department is concerned that an HCE threshold set at $179,972 could unduly restrict the use of the HCE test for employers in lower-wage regions and industries.[278] While the new HCE threshold does not exclude from the HCE test as high a percentage of full-time salaried employees as the HCE threshold initially adopted in 2004, it excludes a sufficiently large percentage (*i.e.,* 85 percent of full-time salaried employees nationwide) to guard against the unintended exemption of employees in higher-income regions and industries who are not bona fide EAP employees.

For all of the reasons provided above, the Department adopts its proposal to set the HCE threshold equal to the annualized weekly earnings of the 85th percentile of full-time salaried workers ($151,164). This new level will be applicable on January 1, 2025.

D. Severability

1. The Department's Proposal

The Department proposed to add a severability provision to its part 541 regulations at § 541.5. Proposed § 541.5 stated that if any provision of this part is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the Department intended that the provision be given the fullest effect permitted by law, unless the provision is held to be completely invalid or unenforceable, in which case, the Department intended the provision to be severable and not to affect the remaining provisions.

The Department illustrated the intended effect of proposed § 541.5 with some examples. The Department noted that it was its intent that the proposed updating mechanism be effective even if the proposed increase in the standard salary level were invalidated. It was also the Department's intent that the proposed increase in the HCE total annual compensation threshold be effective even if the increase in the standard salary level were invalidated. And it was the Department's intent that the proposed increases in the standard salary level and HCE annual total compensation requirement apply even if the updating mechanism was determined to be invalid.[279]

The Department is finalizing § 541.5, Severability, as proposed, with that addition of clarifying language as discussed below.

2. Discussion of Comments and Final Rule

Most commenters did not address proposed § 541.5. Of the few commenters that did address the Department's severability proposal, the Administrative Law Professors and NELP supported the inclusion of a severability provision in the final rule.

In expressing their support, the Administrative Law Professors provided the most in-depth discussion of the Department's proposed severability provision. The Administrative Law Professors explained that a provision of a rule is severable where the agency intends for the remainder of the rule to be effective, even if the provision is invalidated, and the rule would be workable absent the provision, citing precedent from the U.S. Supreme Court and the U.S. Court of Appeals for the District of Columbia Circuit.[280] The professors noted that the Department ''clearly state[d] [its] intention'' in proposed § 541.5 that the updating mechanism in proposed § 541.607 ''be effective even if the proposed increase in the standard salary level is invalidated.'' They further noted that the Department ''expresse[d] the same intention with regard to the implementation of the HCE total annual compensation requirement whether or not the standard salary level is invalidated'' and ''the application of the Department's proposed 2023 earnings thresholds, whether or not automatic updating is upheld.''

The Administrative Law Professors observed that the Department's inclusion of a severability provision in the NPRM was consistent with guidance from the Administrative Conference of the United States (ACUS), which advised agencies in a 2018 report[281] to address severability in the text and preamble of both the NPRM and the final rule where the agency intends the provisions of a rule to be severable and anticipates that the rule may be challenged in court. The professors suggested that the Department further explain in the final rule how the rule ''would remain workable'' if any of its provisions were declared invalid. As an example, the professors suggested stating explicitly that invalidation of the updating provision ''would have no bearing on the rationality or administrability of the standard salary and HCE salary thresholds'' as set in the rule. They further noted that in the event of the invalidation of either the standard salary level or the HCE compensation threshold, the updating provision could function independently because ''updating would simply take as the 2023 baseline the thresholds left in place from the 2019 rule.'' The Administrative Law Professors made clear that expanding the explanation of ''the independent workability of any of the rule's provisions'' should not be seen as an indication of legal vulnerability but instead as merely an acknowledgement of the possibility of legal challenge.

NELP also supported the proposed severability provision, noting the ''vital importance'' of the proposed rule to millions of workers. Specifically, NELP stated that if any provision of the rule ''is deemed legally questionable, only that provision should be stayed while litigation proceeds.''

A small number of commenters representing employer interests specifically opposed the proposed severability provision or criticized the Department's severability proposal. Indiana Chamber of Commerce and U-Haul Holding Company (U-Haul) stated that the proposed severability provision was an acknowledgement of the legal vulnerability of the Department's proposed updating section. The YMCA stated that the Department failed to explain the need for, or appropriateness of, the proposed severability provision, and RILA asserted that the Department failed to explain how the proposed rule would function if any of its provisions were declared invalid. The Chamber and the National Association of Convenience Stores asserted that the Department should withdraw the severability provision.

The Chamber further asserted that, pursuant to the district court decision

[278] *See* 88 FR 62176*; see also* 84 FR 51250.

[279] The Department also stated that it was the Department's intent that its proposal to apply the standard salary level to the U.S territories subject to the Federal minimum wage remain in effect even if the proposed change to the standard salary level were invalidated. As discussed above, *see supra* note 9, at this time the Department is not finalizing in this final rule its proposal to apply the standard salary level to the U.S. territories subject to the Federal minimum wage and to update the special salary levels for American Samoa and the motion picture producing industry.

[280] *See K-Mart Corp.* v. *Cartier,* 486 U.S. 281, 294 (1988); *Davis Cnty. Solid Waste Mgmt.* v. *EPA,* 108 F.3d 1454, 1459–60 (D.C. Cir. 1997).

[281] *See* Admin. Conf. of the U.S., Recommendation 2018–2, *Severability in Agency Rulemaking,* 83 FR 30683, 30685 (June 29, 2018).

invalidating the 2016 rule, ''the automatic increase provision in the Proposed Rule cannot survive if the increase to the minimum salary level is struck down.'' The Department does not read the court's decision as substantively examining the validity of the 2016 rule's automatic updating provision or analyzing whether that provision was severable from the remainder of the rule. And importantly, the 2016 rule did not contain a severability provision or discuss the Department's intent regarding severability of the provisions of that rule. In contrast, the Department's current NPRM included a severability provision and a detailed discussion of the Department's intent that specifically addressed severability of the updating provision. As the Administrative Law Professors noted, as proposed, the updating provision was not dependent on the proposed increases to the standard salary level and the HCE compensation threshold. If either of the new thresholds were vacated, the updating provision would simply use the existing methodologies set in the 2019 rule as the baseline for the update (*i.e.,* the Department would apply those methodologies triennially to update the earnings thresholds as established in § 541.607). This is a significant change from the 2016 updating provision, which would have updated the standard salary level and HCE total compensation requirement based on the specific methodologies set in that rule and facially could not function if those methodologies were invalidated.[282]

Upon consideration of the comments received, the Department is finalizing the severability provision in § 541.5 as proposed, with an additional sentence to further clarify its intent. The Department intends that each of this rule's provisions be considered separate and severable and operate independently from one another. The Department is revising § 541.5 to state this explicitly. In this regard, the Department intends that if any application of a provision is stayed, enjoined, or invalidated, the provision be construed to continue to give the maximum effect to the provision permitted by law. In the event any provision within a section of the rule is stayed, enjoined, or invalidated, the Department intends that all remaining provisions within that section, plus all other sections, remain effective and operative. And in the event any whole section of the rule is stayed, enjoined, or invalidated, the Department intends that all remaining sections remain effective and operative.

It is the Department's position that the provisions and sections of the rule can function sensibly in the event that any specific provisions, sections, or applications are invalidated, enjoined, or stayed. To begin, the new standard salary level set forth in § 541.600(a)(2) of $1,128 per week—the 35th percentile of weekly nonhourly earnings in the lowest-wage Census Region—can function sensibly, even if, for instance, the rule's new updating section or the revision to the HCE total compensation requirement are stayed, enjoined, or invalidated. The revision to the standard salary level under the new methodology operates independently of and does not depend on either the new updating section or the revision to the HCE total compensation requirement. If, for instance, the triennial updating of the standard salary level were invalidated, the new salary level of $1,128 would still go into effect, and it would remain $1,128 per week until the Department conducts further rulemaking. The new standard salary level of $1,128 per week would also still take effect if the initial update to the standard salary level were invalidated.[283] And the new standard salary level would still go into effect and function sensibly if the revision to the HCE total compensation requirement were invalidated as well. Notably, in such an event, the total annual compensation an employee would need to receive to qualify for the HCE test would remain at the existing level; [284] however, the employee's total annual compensation would need to include at least $1,128 per week paid on a salary or fee basis. As discussed in section V.B, the revised standard salary level will work effectively with the standard duties test to better define who is employed in a bona fide EAP capacity by restoring the initial screening function that the salary level long fulfilled and adjusting the salary level to account for the change to a single-test system. Finalizing the new standard salary level will thus accomplish several of the key objectives the Department is seeking to achieve in undertaking this rulemaking, even if all or part of the updating section or the revisions to the HCE total compensation requirement do not also go into effect.

The revised HCE total compensation requirement of $151,164 per year set forth in § 541.601(a)(1)—the 85th percentile of annualized weekly earnings of full-time nonhourly workers nationally—can also function sensibly, even if the other provisions of this final rule are stayed, enjoined, or invalidated. The revision to the HCE total compensation requirement under the new methodology operates independently of, and does not depend on, either the new updating provision or the revision to the standard salary level. Accordingly, if, for instance, the triennial updating of the HCE total compensation requirement were invalidated, the new HCE total compensation requirement of $151,164 per year would still become effective, and the HCE total compensation requirement would remain at that amount until the Department undertakes further rulemaking. If the initial update to the HCE total compensation requirement were invalidated, the revised HCE total compensation requirement would still go into effect, too. And the revised HCE total compensation requirement would still go into effect and function sensibly if the revision to the standard salary level were invalidated. In such an event, an employee would need to be paid the new total annual compensation amount of $151,164 per year to qualify as exempt under the HCE test, though the total annual compensation would need to include only the existing standard salary level [285] per week paid on a salary or fee basis. As noted in section V.C, the HCE test was intended to be limited to those highly paid employees who would almost invariably meet the standard duties test. The revision to the HCE total compensation requirement would restore it to a level that is high enough to avoid the unintended exemption of large numbers of employees in high-wage regions but not so high as to unduly restrict the use of the HCE test in lower-wage regions and industries, even if the revisions to the standard salary level and all or part of the updating provision do not go into effect.

The new updating section can also function sensibly, independent of the other provisions of this final rule. As explained in section V, the updating section provides in § 541.607(a) and (b) that the Department will update the

[282] *See* 81 FR 32251.

[283] As noted in section IV, the initial update to the standard salary level and HCE total annual compensation requirement are applicable July 1, 2024, whereas the new standard salary level and HCE total annual compensation requirement are applicable 6 months later on January 1, 2025.

[284] Under these circumstances, the HCE total annual compensation requirement would be $132,964 per year or, if the initial update to the earnings thresholds under this rule did not go into effect, the current HCE total annual compensation requirement of $107,432 per year.

[285] Under these circumstances, the standard salary level would be $844 per week or, if the initial update to the earnings thresholds under this rule did not go into effect, the current standard salary level of $684 per week.

standard salary level and HCE total compensation requirement, respectively, initially on July 1, 2024 and every 3 years thereafter, to reflect current earnings data, in accordance with the methodology used to set each threshold. Both the triennial updating of the earnings thresholds for exemption and the initial update to these thresholds can function sensibly on their own.

The triennial updating of the earnings thresholds for exemption can function sensibly, even if the new standard salary level and new HCE total compensation requirement are stayed, enjoined, or invalidated, as the triennial updates are based on the methodology used to set each threshold that is in place at the time of the update. If all the provisions of this rule do go into effect (and assuming the Department has not engaged in further rulemaking), as discussed in section V.A, the triennial updates to the standard salary level and HCE total compensation threshold will be based on the new methodologies established in this rule: the 35th percentile of weekly nonhourly earnings in the lowest-wage Census Region and the 85th percentile of annualized weekly earnings of full-time nonhourly workers nationally, respectively. However, the updating provision does not depend on the revisions to the standard salary level and HCE methodologies also going into effect. If, for instance, both the new standard salary level and HCE total compensation requirement were invalidated, the updating provision would, as the Administrative Law Professors noted, use the existing methodologies set in the 2019 rule as the baseline for the each triennial update: the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region and/or retail nationally, in the case of the standard salary level, and the 80th percentile of annualized weekly earnings of full-time nonhourly workers nationally, in the case of the HCE test. The updating section thus ensures that the standard salary level and HCE total compensation requirement continue to reflect current earnings—among the key objectives the Department is seeking to achieve in undertaking this rulemaking, *see* section V.A—even if the new methodologies for setting these earnings thresholds do not go into effect.

The initial update of the earnings thresholds for exemption can function sensibly as well, even if this rule's other revisions do not go into effect, as the baseline for the initial update to each threshold is the current methodology established in 2019. Accordingly, if, for instance, the new standard salary level, new HCE total compensation requirement, and the triennial updating provision were invalidated, the standard salary level and HCE total compensation requirement would still be updated on July 1, 2024 to $844 per week and $132,964 per year, respectively. In undertaking this rulemaking, the Department sought (among other objectives) to account for the considerable earnings growth that has taken place since it last updated the earnings thresholds for exemption.[286] The initial updating of the standard salary level and HCE total compensation requirement ensures these thresholds reflect earnings growth since the Department's 2019 rule, even if the new methodologies for setting the standard salary level and the HCE total compensation requirement and the future triennial updates to these earnings thresholds do not go into effect.

In sum, the Department has taken care to draft this final rule such that its provisions function independently and is including a severability section, § 541.5, to make clear that all the rule's provisions are separate and severable and should be given the fullest possible effect. As the Administrative Law Professors observed, this discussion of severability is not an acknowledgement of the legal vulnerability of any particular provision. However, since some commenters have indicated that they may challenge all or part of this rule, *see e.g.,* AFPI, Chamber, NFIB, and the 2016 and 2019 rules were both subject to legal challenge, the Department, consistent with ACUS guidance, makes explicit in the regulatory text that it considers the provisions of this rule to be severable and explains here how the various provisions of the rule can operate sensibly in the event another provision of the rule is stayed, enjoined, or declared invalid.

VI. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and its attendant regulations, 5 CFR part 1320, require the Department to consider the agency's need for its information collections, the information collections' practical utility, the impact of paperwork and other information collection burdens imposed on the public, and how to minimize those burdens. Under the PRA, an agency may not collect or sponsor an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.[287]

OMB has assigned control number 1235–0021 to the information collection that gathers information from complainants alleging violations of the labor standards that WHD administers and enforces, and OMB has assigned control number 1235–0018 to the information collection, Records to be kept by Employers—Fair Labor Standards Act. In accordance with the PRA, the Department solicited public comments on the proposed burden changes to the information collection under control number 1235–0021 and the proposed burden changes to the information collection under OMB control number 1235–0018.[288] Because OMB control number 1235–0021 was encumbered by a different rulemaking at the time of submission of the NPRM to OMB, the Department at that time created a duplicate ICR of 1235–0021 under OMB control number 1235–0NEW to allow the public to comment on the proposed estimates. The Department submitted a contemporaneous request for OMB review of the proposed revisions to the existing information collection and the duplicate ICR in accordance with 44 U.S.C. 3507(d). On October 12, 2023, OMB issued a notice that assigned the duplicate information collection control number 1235–0035 and indicated the Department should address comments received during the NPRM comment period and resubmit for approval at the time of the final rule. Also on October 12, 2023, OMB issued a notice that continued the previous approval of the information collection under 1235–0018 under the existing terms of clearance and advised the Department to address any comments received during the NPRM comment period and resubmit at the time of the final rule.

Circumstances Necessitating this Collection: This rulemaking revises 29 CFR part 541 and affects provisions that could be considered to entail collections of information including (1) the complaint process under which employees may file a complaint with the Department to investigate potential violations of the laws administered by the Department, including the FLSA; and (2) disclosure and recordkeeping requirements for covered employers under the FLSA. This rulemaking does not impose new information collection requirements. Rather, burdens under the existing requirements would increase due to the changes in the universe of employees for whom employers are

[286] *See* section V.A.2.

[287] *See* 5 CFR 1320.8(b)(3)(vi).

[288] *See* 88 FR 62181.

required to maintain records. The changes adopted in this rulemaking may also cause an initial increase in burden if more employees file complaints with WHD to collect back wages under the overtime pay requirements.

Information and technology: There is no particular order or form of records prescribed by the regulations. A respondent may meet the requirements of this final rule using paper or electronic means. WHD, to reduce burden caused by the filing of complaints that are not actionable by the agency, uses a complaint filing process in which complainants discuss their concerns with WHD professional staff. This process allows agency staff to refer complainants raising concerns that are not actionable under federal wage and hour laws and regulations to an agency that may be able to assist.

Public comments: The Department invited public comment on its analysis that the rule would create a slight increase in the paperwork burden associated with the complaint ICR 1235–0021 (submitted as a duplicate ICR at the NPRM stage under control number 1235–0NEW and later assigned by OMB as 1235–0035) and on the burden associated with ICR 1235–0018, Records to be kept by employers—Fair Labor Standards Act. The Department did not receive comments on the ICRs themselves or any comments submitted regarding the PRA analysis in particular, including the methodology. No comments were received with respect to the complaint ICR (1235–0021). However, commenters addressed aspects of the information collections while commenting on the text of the proposed rule as it relates the records ICR (1235–0018).

For example, Horizon Health Services commented that ''[r]equiring supervisors to record their hours worked and request overtime, as needed, would [be] a disruption to business operations by adding a significant administrative burden.'' The University of Dayton agreed that a change would require additional administrative burden stating, ''new training and systems would need to be put in place for newly nonexempt employees to record their time and for their supervisors to track and approve their time. They would have to become accustomed to tracking their hours, being sure not to work unbudgeted hours and overtime unless approved, and so forth.'' Others, like Argentum & ASHA and Oklahoma Wesleyan University, similarly expressed concerns about the costs associated with having newly nonexempt employees record their time. SBA Advocacy stated that ''DOL should consider'' that ''small entities face vast administrative and operational costs to schedule and track employee hours to minimize overtime costs.'' In addition, some commenters expressed concern that the Department's cost estimates related to recordkeeping were too low, given among other things that employers would need to adjust their recordkeeping and payroll systems for newly overtime-eligible employees. *See, e.g.,* NFIB; PPWO; Seyfarth Shaw. The National Roofing Contractors Association stated that it ''is concerned the proposed regulation would result in dramatically increased labor costs and additional paperwork burdens for employers, while also reducing workplace flexibility and compensation for many workers.''

In response to these comments, the Department observes that most employers currently have both exempt and nonexempt workers and therefore have systems already in place for employers to track hours. Additionally, commenters did not offer alternatives for estimates or make suggestions regarding the methodology for calculating the PRA burdens. The actual recordkeeping requirements are not changing in the final rule. However, the pool of workers for whom employers will be required to make and maintain records has increased under the final rule, and as a result the burden hours have increased. Included in this PRA section are the regulatory familiarization costs for this final rule. However, this is a duplication of the regulatory familiarization costs contained in section VII, economic impact analysis.

The Department plans to submit these ICR's to OMB upon publication of the final rule. The agency will publish a notice in the **Federal Register** to inform the public of OMB's decision.

Total burden for the subject information collections, including the burdens that will be unaffected by this final rule and any changes, is summarized as follows:

Type of review: Revision to currently approved information collections.

Agency: Wage and Hour Division, Department of Labor.

Title: Employment Information Form.

OMB Control Number: 1235–0021.

Affected public: Private sector, businesses or other for-profits and Individuals or Households.

Estimated number of respondents: 29,160 (2,150 from this rulemaking).

Estimated number of responses: 29,160 (2,150 from this rulemaking).

Frequency of response: On occasion.

Estimated annual burden hours: 9,720 (717 burden hours due to this rulemaking).

Capital/Start-up costs: $0 ($0 from this rulemaking).

Title: Records to be kept by Employers—Fair Labor Standards Act.

Type of review: Revision to currently approved information collections.

Agency: Wage and Hour Division, Department of Labor.

OMB Control Number: 1235–0018.

Affected public: Private sector, businesses or other for-profits and Individuals or Households.

Estimated number of respondents: 4,068,419 (0 from this rulemaking).

Estimated number of responses: 42,725,207 (10,320,000 from this rulemaking).

Frequency of response: On occasion.

Estimated annual burden hours: 1,157,993 (344,000 from this rulemaking).

Capital/Start-up costs: $0 ($0 from this rulemaking).

VII. Analysis Conducted in Accordance With Executive Order 12866, Regulatory Planning and Review, and Executive Order 13563, Improving Regulation and Regulatory Review

Under Executive Order 12866, OMB's Office of Information and Regulatory Affairs (OIRA) determines whether a regulatory action is significant and, therefore, subject to the requirements of the Executive Order and OMB review. As amended by Executive Order 14094, section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as a regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive Order. OIRA has determined that this rule is a ''significant regulatory action'' within the scope of section 3(f)(1) of Executive Order 12866.

Executive Order 13563 directs agencies to, among other things, propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; that it is tailored to impose the least burden on society, consistent with obtaining the regulatory

objectives; and that, in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. Executive Order 13563 recognizes that some costs and benefits are difficult to quantify and provides that, when appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts. The analysis below outlines the impacts that the Department of Labor (Department) anticipates may result from this rule and was prepared pursuant to the above-mentioned executive orders.

A. Introduction

1. Background

The Fair Labor Standards Act (FLSA or Act) requires covered employers to (1) pay employees who are covered and not exempt from the Act's requirements not less than the Federal minimum wage for all hours worked and overtime premium pay at a rate of not less than one and one-half times the employee's regular rate of pay for all hours worked over 40 in a workweek, and (2) make, keep, and preserve records of their employees and of the wages, hours, and other conditions and practices of employment.

The FLSA provides a number of exemptions from the Act's minimum wage and overtime pay provisions, including one for bona fide executive, administrative, and professional (EAP) employees. The exemption applies to employees employed in a bona fide executive, administrative, or professional capacity, as those terms are ''defined and delimited'' by the Department.[289] The Department's regulations implementing these ''white-collar'' exemptions are codified at 29 CFR part 541. Since 1940, the regulations implementing the exemption have generally required each of the following three tests to be met: (1) the employee must be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test); (2) the amount of salary paid must meet a minimum specified amount (the salary level test); and (3) the employee's job duties must primarily involve executive, administrative, or professional duties as defined by the regulations (the duties test).

The Department has updated the salary level test many times since its implementation in 1938. Table 1 presents the weekly salary levels associated with the EAP exemptions since 1938, organized by exemption and long/short/standard duties tests. From 1949 to 2004, the Department determined exemption status using a two-test system comprised of a long test (a lower salary level paired with a more rigorous duties test that limited performance of nonexempt work to no more than 20 percent for most employees) and a short test (a higher salary level paired with a less rigorous primary duties requirement that did not have a numerical limit on the amount of nonexempt work). In 2004, rather than update the two-test system, the Department chose to establish a new single-test system for determining exemption status, setting the standard salary level test at $455 a week, which was equivalent to the long test salary level, and pairing it with a standard duties test that was substantially equivalent to the more lenient short duties test. Because the single standard duties test was equivalent to the short duties test, employees who met the long test salary level and previously passed either the more rigorous long, or less rigorous short, duties test passed the standard duties test. The Department also added a new highly compensated employee (HCE) test, which used a very minimal duties test and a very high total compensation test set at $100,000 per year (*see* section II.B.2 for further discussion). In 2016, to address the concern that the standard test exempted lower-paid salaried employees performing large amounts of nonexempt work who had previously been protected by the more rigorous long duties test, the Department published a final rule setting the standard salary level at $913 per week, which was equivalent to the low end of the historic range of short test salary levels, and the HCE annual compensation level at $134,004. This approach restored overtime protection for employees performing substantial amounts of nonexempt work who earned between the long test salary level and the low end of the short test salary range, as they failed the new standard salary level test. As previously discussed, the U.S. District Court for Eastern District of Texas held the 2016 rule invalid. In 2019, in part to address the concern raised in the litigation that the approach taken in the 2016 rulemaking would have prevented employers from using the exemption for employees who earned between the long test salary level and the low end of the short test salary range and met the more rigorous long duties test, the Department returned to the methodology used in the 2004 rule and set the salary level at the 20th percentile of weekly earnings of full-time salaried workers in the South and in the retail industry nationally. Applying this method to the earnings data available in 2019 produced a standard salary level that was below the long test salary level. The current earnings thresholds, as published in 2019, are $684 a week for the standard salary test and $107,432 per year for the HCE test.

[289] 29 U.S.C. 213(a)(1).

Table 1—Historical Weekly Salary Levels for the EAP Exemptions

Date Enacted	Long Duties Test			Short Duties Test
	Executive	Administrative	Professional	
1938	$30*	$30	-	-
1940	$30	$200 (per month)	$200 (per month)	-
1949	$55	$75	$75	$100
1958	$80	$95	$95	$125
1963	$100	$100	$115	$150
1970	$125	$125	$140	$200
1975	$155	$155	$170	$250
Standard Duties Test				
2004	$455			
2019	$684			

*Unless otherwise specified, all figures are dollars per week

2. Need for Rulemaking

The goal of this rulemaking is to set effective earnings thresholds to help define and delimit the FLSA's EAP exemption. To this end, the Department is finalizing its proposed change to the standard salary level. Specifically, the Department is adjusting the standard salary level by setting it equal to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South), based on the most recent year of Current Population Survey (CPS) data at the time of drafting.[290] Using the Bureau of Labor Statistics (BLS) 2023 data on percentiles of usual weekly earnings of nonhourly full-time workers, the standard salary level will be set at $1,128 per week.[291] Additionally, to maintain the effectiveness of this test, the Department is finalizing an updating mechanism that will update the earnings thresholds to reflect current wage data initially on July 1, 2024 and every 3 years thereafter.

The Department's new standard salary level will, in combination with the standard duties test, better define and delimit which employees are employed in a bona fide EAP capacity in a one-test system. As explained in greater detail in sections III and V.B, setting the standard salary level at or below the long test salary level, as the 2004 and 2019 rules did, results in the exemption of lower-salaried employees who traditionally were entitled to overtime protection under the long test either because of their low salary or because they perform large amounts of nonexempt work, in effect significantly broadening the exemption compared to the two-test system. Setting the salary level at the low end of the historic range of short test salary levels, as the 2016 rule did, would have restored overtime protections to those employees who perform substantial amounts of nonexempt work and earned between the long test salary level and the low end of the short test salary range. However, it also would have resulted in denying employers the use of the exemption for lower-salaried employees who traditionally were not entitled to overtime compensation under the long test, which raised concerns that the Department was in effect narrowing the exemption. By setting a salary level above the equivalent of the long test salary level (using current data), the final rule will restore the right to overtime pay for salaried white-collar employees who prior to the 2019 rule were always considered nonexempt if they earned below the long test (or long test-equivalent) salary level. And it will ensure that fewer lower paid white-collar employees who perform significant amounts of nonexempt work are included in the exemption. At the same time, by setting it well below the equivalent of the short test salary level (using current data), the rule will allow employers to continue to use the exemption for many lower paid white-collar employees who were made exempt under the 2004 standard duties test. The new salary level will also more reasonably distribute between employees and their employers what the Department now understands to be the impact of the shift from a two-test to a one-test system on employees earning between the long and short test salary levels.

As the Department has previously noted, the amount paid to an employee is ''a valuable and easily applied index to the 'bona fide' character of the employment for which exemption is claimed, as well as the ''principal[ ]'' ''delimiting requirement . . . prevent[ing] abuse'' of the exemption.[292] Additionally, the salary level test facilitates application of the exemption by saving employees and employers from having to apply the more time-consuming duties analysis to a large group of employees who will not pass it. For these reasons, the salary level test has been a key part of how the Department defines and delimits the EAP exemption since the beginning of its rulemaking on the EAP exemption.[293] At the same time, the salary test's role in defining and delimiting the scope of the EAP exemption must allow for appropriate examination of employee duties.[294] Under the final rule, duties will continue to determine the exemption status for most salaried white-collar employees.

The Department also will adjust the HCE total annual compensation requirement to the annualized weekly earnings of the 85th percentile of full-

[290] The Department uses the terms *salaried* and *nonhourly* interchangeably in this rule because, consistent with its 2004, 2016, and 2019 rules, the Department considered data representing compensation paid to nonhourly workers to be an appropriate proxy for compensation paid to salaried workers. The Department also notes that the terms *employee* and *worker* are used interchangeably throughout this analysis.

[291] BLS publishes quarterly and annual estimates of percentile earnings values beginning with 2022 data at *https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.*

[292] Stein Report at 19, 24; *see also* 81 FR 32422.

[293] *See* 84 FR 51237.

[294] *See* 84 FR 51238.

time salaried workers nationally ($151,164 using 2023 data). Though not as high a percentile as the HCE threshold initially adopted in 2004, which covered 93.7 percent of all full-time salaried workers,[295] the Department's new HCE threshold will ensure it continues to serve its intended function, because the HCE total annual compensation level will be high enough to exclude all but those employees at the very top of the economic ladder.

In this final rule, the Department is not finalizing its proposal in section IV.B.1 and B.2 of the NPRM to apply the standard salary level to the U.S. territories subject to the federal minimum wage and to update the special salary levels for American Samoa and the motion picture industry.[296]

In its three most recent part 541 rulemakings, the Department has expressed its commitment to keeping the earnings thresholds up to date to ensure that they remain effective in helping differentiate between exempt and nonexempt employees. Long intervals between rulemakings have resulted in eroded earnings thresholds based on outdated earnings data that were ill-equipped to help identify bona fide EAP employees. In contrast, routine updates of the earnings thresholds to reflect wage growth will bring certainty and stability to employers and employees alike. Based on its long experience with updating the salary levels, the Department has determined that adopting a regulatory provision for regularly updating the salary levels, with an exception for pausing future updates under certain conditions, is the most viable and efficient way to ensure the EAP exemption earnings thresholds keep pace with changes in employee pay and thus remain effective in helping determine exemption status. Accordingly, in addition to the salary level changes discussed above, the Department is including in this rule a mechanism for updating the salary and compensation levels to reflect current wage data initially on July 1, 2024 and every 3 years thereafter. As explained in greater detail in section V.A, employees and employers alike will benefit from the certainty and stability of regularly scheduled updates.

3. Summary of Affected Workers, Costs, Benefits, and Transfers

The Department estimated the number of affected workers and quantified costs and transfer payments associated with this final rule using pooled CPS Merged Outgoing Rotation Group (MORG) data. *See* section VII.B.2. The Department estimates in the first year after implementation, there will be 4.3 million affected workers.[297] This includes 4.0 million workers (1.0 million at the first update and 3.0 million when the new salary level is applied) who meet the standard duties test and earn at least $684 per week but less than $1,128 per week and will either become eligible for overtime or have their salary increased to at least $1,128 per week (Table 2).[298] An estimated 292,900 workers will be affected by the increase in the HCE compensation test from $107,432 per year to $151,164 per year. In Year 10, with triennial updating of the standard salary and HCE thresholds, the Department projects that 5.0 million workers will be affected by the change in the standard salary level test and 1.0 million workers will be affected by the change in the HCE total annual compensation test.[299]

This analysis quantifies three direct costs to employers: (1) regulatory familiarization costs; (2) adjustment costs; and (3) managerial costs (*see* section VII.C.3). Total annualized direct employer costs over the first 10 years were estimated to be $802.9 million, assuming a 7 percent discount rate.[300] This rule will also transfer income from employers to employees in the form of increased wages. The Department estimated annualized transfers will be $1.5 billion. Most of these transfers will be attributable to wages paid under the FLSA's overtime provision; a smaller share will be attributable to the FLSA's minimum wage requirement. These transfers also account for employers who may choose to increase the salary of some affected workers to at least the new threshold so that they can continue to use the EAP exemption.

The Department also provides a qualitative discussion of the potential benefits and unquantified transfers of this rule, including strengthened overtime protections for some workers, increased worker productivity, increased personal time for workers, and reduced reliance on social assistance programs. *See* section VII.C.5.

[295] *See* 69 FR 22169 (Table 3).

[296] The Department will address these aspects of its proposal in a future final rule. While the Department is not finalizing its proposal, it is making nonsubstantive changes in provisions addressing the territories as a result of other changes in this final rule.

[297] The term ''affected workers'' refers to the population of potentially affected EAP workers who either pass the standard duties test and earn at least $684 but less than the new salary level of $1,128 per week or pass only the HCE duties test and earn at least $107,432 but less than the new HCE compensation level of $151,164 per year.

[298] Here and elsewhere in this analysis, numbers are reported at varying levels of aggregation, and are generally rounded to a single decimal point. However, calculations are performed using exact numbers. Therefore, some numbers may not match the reported totals or the calculations shown due to rounding of components.

[299] In later years, earnings growth will cause some initially affected workers to no longer be affected because their earnings will exceed the new salary or compensation threshold. This occurs both in update years (*i.e.,* triennially) and non-update years but will occur to a much greater degree in non-update years. Additionally, some workers will become newly affected because their earnings will reach at least $684 per week, and in the absence of this rule they would lose their overtime protections. To estimate the total number of affected workers over time, the Department accounts for both of these effects.

[300] Hereafter, unless otherwise specified, annualized values will be presented using the 7 percent real discount rate.

Table 2—Summary of Affected Workers, Regulatory Costs, and Transfers—Standard and HCE Salary Levels

Impact	Year 1	Future Years [a]		Annualized Value	
		Year 2	Year 10	3% Real Discount Rate	7% Real Discount Rate
Affected Workers (1,000s)					
Standard	4,045	3,783	4,978	[b]	[b]
HCE	293	323	1,015	[b]	[b]
Total	4,337	4,106	5,993	[b]	[b]
Costs and Transfers (Millions in $2022) [c]					
Direct employer costs	$1,436.2	$641.5	$906.1	$794.0	$802.9
Transfers [d]	$1,509.2	$1,094.3	$2,490.1	$1,565.2	$1,534.1

[a] These cost and transfer figures represent a range over the nine-year span.

[b] Not annualized.

[c] Costs and transfers for affected workers passing the standard and HCE tests are combined.

[d] This is the net transfer from employers to workers. There may also be transfers of hours and income from some workers to others.

B. Number of Affected EAP Workers

1. Overview

This section explains the methodology used to estimate the number of workers who will be affected by the final rule. The pool of potentially affected workers is workers who are currently EAP exempt. In this final rule, as in previous rules, the Department estimated the current number of EAP exempt workers because there is no data source that identifies workers as EAP exempt. Employers are not required to report EAP exempt workers to any central data collection agency or as part of any employee or establishment survey. The methodology described in this final rule is consistent with the approach the Department used in the 2004, 2016, and 2019 final rules.[301] To estimate the number of workers who will be affected by the rule, the new standard salary level and the new HCE total annual compensation threshold are applied to the earnings of current EAP exempt workers.

2. Data

All estimates of numbers of workers used in this analysis were based on data from the CPS MORG, which is sponsored jointly by the U.S. Census Bureau and BLS.[302] The CPS is a large, nationally representative sample. Households are surveyed for 4 months, excluded from the survey for 8 months, surveyed for an additional 4 months, then permanently dropped from the sample. During the last month of each rotation in the sample (month 4 and month 16), employed respondents complete a supplementary questionnaire in addition to the regular survey.[303] The data in this supplement contain the detailed information on earnings necessary to estimate a worker's exemption status. Responses are based on the reference week, which is always the week that includes the 12th day of the month.

Although the CPS MORG is a large-scale survey, administered to approximately 15,000 households monthly representing the entire nation, it is still possible to have relatively few observations when looking at subsets of employees, such as workers in a specific occupation employed in a specific industry, or workers in a specific geographic location. To increase the sample size, the Department pooled 3 years of CPS MORG data (2021–2023). Earnings for each observation from 2021 and 2022 were inflated to 2023 dollars using the Consumer Price Index for All Urban Consumers (CPI–U).[304] The weight of each observation was adjusted so that the total number of potentially affected EAP workers in the pooled sample remained the same as the number for the 2023 CPS MORG. Thus, the pooled CPS MORG sample uses roughly three times as many observations to represent the same total

[301] *See* 69 FR 22196–209; 81 FR 32453–60; 84 FR 51255–60. Where the proposal follows the methodology used to determine affected workers in the 2004, 2016, and 2019 final rules, citations to these rules are not always included.

[302] In 2015, RAND released results from a survey conducted to estimate EAP exempt workers. However, this survey does not have the variables or sample size necessary for the Department to base its regulatory impact analysis (RIA) on this analysis. Rohwedder, S. and Wenger, J.B. (2015). The Fair Labor Standards Act: Worker Misclassification and the Hours and Earnings Effects of Expanded Coverage. RAND Labor and Population.

[303] This is the outgoing rotation group (ORG); however, this analysis uses the data merged over 12 months and thus it is referred to as MORG.

[304] Previous rulemakings also adjusted salaries in the pooled data using the CPI–U, but the Department recognizes that the relationship between wage growth and inflation between 2021 and 2023 may not be consistent. During the pandemic, large employment losses in low-wage industries resulted in stronger wage growth at the aggregate level. In part of the 2021–2023 period, high inflation outpaced overall wage growth. Given these mixed effects, the Department decided to continue its prior practice of adjusting these observations using CPI–U.

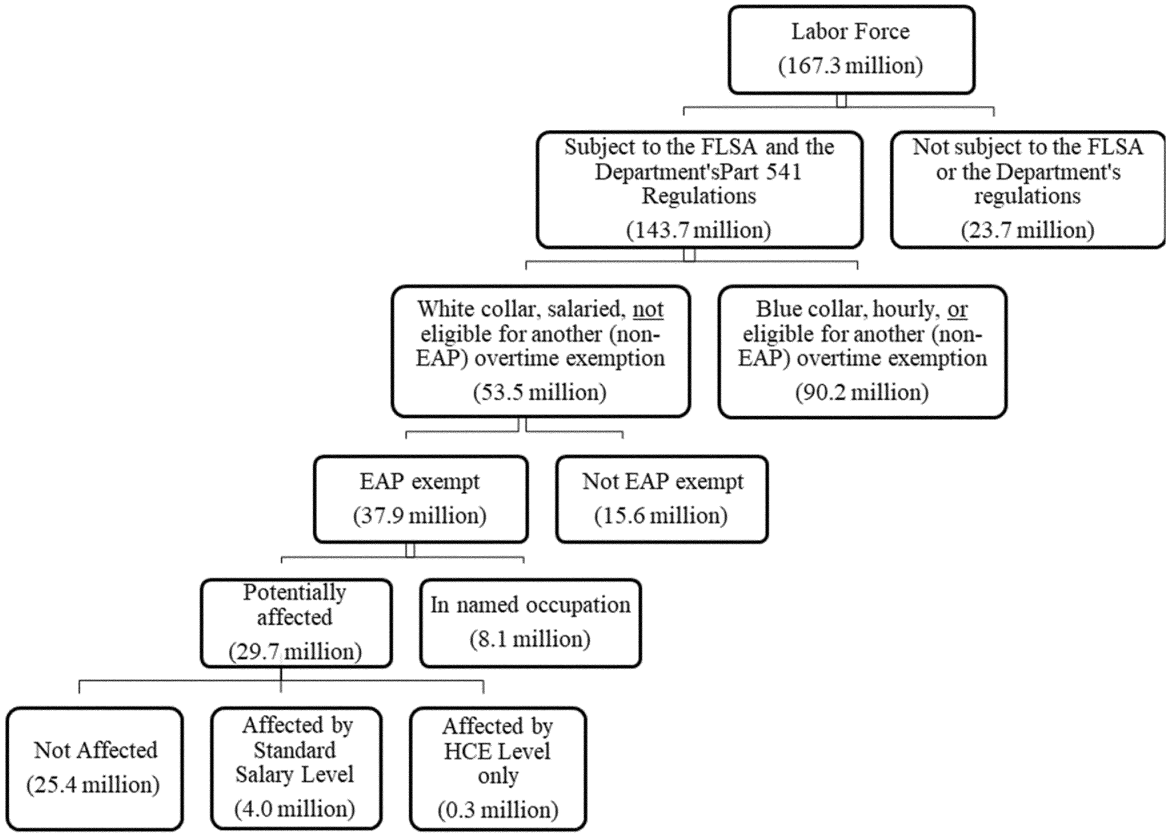
number of workers in 2023. The additional observations allow the Department to better characterize certain attributes of the potentially affected labor force. This pooled dataset is used to estimate all impacts of the final rule.

Some assumptions and adjustments were necessary to use these data as the basis for the analysis. For example, the Department eliminated workers who reported that their weekly hours vary and who provided no additional information on hours worked. This was done because the Department cannot estimate effects for these workers since it is unknown whether they work overtime and therefore unknown whether there would be any need to pay for overtime if their status changed from exempt to nonexempt. The Department reweighted the rest of the sample to account for this change (*i.e.,* to keep the same total employment estimates).[305] This adjustment assumes that the distribution of hours worked by workers whose hours do not vary is representative of hours worked by workers whose hours vary. The Department believes that without more information, this is an appropriate assumption.[306]

3. Number of Workers Subject to the FLSA and the Department's Part 541 Regulations

As a starting point for the analysis, based on the CPS MORG data, the Department estimates that there would be 167.3 million wage and salary workers in Year 1. Figure 1 illustrates how the Department analyzed the U.S. civilian workforce through successive stages to estimate the number of affected workers.

Figure 1—Flow Chart of FLSA Exemptions and Estimated Number of Affected Workers



Note: The NPRM referred to the group in the top box as "Wage and salary workers." Because the estimate in this box includes the unemployed, it has been renamed to "Labor Force" for accuracy.

The Department first excluded workers who are unemployed, not subject to its regulations, or not covered by the FLSA from the overall total number of wage and salary workers. Excluded workers include military personnel, unpaid volunteers, self-employed individuals, clergy and other religious workers, and Federal employees (with a few exceptions described below).

Many of these workers are excluded from the CPS MORG, including members of the military on active duty and unpaid volunteers. Self-employed and unpaid workers are included in the CPS MORG, but have no earnings data reported and thus are excluded from the analysis. The Department identified religious workers by their occupation codes: 'clergy' (Census occupational

[305] The Department also reweighted for workers reporting zero earnings. In addition, the Department eliminated, without reweighting, workers who reported both usually working zero hours and working zero hours in the past week.

[306] This is justifiable because demographic and employment characteristics are similar across these two populations (*e.g.,* age, gender, education, distribution across industries, share paid nonhourly). The share of all workers who stated that their hours vary (but provided no additional information) is 4.4 percent. To the extent these excluded workers are exempt, if they tend to work more overtime than other workers, then transfer payments and costs may be underestimated. Conversely, if they work fewer overtime hours, then transfer payments and costs may be overestimated.

code 2040), 'directors, religious activities and education' (2050), and 'religious workers, all other' (2060). Most employees of the Federal Government are covered by the FLSA but not the Department's part 541 regulations because the Office of Personnel Management (OPM) regulates their entitlement to minimum wage and overtime pay.[307] Exceptions exist for U.S. Postal Service employees, Tennessee Valley Authority employees, and Library of Congress employees.[308] The analysis identified and included these covered Federal workers using occupation and/or industry codes and removed other Federal employees.[309]

The FLSA also does not cover employees of firms that have annual revenue of less than $500,000 and who are not engaged in interstate commerce. The Department does not exclude them from the analysis, however, because there is no data set that would adequately inform an estimate of the size of this worker population, although the Department believes it is a small percentage of workers. The 2004, 2016, and 2019 final rules similarly did not adjust for these workers.

Of the 167.3 million wage and salary workers in the United States, the Department estimates that 143.7 million are covered by the FLSA and subject to the Department's regulations (85.9 percent). The remaining 23.7 million workers are excluded from FLSA coverage for the reasons described above.

4. Number of Workers Who Are White-Collar, Salaried, Not Eligible for Another (Non-EAP) Overtime Exemption

After limiting the analysis to workers covered by the FLSA and subject to the Department's part 541 regulations, several other groups of workers were identified and excluded from further analysis since this final rule is unlikely to affect them. These include blue-collar workers,[310] workers paid on an hourly basis, and workers who are exempt under certain other (non-EAP) exemptions.

The Department excluded a total of 90.2 million workers from the analysis for one or more of these reasons, which often overlapped (*e.g.,* many blue-collar workers are also paid hourly). For example, the Department estimated that there are 49.1 million blue-collar workers. These workers were identified in the CPS MORG data following the methodology from the U.S. Government Accountability Office's (GAO) 1999 white-collar exemptions report [311] and the Department's 2004, 2016, and 2019 regulatory impact analyses.[312] Supervisors in traditionally blue-collar industries were classified as white-collar workers because their duties are generally managerial or administrative, and therefore they were not excluded as blue-collar workers. Using the CPS variable indicating a respondent's hourly wage status, the Department determined that 80.3 million workers were paid on an hourly basis in 2023.[313]

Also excluded from further analysis were workers who are exempt under certain other (non-EAP) exemptions. Although some of these workers may also be exempt under the EAP exemptions, they would independently remain exempt from the FLSA's minimum wage and/or overtime pay provisions based on the non-EAP exemptions. The Department excluded an estimated 3.7 million workers, including some agricultural and transportation workers, from further analysis because they are subject to another (non-EAP) overtime exemption. *See* Appendix A: Methodology for Estimating Exemption Status, contained in the rulemaking docket, for details on how this population was identified.

Agricultural and transportation workers are two of the largest groups of workers excluded from the population of potentially affected EAP workers in the current analysis, and with some exceptions, they were similarly excluded in other recent rulemakings. The 2004 rule excluded all workers in agricultural industries from the analysis,[314] while more recent analyses only excluded agricultural workers from specified occupational-industry combinations since not all workers in agricultural industries qualify for the agricultural overtime pay exemptions. This final rule followed the more recent analyses and only excluded agricultural workers in certain occupation-industry combinations. [315] The exclusion of transportation workers matched the method for the 2004, 2016, and 2019 final rules. [316] Transportation workers are defined as those who are subject to the following FLSA exemptions: section 13(b)(1), section 13(b)(2), section 13(b)(3), section 13(b)(6), or section 13(b)(10). The Department excluded 1.0 million agricultural workers and 2.1 million transportation workers from the analysis.

In addition, the Department excluded another 22,700 workers who qualify for one or more other FLSA minimum wage and overtime exemptions (and are not either blue-collar or hourly). The criteria for determining exemption status for these workers are detailed in Appendix A.

After excluding workers not subject to the Department's FLSA regulations and workers who are unlikely to be affected by this final rule (*i.e.,* blue-collar workers, workers paid hourly, workers who are subject to another (non-EAP) overtime exemption), the Department estimated there are 53.5 million salaried white-collar workers for whom employers might claim either the standard EAP exemption or the HCE exemption.

5. Number of Current EAP Exempt Workers

To determine the number of workers for whom employers might currently claim the EAP exemption, the standard EAP test and HCE test were applied. Both tests include earnings thresholds and duties tests. Aside from workers in named occupations (which are not subject to an earnings requirement and are discussed in the next subsection), to be exempt under the standard EAP test, the employee generally must:

- be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test); [317]

[307] *See* 29 U.S.C. 204(f). Federal workers are identified in the CPS MORG with the class of worker variable PEIO1COW.

[308] *See id.*

[309] Postal Service employees were identified with the Census industry classification for postal service (6370). Tennessee Valley Authority employees were identified as Federal workers employed in the electric power generation, transmission, and distribution industry (570) and in Kentucky, Tennessee, Mississippi, Alabama, Georgia, North Carolina, or Virginia. Library of Congress employees were identified as Federal workers under Census industry 'libraries and archives' (6770) and residing in Washington DC.

[310] ''The section 13(a)(1) exemptions and the regulations in [Part 541] do not apply to manual laborers or other 'blue collar' workers who perform work involving repetitive operations with their hands, physical skill and energy.'' § 541.3(a).

[311] GAO/HEHS. (1999). Fair Labor Standards Act: White Collar Exemptions in the Modern Work Place. GAO/HEHS–99–164, 40–41, *https://www.gao.gov/assets/230/228036.pdf.*

[312] *See* 69 FR 22240–44.

[313] CPS MORG variable PEERNHRY.

[314] 69 FR 22197.

[315] 84 FR 51257; 81 FR 32456, n.114.

[316] 84 FR 51257; 81 FR 32456–57; 69 FR 22197.

[317] Some computer employees may be exempt even if they are not paid on a salary basis. Hourly computer employees who earn at least $27.63 per hour and perform certain duties are exempt under section 13(a)(17) of the FLSA. These workers are considered part of the EAP exemptions but were excluded from the analysis because they are paid hourly and will not be affected by this rule (these workers were similarly excluded in the 2004, 2016, and 2019 analyses). Salaried computer workers are exempt if they meet the salary and duties tests applicable to the EAP exemptions and are included in the analysis since they will be impacted by this rule. Additionally, administrative and professional employees may be paid on a fee basis, as opposed to a salary basis. § 541.605(a). Although the CPS

• earn at least a designated salary amount (the standard salary level test, currently $684 per week); and

• primarily perform exempt work, as defined by the regulations (the standard duties test).

The HCE test allows certain highly paid employees to qualify for exemption if they customarily and regularly perform one or more exempt job duties (the HCE duties test). The current HCE annual compensation level is $107,432, including at least $684 per week paid on a salary or fee basis.

i. Salary Basis

The Department included only nonhourly workers in the analysis based on CPS data.[318] For this NPRM, the Department considered data representing compensation paid to nonhourly workers to be an appropriate proxy for compensation paid to salaried workers. The Department notes that it made the same assumption regarding nonhourly workers in the 2004, 2016, and 2019 final rules.[319]

The CPS population of ''nonhourly'' workers includes salaried workers along with those who are paid a piece rate, day rate, or largely on bonuses or commissions. Data in the CPS are not available to distinguish between salaried workers and these other nonhourly workers. However, the Panel Study of Income Dynamics (PSID) provides additional information on how nonhourly workers are paid.[320] In the PSID, respondents are asked how they are paid on their main job and are also asked for more detail if their response is other than salaried or hourly. Possible responses include piecework, commission, self-employed/farmer/profits, and by the job/day/mile. The Department analyzed the PSID data and found that relatively few nonhourly workers were paid by methods other than salaried. The Department is not aware of any statistically robust source that more closely reflects salary as defined in its regulations.

ii. Salary Level

Weekly earnings are available in the CPS MORG data, which allowed the Department to estimate how many nonhourly workers pass the compensation thresholds.[321] However, the CPS earnings variable does not perfectly reflect the Department's definition of earnings. First, the CPS includes all nondiscretionary bonuses and commissions if they are part of usual weekly earnings. However, the regulation allows nondiscretionary bonuses and commissions to satisfy up to 10 percent of the standard salary level. This discrepancy between the earnings variable used and the regulatory definition of salary may cause a slight overestimation or underestimation of the number of workers estimated to meet the standard salary level and HCE compensation tests.[322] Second, CPS earnings data include overtime pay. The Department notes that employers may factor into an employee's salary a premium for expected overtime hours worked. To the extent they do so, that premium would be reflected accurately in the data. Third, the earnings measure includes tips and discretionary commissions which do not qualify towards the required salary. The Department believes tips are an uncommon form of payment for these white-collar workers. Discretionary commissions tend to be paid irregularly and hence are unlikely to be counted as ''usual earnings.'' Additionally, as noted above, most salaried workers do not receive commissions.

Lastly, the CPS annual earnings variable is topcoded at $150,000 through the March 2023 data.[323] Topcoding refers to how data sets handle observations at the top of the distribution and is performed to protect the confidentiality of data provided by CPS respondents. For the CPS annual earnings variable, workers earning above $2,884.61 ($150,000 ÷ 52 weeks) per week are reported as earning $2,884.61 per week. The Department imputed earnings for topcoded workers in the CPS data to adequately estimate impacts.[324]

iii. Duties

The CPS MORG data do not capture information about job duties. Therefore, the Department used probability estimates of passing the duties test by occupational title to estimate the number of workers passing the duties test. This is the same methodology used in recent part 541 rulemakings, and the Department believes it continues to be the best available methodology. The probabilities of passing the duties test are from an analysis performed by WHD in 1998 in response to a request from the GAO. Because WHD enforces the FLSA's overtime requirements and regularly assesses workers' exempt status, WHD was uniquely qualified to provide the analysis. The analysis was originally published in the GAO's 1999 white-collar exemptions report.[325]

WHD examined 499 occupational codes and determined that 251 occupational codes likely included EAP exempt workers.[326] For each, WHD assigned one of four probability codes reflecting the estimated likelihood, expressed as ranges, that a worker in that occupation would perform duties required to meet the EAP duties tests (Table 3). All occupations and their associated probability codes are listed in Appendix A. Just as in the 2004, 2016, and 2019 final rules, the Department has supplemented this analysis to account for the HCE exemption. The Department modified the four probability codes to reflect probabilities of passing the HCE duties test based on its analysis of the provisions of the highly compensated test relative to the standard duties test. To illustrate, WHD assigned exempt probability code 4 to the occupation ''first-line supervisors/managers of construction trades and extraction workers'' (Census code 6200), which indicates that a worker in this occupation has a 0 to 10 percent likelihood of meeting the standard EAP duties test. However, if that worker earned at least $100,000 annually (now $107,432 annually), they were assigned a 15 percent probability of passing the more lenient HCE duties test.[327]

MORG does not identify workers paid on a fee basis, they are considered nonhourly workers in the CPS and consequently are correctly classified as ''salaried'' (as was done in previous rules).

[318] The CPS variable PEERNHRY identifies workers as either hourly or nonhourly.

[319] *See* 69 FR 22197; 81 FR 32414; 84 FR 51258.

[320] University of Michigan, Institute for Social Research. 2019 PSID. Data available at: *https://simba.isr.umich.edu/data/data.aspx.*

[321] The CPS MORG variable PRERNWA, which measures weekly earnings, is used to identify weekly salary.

[322] In some instances, this may include too much nondiscretionary bonuses and commissions (*i.e.,* when it is more than 10 percent of usual earnings). But in other instances, it may not include enough nondiscretionary bonuses and commissions (*i.e.,* when the respondent does not count them as usual earnings).

[323] Beginning in the April 2023 data, the CPS data are topcoded independently each month and represent the average earnings of the top 3 percent of earnings reported. *See https://www.census.gov/content/dam/Census/programs-surveys/cps/updated-2022-cps-puf-changes.pdf* for additional details.

[324] The Department used the standard Pareto distribution approach to impute earnings above the topcoded value as described in Armour, P. and Burkhauser, R (2013). Using the Pareto Distribution to Improve Estimates of Topcoded Earnings. Center for Economic Studies (CES).

[325] Fair Labor Standards Act: White Collar Exemptions in the Modern Work Place, *supra* note 311, at 40–41.

[326] WHD excluded nine that were not relevant to the analysis for various reasons. For example, one code was assigned to unemployed persons whose last job was in the Armed Forces, some codes were assigned to workers who are not FLSA covered, others had no observations.

[327] The HCE duties test is used in conjunction with the HCE total annual compensation requirement to determine eligibility for the HCE

Continued

Table 3—Probability Worker in Category Passes the Duties Tests

Probability Code	The Standard EAP Test		The HCE Test	
	Lower Bound	Upper Bound	Lower Bound	Upper Bound
0	0%	0%	0%	0%
1	90%	100%	100%	100%
2	50%	90%	94%	96%
3	10%	50%	58.4%	60%
4	0%	10%	15%	15%

exemption. It is much less stringent than the standard and short duties tests to reflect that very highly paid employees are much more likely to be properly classified as exempt.

The occupations identified in GAO's 1999 report map to an earlier occupational classification scheme (the 1990 Census occupational codes).[328] For this final rule, the Department used occupational crosswalks to map the previous occupational codes to the 2018 Census occupational codes, which are used in the CPS MORG 2021 through 2023 data. If a new occupation comprises more than one previous occupation, then the new occupation's probability code is the weighted average of the previous occupations' probability codes, rounded to the closest probability code.

These codes provide information on the likelihood that an employee met the duties tests, but they do not identify which workers in the CPS MORG met the duties test. For example, for every ten public relations managers, between five and nine are assumed to meet the standard duties test (based on probability category 2). However, it is unknown which of these ten workers are exempt; therefore, for the purposes of producing an estimate, the Department must assign a status to these workers. Exemption status could be randomly assigned with equal probability, but this would ignore the earnings of the worker as a factor in determining the probability of exemption. The probability of qualifying for the exemption increases with earnings because higher paid workers are more likely to perform the required duties.[329]

The Department estimated the probability of qualifying for the standard exemption for each worker as a function of both earnings and the occupation's exempt probability category using a gamma distribution.[330] Based on these revised probabilities, each worker was assigned exempt or nonexempt status based on a random draw from a binomial distribution using the worker's revised probability as the probability of success. Thus, if this method is applied to ten workers who each have a 60 percent probability of being exempt, six workers would be expected to be designated as exempt.[331] For details, *see* Appendix A (in the rulemaking docket).

As previously discussed in section V.B.5, some commenters challenged the Department's use of its probability codes to determine whether a worker meets the duties test. The Department acknowledges that the probability codes used to determine the share of workers in an occupation who are EAP exempt are 25 years old. However, the Department believes the probability codes continue to estimate exemption status accurately given the fact that the standard duties test is not substantively different from the former short duties tests reflected in the codes. For the 2016 rulemaking, the Department reviewed O*NET[332] to determine the extent to which the 1998 probability codes reflected current occupational duties. The Department's review of O*NET verified the continued appropriateness of the 1998 probability codes.[333] The 2019 final rule also used these probability codes and likewise found that these codes are the best available methodology to accurately estimate exemption status.[334]

The Department estimates that of the existing 53.5 million salaried white-collar workers considered in the analysis, 37.9 million currently qualify for the EAP exemption.

6. Potentially Affected Exempt EAP Workers

The Department excluded some of the current EAP exempt workers from further analysis because the final rule will not affect them. Specifically, the Department excluded workers in named occupations who are not required to pass the salary requirements (although they must still pass a duties test) and therefore whose exemption status does not depend on their earnings. These occupations include physicians (identified with Census occupation codes 3010, 3040, 3060, 3120), lawyers (2100), teachers (occupations 2200–2550 and industries 7860 or 7870), academic administrative personnel (school counselors (occupation 2000 and industries 7860 or 7870) and educational administrators (occupation 0230 and industries 7860 or 7870)), and outside sales workers (a subset of occupation 4950). Out of the 37.9 million workers who were EAP exempt, 8.1 million, or 21.4 percent, were expected to be in named occupations.

[328] Census occupation codes were also updated in 2002 and 2010. References to occupational codes in this analysis refer to the 2002 Census occupational codes. Crosswalks and methodology available at: *https://www.census.gov/topics/employment/industry-occupation/guidance/code-lists.html*.

[329] For the standard exemption, the relationship between earnings and exemption status is not linear and is better represented with a gamma distribution. For the HCE exemption, the relationship between earnings and exemption can be well represented with a linear function because the relationship is linear at high salary levels (as determined by the Department in the 2004 rule). Therefore, the gamma model and the linear model would produce similar results for highly compensated workers. *See* 69 FR 22204–08, 22215–16.

[330] The gamma distribution was chosen because, during the 2004 revision, this non-linear distribution best fit the data compared to the other non-linear distributions considered (*i.e.,* normal and lognormal). A gamma distribution is a general type of statistical distribution that is based on two parameters that control the scale (alpha) and shape (in this context, called the rate parameter, beta).

[331] A binominal distribution is frequently used for a dichotomous variable where there are two possible outcomes; for example, whether one owns a home (outcome of 1) or does not own a home (outcome of 0). Taking a random draw from a binomial distribution results in either a zero or a one based on a probability of ''success'' (outcome of 1). This methodology assigns exempt status to the appropriate share of workers without biasing the results with manual assignment.

[332] The O*NET database contains hundreds of standardized and occupation-specific descriptors. *See https://www.onetcenter.org*.

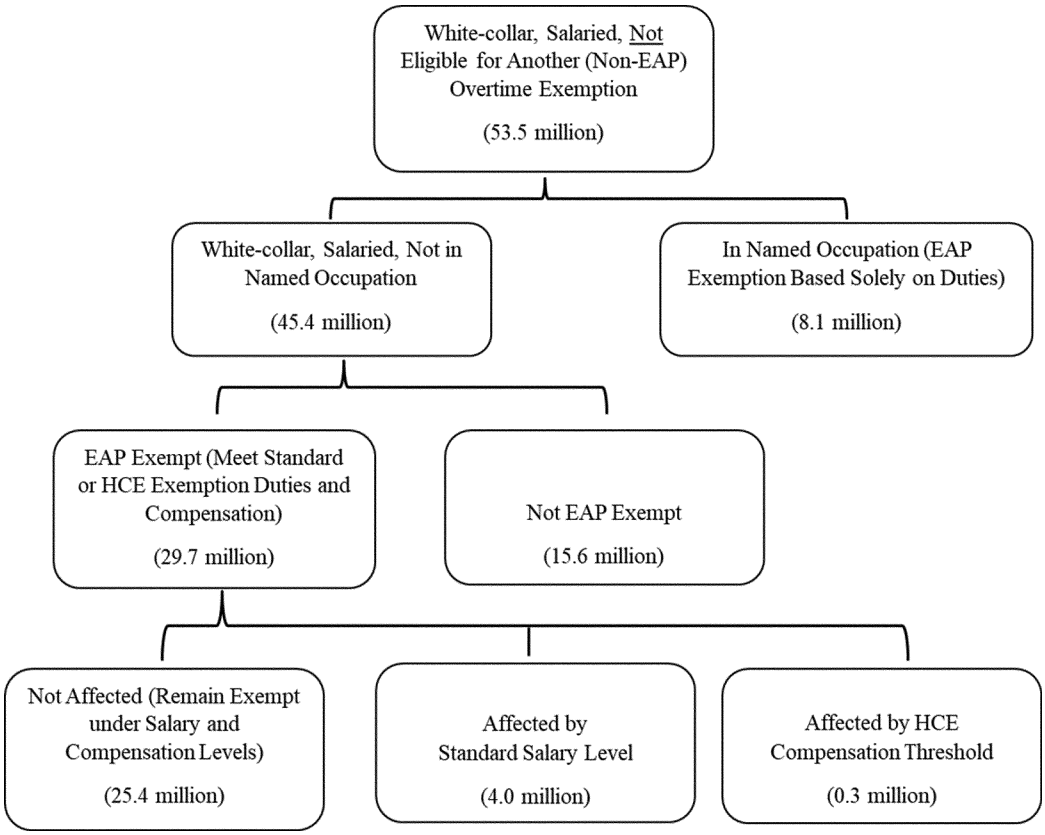
[333] 81 FR 32459.

[334] 84 FR 51259.

Thus, the changes to the standard salary level and HCE compensation tests would not affect these workers. The 29.7 million EAP exempt workers remaining in the analysis are referred to in this final rule as ''potentially affected'' (17.8 percent of all workers).

Based on analysis of the occupational codes and CPS earnings data (described above), the Department has concluded there are 29.7 million potentially affected EAP workers.[335]

Figure 2—Exemption Status and Number of Affected Workers



As shown in Figure 2 above, 8.1 million of the 53.5 million salaried white-collar workers are in named occupations and will not be affected by a change in the earnings requirements. The Department also estimates that of the remaining 45.4 million salaried white-collar workers, about 12.7 million earn below the Department's new standard salary level of $1,128 per week and about 32.7 million earn above the Department's new salary level. Thus, approximately 28 percent of salaried white-collar employees earn below the new salary level, whereas approximately 72 percent of salaried white-collar employees earn above the salary level and will have their exemption status turn on their job duties.

7. Number of Affected EAP Workers

The Department estimated that the increase in the standard salary level from $684 per week to $1,128 per week will affect 4.0 million workers in Year 1 (of these 4.0 million affected employees, 1.8 million earn less than the long test salary level ($942)).[336] The Department estimated that the increase in the HCE annual compensation level from $107,432 to $151,164 will impact 292,900 workers (Figure 3).[337] In total, the Department expects that 4.3 million workers out of the 29.7 million potentially affected workers will be affected in Year 1. This estimate of 4.3 million affected workers represents only approximately 10 percent of all salaried white-collar workers who are not in named occupations (45.4 million).

As illustrated in Figure 1 above, this final rule affects a specific and small portion of all employed workers. In particular, the number of affected workers is 2.6% of total employed workers in 2023 and represents about 8 percent of all white-collar salaried workers (including workers in named occupations). While Figure 1 provides a snapshot of the impacts of this rule in the context of the broader labor market of 2023, it may also be helpful to understand how the labor market has grown since the Department first introduced a one-test system in 2004. Broadly, since 2004 the size of the labor force and the white-collar workforce has grown considerably. Between 2004 and 2023, total employment grew by 21.8 million, with employment increasing by nearly 10 million since 2016 and 3.5

[335] Of these workers, approximately 16.5 million pass only the standard test, 12.8 million pass both the standard and the HCE tests, and 446,600 pass only the HCE test.

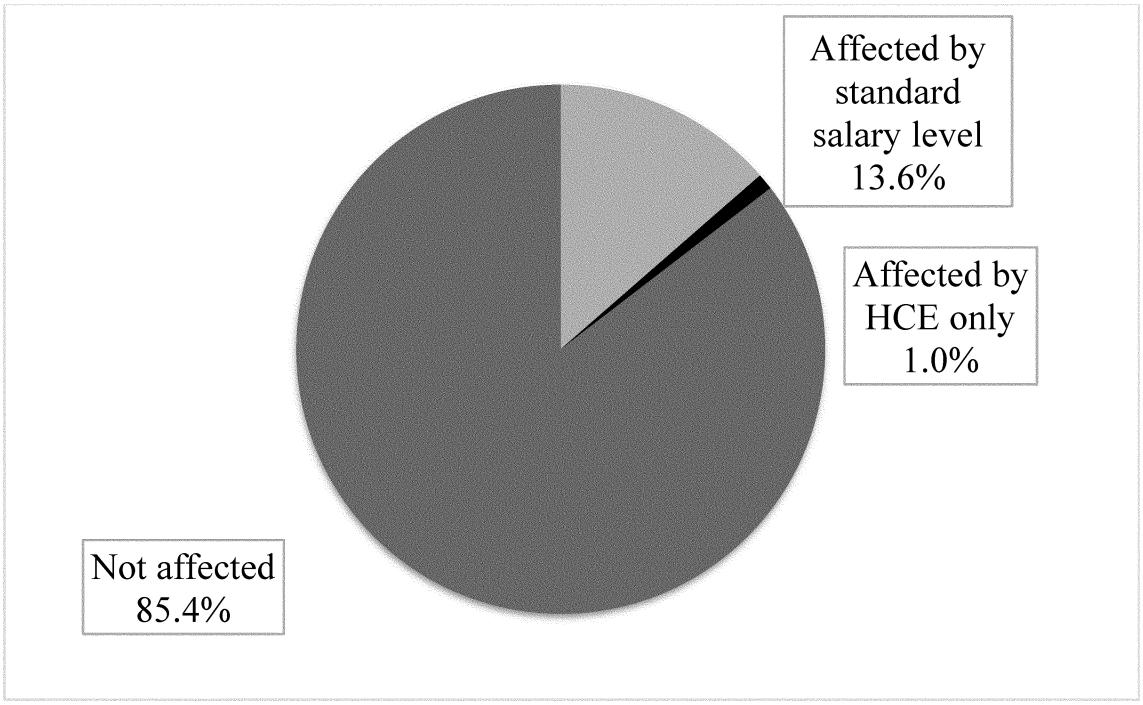
[336] *See* section VII.C.8 (Alternative 2). As discussed in section V.B, such employees were always excluded from the EAP exemption prior to 2019, either by the long test salary level itself, or under the 2004 rule salary level, which was equivalent to the long test salary level. The remaining 2.2 million of these affected employees earn between the long test salary level and the Department's new standard salary level.

[337] This group includes workers who may currently be nonexempt under more protective state EAP laws and regulations, such as some workers in Alaska, California, Colorado, Maine, New York, Washington, and Wisconsin.

[338] Employment status of the civilian noninstitutional population, 1953 to date. BLS

million since 2019.[338] Over this period, the size of the white-collar workforce has also increased considerably. In 2004, the total number of white-collar workers who were subject to the Part 541 regulations, including the salary level test, was 31.7 million. By 2016 it had reached 37.4 million; in 2019 it was 39.8 million; and in 2023 it was nearly 45.4 million.

Figure 3—Pie Chart of Potentially Affected Employees and Their Affected Status



Several commenters stated that the Department's estimates of affected workers were incorrect because of the application of the probability codes. For example, NCFC stated that ''the Department's impact calculations rely on outdated and flawed data'' because the ''Department's predictions as to the probability of employees passing the duties test are based on a 1999 study . . . which itself relied upon information provided by DOL in the 1990s—more than three decades ago.'' AFPI further added that since the Department's probability codes were developed, ''occupational codes have changed; the Part 541 duties tests have changed; and litigation has resulted in thousands of court decisions finding employees to be exempt or non-exempt.'' Similarly, NRF included a report by Oxford Economics stating that there have been numerous economics changes since 1998, ''includ[ing] increases in automation, virtual work, computerized scheduling, and the effects of a global pandemic.'' [339] The Oxford Economics report also stated that ''if the relationship between salaried [status] and EAP exemption status is tighter than the [Department] . . . assumes,'' the number of affected workers could be as high as 7.2 million. AFPI asserted that approximately ''7.5 million employees would be non-exempt for the first time based on salary alone[.]'' Rachel Greszler stated that the correct figure is as high as 12.3 million workers.

The Department disagrees with commenters that challenged its use of its probability codes. The Department has used its probability codes to estimate the number of workers who meet the duties test in its 2004, 2016, and 2019 rules. The Department reiterates that these codes have been updated and mapped onto current occupational codes, as explained above. As also noted above, the standard duties test is not substantively different from the former short duties tests reflected in the codes. In consequence, the probability codes remain relevant and are currently the most accurate way to estimate the probability of a worker satisfying the duties test. Furthermore, while several occupations have changed over time, modifications affecting specific occupations would only affect the validity of these probability codes if they systematically affected an occupation's probability of performing exempt tasks. In contrast, other changes, such as employees performing remotely the job duties they once performed in-person, do not affect the validity of these probabilities. Additionally, the probability codes can still effectively predict whether employees in new industries will meet the duties test insofar as these occupations existed in other industries. Finally, as previously noted, the Department used the O*NET database to confirm the appropriateness of the probability codes in 2016. Commenters did not provide a basis for concluding that the Department's 2016 evaluation is obsolete or that the probability codes no longer provide the most reasonable basis for estimating the population of affected workers.

Current Population Survey. *https://www.bls.gov/cps/cpsaat01.htm.*

[339] The Oxford Economics report also noted that there has been a 6-percent rise in ''the share of salaried workers in the economy . . . since 1998.'' However, any increase in the number of salaried workers does not have any bearing on the validity of the probability codes, which the Department uses to estimate whether a worker passes the duties test. Being paid on a salary basis is one of the three tests for exemption, *see* § 541.602(a), and is distinct from the duties test. Accordingly, the Department only applies the probability codes to nonhourly workers—whom, as discussed above, the Department considers to be an appropriate proxy for workers paid on a salary basis.

The Department also does not agree with commenters that stated that it underestimated the number of affected workers in the NPRM. As discussed above, *see* section V.B.5.iii, commenters that asserted the number of affected workers could be much higher generally referenced estimates of the number of workers earning between the current salary level and the proposed salary level, regardless of whether they passed the duties test, and then posited that up to that many workers (*e.g.,* 7.2 million, 7.5 million, or 12.3 million) could be affected. The position that all workers earning below the new salary level, regardless of their duties, will be affected by the new salary level fails to account for the fact that that millions of these workers are already nonexempt because they do not meet the duties test.

C. Effects of Revised Salary and Compensation Levels

1. Overview and Summary of Quantified Effects

The Department is setting the standard salary level using the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census region (currently the South) and setting the HCE compensation level at the annualized weekly earnings of the 85th percentile of full-time salaried workers nationwide. In both cases the Department used 2023 CPS data to calculate the levels.[340]

Transfers both from employers to employees and between employees, and direct employer costs, will depend on how employers respond to this rulemaking. Employer response is expected to vary by the characteristics of the affected EAP workers. Assumptions related to employer responses are discussed below.

Table 4 presents the estimated number of affected workers, costs, and transfers associated with increasing the standard salary and HCE compensation levels. The Department estimated that the direct employer costs of this rule will total $1.4 billion in the first year, with 10-year annualized direct costs of $802.9 million per year using a 7 percent discount rate.

In addition to these direct costs, this rule will transfer income from employers to employees. Estimated Year 1 transfers will equal $1.5 billion, with annualized transfers of $1.5 billion per year using the 7 percent real discount rates and $1.6 billion using the 3 percent discount rate. Potential employer costs due to reduced profits and additional hiring were not quantified but are discussed in section VII.C.3.v. These estimates encompass in Year 1 both the impact of the initial update to the earnings thresholds and the change in those thresholds that will become applicable 6 months later.[341]

[340] Full-time is defined as 35 or more hours per week.

[341] The Department estimates the initial update to the standard salary level will result in 959,000 affected workers earning between $684 and $844 per week. The Department estimates the adjustment and managerial costs for this update will be $202.3 million and transfers will be $204.3 million. For the initial update to the HCE total annual compensation threshold, the Department estimates that the update will result in 223,000 affected workers, $58.7 million in adjustment and managerial costs, and $164.5 million in transfer payments.

Table 4—Summary of Affected Workers and Regulatory Costs and Transfers

Impact [a]	Year 1	Future Years [b]		Annualized Value	
		Year 2	Year 10	3% Real Discount Rate	7% Real Discount Rate
Affected Workers (1,000s)					
Standard	4,045	3,783	4,978	[c]	[c]
HCE	293	323	1,015	[c]	[c]
Total	4,337	4,106	5,993	[c]	[c]
Direct Employer Costs (Millions in $2023)					
Regulatory familiarization	$451.6	$0.0	$68.9	$71.8	$79.3
Adjustment [c]	$299.1	$9.4	$20.9	$44.6	$50.0
Managerial	$685.5	$632.1	$816.3	$677.6	$673.6
Total direct costs [d]	$1,436.2	$641.5	$906.1	$794.0	$802.9
Transfers from Employers to Workers (Millions in $2023) [e]					
Due to minimum wage	$87.5	$46.5	$22.6	$43.2	$44.8
Due to overtime pay	$1,421.7	$1,047.8	$2,467.5	$1,522.0	$1,489.3
Total transfers [f]	$1,509.2	$1,094.3	$2,490.1	$1,565.2	$1,534.1

[a] Additional costs and benefits of the rule that could not be quantified or monetized are discussed in the text.

[b] These costs/transfers represent a range over the nine-year span.

[c] Not annualized.

[d] Adjustment costs occur in all years when there are newly affected workers. Adjustment costs may occur in years without updated earnings thresholds because some workers' projected earnings are estimated using negative earnings growth.

[e] Components may not add to total due to rounding.

[f] This is the net transfer from employers to workers. There may also be transfers between workers.

2. Characteristics of Affected EAP Workers

Table 5 presents the number of affected EAP workers, the mean number of overtime hours they work per week, and their average weekly earnings. The Department considered two types of overtime workers in this analysis: regular overtime workers and occasional overtime workers.[342] Regular overtime workers typically worked more than 40 hours per week. Occasional overtime workers typically worked 40 hours or less per week, but they worked more than 40 hours in the week they were surveyed. The Department considered these two populations separately in the analysis because labor market responses to overtime pay requirements may differ for these two types of workers.

The 4.0 million workers affected by the combined effect of the initial update and the subsequent application of the new standard salary level work on average 1.6 usual hours of overtime per week and earn on average $948 per week.[343] However, most of these workers (about 86 percent) usually do not work overtime. The 14 percent of affected workers who usually work overtime average 11.1 hours of overtime per week. In a representative week, roughly 135,000 (or 3.3 percent) of the 4.0 million affected workers occasionally work overtime; they averaged 8.5 hours of overtime in the weeks they worked overtime.[344] Finally, 20,000 (or 0.5 percent) of all workers affected by the increase in the standard salary level earn less than the minimum wage. [345]

[342] Regular overtime workers were identified in the CPS MORG with variable PEHRUSL1. Occasional overtime workers were identified with variables PEHRUSL1 and PEHRACT1.

[343] CPS defines ''usual hours'' as hours worked 50 percent or more of the time.

[344] This group represents the number of workers with occasional overtime hours in the week the CPS MORG survey was conducted. Because the survey week is a representative week, the Department believes the prevalence of occasional overtime in the survey week and the characteristics of these workers are representative of other weeks (even though a different group of workers would be identified as occasional overtime workers in a different week).

[345] A small proportion (0.5 percent) of all affected EAP workers earn implicit hourly wages that are less than the applicable minimum wage (the higher of the state or Federal minimum wage). The implicit hourly wage is calculated as total weekly earnings divided by total weekly hours worked. For example, workers earning the $684 per week standard salary level would earn less than the Federal minimum

Continued

The 292,900 workers affected by the change in the HCE compensation level average 2.9 hours of overtime per week and earn an average of $2,397 per week ($124,668 per year). About 73 percent of these workers do not usually work overtime, while the 27 percent who usually work overtime average 11.0 hours of overtime per week. Among the 2.6 percent who occasionally work overtime, they averaged 8.2 hours in the weeks that they worked overtime.

Although most affected workers who typically do not work overtime will be unlikely to experience significant changes in their daily work routine, those who regularly work overtime may experience significant changes. Moreover, affected EAP workers who routinely work overtime and earn less than the minimum wage will be most likely to experience significant changes. Impacts on employee hours and earnings are discussed further in section VII.C.4.

Table 5—Number of Affected EAP Workers, Mean Overtime Hours, and Mean Weekly Earnings, Year 1

Type of Affected EAP Worker	Affected EAP Workers [a]		Mean Overtime Hours	Mean Usual Weekly Earnings
	Number (1,000s)	% of Total		
Standard Salary Level				
All affected EAP workers	4,045	100%	1.6	$948
Earn less than the minimum wage [b]	20	0.5%	25.8	$828
Regularly work overtime	575	14.2%	11.1	$959
Occasionally work overtime [c]	135	3.3%	8.5	$955
HCE Compensation Level				
All affected EAP workers	293	100%	2.9	$2,397
Earn less than the minimum wage [b]	--	--	--	--
Regularly work overtime	78	26.7%	11.0	$2,406
Occasionally work overtime [c]	8	2.6%	8.2	$2,392

Note: Pooled CPS data for 2021–2023 adjusted to reflect 2023.

[a] Estimated number of workers exempt under the EAP exemptions who will be entitled to overtime protection under the updated salary levels (if their weekly earnings do not increase to the new salary levels).

[b] The applicable minimum wage is the higher of the Federal minimum wage and the state minimum wage. These workers all regularly work overtime and are also included in that row. HCE workers will not be affected by the minimum wage provision.

[c] Workers who do not usually work overtime but did in the CPS reference week. Mean overtime hours are actual overtime hours in the reference week. Other workers may occasionally work overtime in other weeks.

This section characterizes the population of affected workers by industry, occupation, employer type, location of residence, and demographics. The Department chose to provide as much detail as possible while maintaining adequate sample sizes.

Table 6 presents the distribution of affected EAP workers by industry and occupation, using Census industry and occupation codes. The industry with the most affected EAP workers is professional and business services (827,000), while the industry with the highest percentage of EAP workers affected is leisure and hospitality (about 24 percent). The occupational category with the most affected EAP workers is management, business, and financial (2.0 million), while the occupation category with the highest percentage of EAP workers affected is farming, fishing, and forestry (about 45 percent).

Potentially affected workers in private-sector nonprofits are more likely to be affected than workers in private-sector for-profit firms (18.9 percent compared with 13.6 percent). However, as discussed in section VII.B.3, the estimates of workers subject to the FLSA include workers employed by enterprises that are not subject to the FLSA under the law's enterprise coverage requirements because there is no data set that would adequately inform an estimate of the size of this worker population in order to exclude them from these estimates. Although failing to exclude workers who work for non-covered enterprises would only affect a small percentage of workers generally, it may have a larger effect (and result in a larger overestimate) for workers in nonprofits because when determining FLSA enterprise coverage only revenue derived from business operations, not charitable activities, is included.

wage if they work 95 or more hours in a week ($684 ÷ 95 hours = $7.20 per hour).

Table 6—Estimated Number of Workers and Whether They Will Be Affected by the New Earnings Thresholds, by Industry and Occupation, Year 1

Industry / Occupation / Nonprofit	Workers subject to FLSA (Millions)	Potentially Affected EAP Workers (Millions) [a]	Not-Affected (Millions) [b]	Affected (Millions) [c]	Affected as Share of Potentially Affected
Total	143.68	29.75	25.41	4.34	14.6%
By Industry [d]					
Agriculture, forestry, fishing, & hunting	1.31	0.06	0.05	0.01	22.8%
Mining	0.59	0.16	0.14	0.02	11.8%
Construction	9.31	1.27	1.08	0.18	14.6%
Manufacturing	15.52	4.06	3.71	0.35	8.6%
Wholesale trade	3.16	0.85	0.74	0.11	13.2%
Retail trade	15.65	1.97	1.59	0.38	19.2%
Transportation & utilities	8.90	1.07	0.92	0.15	14.3%
Information	2.71	1.08	0.95	0.13	12.2%
Financial activities	9.93	4.35	3.79	0.56	13.0%
Professional & business services	17.46	7.13	6.30	0.83	11.6%
Education	14.29	1.20	0.96	0.24	20.3%
Healthcare & social services	21.03	3.75	3.01	0.74	19.8%
Leisure & hospitality	12.53	0.94	0.71	0.23	24.3%
Other services	5.53	0.76	0.60	0.16	21.5%
Public administration	5.75	1.10	0.88	0.23	20.6%
By Occupation [d]					
Management, business, & financial	24.74	15.32	13.33	1.99	13.0%
Professional & related	35.90	10.72	9.23	1.49	13.9%
Services	22.85	0.15	0.10	0.04	28.7%
Sales and related	12.66	2.41	1.96	0.46	18.9%
Office & administrative support	15.98	0.93	0.61	0.32	34.4%
Farming, fishing, & forestry	0.91	0.00	0.00	0.00	44.7%

Construction & extraction	6.97	0.03	0.02	0.01	21.9%
Installation, maintenance, & repair	4.58	0.05	0.04	0.01	15.3%
Production	8.18	0.09	0.08	0.01	10.8%
Transportation & material moving	10.91	0.05	0.04	0.01	24.8%
By Nonprofit and Government Status					
Nonprofit, private	10.17	2.44	1.98	0.46	18.9%
For profit, private	114.56	24.95	21.56	3.39	13.6%
Government (state, local, and Federal)	18.95	2.35	1.86	0.48	20.6%

Note: Pooled CPS data for 2021–2023 adjusted to reflect 2023.

[a] Exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.

[b] Workers who continue to be exempt after the increases in the salary levels (assuming affected workers earning below the new salary level do not have their weekly earnings increased to the new level).

[c] Estimated number of workers exempt under the EAP exemptions who will be entitled to overtime protection under the updated salary levels (if their weekly earnings do not increase to the new salary levels).

[d] Census industry and occupation categories.

Table 7 presents the distribution of affected EAP workers based on Census Regions and Divisions, and metropolitan statistical area (MSA) status. The region with the most affected workers will be the South (1.9 million), but the South's percentage of potentially affected workers who are estimated to be affected is relatively small (17.9 percent). Although 90 percent of affected EAP workers will reside in MSAs (3.92 of 4.34 million), so do a corresponding 88 percent of all workers subject to the FLSA.[346]

Employers in low-wage industries, regions, and in non-metropolitan areas may be more affected because they typically pay lower wages and salaries. The Department believes the salary level included in this rule is appropriate for these lower-wage sectors, in part because the methodology uses earnings data from the lowest-wage census region. Moreover, the duties test will continue to determine exemption status for the vast majority of workers in low-wage regions and industries under the rule. For example, as displayed in Table 7, 82.1 percent of potentially affected EAP workers in the South Census Region earn more than the new salary levels and thus will not be affected by the rule (8.59 ÷ 10.46). Effects by region and industry are considered in section VII.C.7.

[346] Identified with CPS MORG variable GTMETSTA.

Table 7—Estimated Number of Workers and Whether They Will Be Affected by the New Earnings Thresholds, by Region, Division, and MSA Status, Year 1

Region / Division / Metropolitan Status	Workers subject to FLSA (Millions)	Potentially Affected EAP Workers (Millions) [a]	Not-Affected (Millions) [b]	Affected (Millions) [c]	Affected as Share of Potentially Affected
Total	143.68	29.75	25.25	4.49	15.1%
By Region / Division					
Northeast	25.51	6.04	5.30	0.74	12.3%
New England	7.01	1.80	1.61	0.20	11.0%
Middle Atlantic	18.50	4.23	3.69	0.54	12.8%
Midwest	31.14	6.08	5.15	0.93	15.4%
East North Central	21.06	4.14	3.52	0.62	14.9%
West North Central	10.08	1.94	1.63	0.32	16.3%
South	53.18	10.46	8.59	1.87	17.9%
South Atlantic	27.71	5.80	4.77	1.03	17.7%
East South Central	7.92	1.24	0.99	0.25	20.4%
West South Central	17.54	3.42	2.83	0.59	17.2%
West	33.85	7.17	6.38	0.79	11.0%
Mountain	11.12	2.21	1.89	0.32	14.4%
Pacific	22.73	4.95	4.48	0.47	9.5%
By Metropolitan Status					
Metropolitan	126.89	27.91	23.98	3.92	14.1%
Non-metropolitan	15.74	1.70	1.32	0.38	22.3%
Not identified	1.05	0.14	0.11	0.03	23.8%

Note: Pooled CPS data for 2021–2023 adjusted to reflect 2023.

[a] Exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.

[b] Workers who continue to be exempt after the increases in the salary levels (assuming affected workers earning below the new salary level do not have their weekly earnings increased to the new level).

[c] Estimated number of workers exempt under the EAP exemptions who will be entitled to overtime protection under the updated salary levels (if their weekly earnings do not increase to the new salary levels).

Table 8 presents the distribution of affected EAP workers by demographics. Potentially affected women, Black workers, Hispanic workers, young workers, and workers with less education are all more likely to be affected than other worker types. This is because EAP exempt workers with these characteristics are more likely to earn within the affected standard salary range than EAP exempt workers without these characteristics. For example, of potentially affected workers, women tend to have lower salaries and are therefore more likely to be in the affected range. Median weekly earnings for potentially affected women are $1,709 compared to $2,108 for men.

Among potentially affected workers, certain demographic groups—women, Black workers, Hispanic workers, young

workers, and workers with less education—have an increased likelihood of being affected by this rulemaking, even though workers in these demographic groups are less likely to be EAP exempt in the first place. Therefore, as a share of all workers, not just potentially affected workers, workers in these demographic groups may not be more likely to be affected. For example, when looking at potentially affected workers, 21.7 percent of potentially affected Black workers are affected, while only 14.5 percent of potentially affected white workers are affected. However, when looking at total workers, about the same shares of total Black and total white workers would be affected (2.9 percent of Black workers and 3.0 percent of white workers).

Table 8—Estimated Number of Workers and Whether They Will Be Affected by the New Earnings Thresholds, by Demographics, Year 1

Demographic	Workers subject to FLSA (Millions)	Potentially Affected EAP Workers (Millions) [a]	Not-Affected (Millions) [b]	Affected (Millions) [c]	Affected as Share of All Workers	Affected as Share of Potentially Affected
Total	143.68	29.75	25.41	4.34	3.0%	14.6%
By Sex						
Male	74.37	17.38	15.46	1.92	2.6%	11.0%
Female	69.31	12.37	9.95	2.42	3.5%	19.6%
By Race						
White only	109.96	22.95	19.63	3.32	3.0%	14.5%
Black only	18.47	2.48	1.94	0.54	2.9%	21.7%
All others	15.25	4.32	3.83	0.48	3.2%	11.2%
By Ethnicity						
Hispanic	27.02	2.80	2.25	0.55	2.0%	19.5%
Not Hispanic	116.66	26.95	23.15	3.79	3.3%	14.1%
By Age						
16-25	22.34	1.37	0.96	0.40	1.8%	29.6%
26-35	34.25	7.51	6.20	1.30	3.8%	17.4%
36-45	30.91	7.96	6.97	0.99	3.2%	12.4%
46-55	27.89	7.00	6.13	0.87	3.1%	12.4%
56+	28.30	5.92	5.15	0.77	2.7%	13.1%
By Education						
No degree	10.77	0.15	0.09	0.06	0.5%	39.7%
High school diploma	59.52	4.75	3.55	1.19	2.0%	25.1%
Associate's degree	15.09	2.01	1.56	0.45	3.0%	22.5%
Bachelor's degree	37.05	14.30	12.43	1.86	5.0%	13.0%
Master's degree	16.08	7.11	6.46	0.65	4.0%	9.1%
Professional degree	2.06	0.40	0.36	0.04	2.0%	10.4%
PhD	3.11	1.03	0.95	0.08	2.6%	7.8%

Note: Pooled CPS data for 2021–2023 adjusted to reflect 2023.

[a] Exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.

[b] Workers who continue to be exempt after the increases in the salary level (assuming affected workers' weekly earnings do not increase to the new salary level).

[c] Estimated number of workers exempt under the EAP exemptions who would be entitled to overtime protection under the updated salary levels (if their weekly earnings do not increase to the new salary level).

3. Costs

i. Summary

The Department quantified three direct costs to employers in this analysis: (1) regulatory familiarization costs; (2) adjustment costs; and (3) managerial costs. These are the same costs quantified in the 2016 and 2019 rulemakings. The Department estimated that in Year 1, regulatory familiarization costs will be $451.6 million, adjustment costs will be $299.1 million, and managerial costs will be $685.5 million (Table 9). Total direct employer costs in Year 1 will be $1.4 billion. Recurring costs are projected in section VII.C.10. The Department discusses costs that are not quantified in section VII.C.3.v.

Table 9—Summary of Year 1 Direct Employer Costs (Millions)

Direct Employer Costs	Standard Salary Level	HCE Compensation Level	Total
Regulatory familiarization [a]	--	--	$451.6
Adjustment	$279.0	$20.1	$299.1
Managerial	$626.3	$59.2	$685.5
Total direct costs	$905.4	$79.2	$1,436.2

[a] Regulatory familiarization costs are assessed jointly for the change in the standard salary level and the HCE compensation level.

ii. Regulatory Familiarization Costs

This rulemaking will impose direct costs on firms by requiring them to review the regulation. To estimate these ''regulatory familiarization costs,'' three pieces of information must be estimated: (1) the number of affected establishments; (2) a wage level for the employees reviewing the rule; and (3) the amount of time spent reviewing the rule. The Department generally used the same methodology for calculating regulatory familiarization costs that it used in the NPRM and recent rulemakings.

Regulatory familiarization costs can be calculated at an establishment level or at a firm level. The Department assumed that regulatory familiarization occurs at a decentralized level and used the number of establishments in its cost estimate; this results in a higher estimate than would result from using the number of firms. The most recent data on private sector establishments and firms at the time this rule was drafted are from the 2021 Statistics of U.S. Businesses (SUSB), which reports 8.15 million establishments with paid employees.[347] Additionally, there were an estimated 90,126 state and local governments in 2017, the most recent data available.[348] The Department thus estimated 8.24 million entities (the term ''entities'' is used to refer to the combination of establishments and governments).

The Department assumes that all entities will incur some regulatory familiarization costs, even if they do not employ exempt workers, because all entities will need to confirm whether this rulemaking affects their employees. Entities with more affected EAP workers will likely spend more time reviewing the regulation than entities with fewer or no affected EAP workers (since a more careful reading of the regulation will probably follow the initial decision that the entity is affected). However, the Department did not know the distribution of affected EAP workers across entities, so it used an average cost per entity.

The Department believes an average of 1 hour per entity is appropriate because the regulated community is likely to be familiar with the content of this rulemaking. EAP exemptions have existed in one form or another since 1938, and a final rule was published as recently as 2019. Furthermore, employers who use the exemptions must apply them every time they hire an employee whom they seek to classify as exempt. Thus, employers should be familiar with the exemptions. The most significant changes in this rulemaking are setting a new standard salary level and a new HCE compensation level for exempt workers and establishing a mechanism for keeping these thresholds up to date. The changed regulatory text is only a few pages, and the Department will provide summaries and other compliance assistance materials that will help inform employers that are implementing the final rule. The Department thus believes, consistent with its approach in the 2016 and 2019 rules, that 1 hour is an appropriate average estimate for the time each entity will spend reviewing the changes made by this rulemaking. Additionally, the estimated 1 hour for regulatory familiarization represents an assumption about the average for all entities in the U.S., even those without any affected or exempt workers, which are unlikely to spend much time reviewing the rulemaking. Some businesses, of course, will spend more than 1 hour, and some will spend less.

The Department's analysis assumes that compensation, benefits, and job analysis specialists (SOC 13–1141) with a median wage of $32.59 per hour will review the rulemaking.[349] [350] The Department also assumed that benefits are paid at a rate of 45 percent of the base wage [351] and overhead costs are paid at a rate of 17 percent of the base wage,[352] resulting in an hourly rate of

[347] Statistics of U.S. Businesses 2021, *https://www.census.gov/programs-surveys/susb.html.*

[348] 2017 Census of Governments. Table 1, *https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html.*

[349] OEWS 2022. Available at: *https://www.bls.gov/oes/current/oes131141.htm.*

[350] Previous related rulemakings used the CPS to estimate wage rates. The Department is using OEWS data now to conform with standard practice for the Department's economic analyses.

[351] The benefits-earnings ratio is derived from BLS's Employer Costs for Employee Compensation (ECEC) data using variables CMU1020000000000D and CMU1030000000000D. This fringe benefit rate includes some fixed costs such as health insurance. As of when this final rule was drafted, 2023 ECEC data were available only through the third quarter, so the Department continued to use the 2022 full-year data to calculate the benefits share.

[352] The Department believes that the overhead costs associated with this rulemaking are small because existing systems maintained by employers to track currently hourly employees can be used for newly overtime-eligible workers. However, acknowledging that there might be additional overhead costs, the Department has included an overhead rate of 17 percent.

$54.82 in 2023 dollars.[353] The Department thus estimates regulatory familiarization costs in Year 1 would be $451.6 million ($54.82 per hour × 1 hour × 8.24 million entities).

The Department also conducted a sensitivity analysis. First, as previously noted, the Department used the number of establishments rather than the number of firms, which results in a higher estimate of the regulatory familiarization cost. Using the number of firms, 6.4 million, would result in a reduced regulatory familiarization cost estimate of $350.0 million in Year 1.

Some commenters representing employer interests stated that rule familiarization costs are underestimated. *See, e.g.,* ABC; IEC; Job Creators Network Foundation; NSBA; SBA Office of Advocacy. For instance, ABC commented that ''compliance with the proposal will not be as simple as reviewing the salary level and making a one-time decision'' and that ''82% of recently surveyed ABC members . . . responded that reviewing the final rule would take three hours or longer, with 47% saying it would take five hours or more.''

While the Department acknowledges that some employers will spend more than an hour reviewing the rule, the estimate of 1 hour for rule familiarization is an assumption about the average representing all establishments, even those without any affected or exempt workers. Those establishments will likely not need to spend any time reviewing the rule. Employers in industries with more affected workers may spend more time reviewing the rule, but across all industries, the Department believes that 1 hour continues to be appropriate. The Department used the same 1 hour estimate in its 2016 and 2019 rules,[354] and the Department did not receive comments with concrete data that is representative across all industries from which to conclude that its average estimate of one hour is incorrect. The Department continues to believe that businesses are already familiar with this rulemaking. The EAP exemptions have existed for a long time, and recent rules were published in 2016 and 2019. This rulemaking sets a new standard salary level and a new HCE compensation level for exempt workers and establishes a mechanism for keeping these thresholds up to date. However, this rulemaking does not fundamentally change the existing method for determining whether an employee qualifies for the EAP exemption. To the extent commenters' familiarization cost concerns related to time needed to comply with the rule, these costs are addressed separately under the Department's managerial and adjustment cost estimates. As for concerns relating to the hourly wage rate used to calculate rule familiarization costs, the Department notes that it relies on the standard occupation used in previous WHD and DOL rulemakings.

iii. Adjustment Costs

This rulemaking will also impose direct costs on establishments by requiring them to evaluate the exemption status of employees, update and adapt overtime policies, notify employees of policy changes, and adjust their payroll systems. For each affected worker who works overtime, an employer will need to decide whether they will increase their salary, adjust their hours, or some combination of the two. The Department believes the size of these ''adjustment costs'' will depend on the number of affected EAP workers and will occur in any year when exemption status is changed for any workers. To estimate adjustment costs, three pieces of information must be estimated: (1) a wage level for the employees making the adjustments; (2) the amount of time spent making the adjustments; and (3) the estimated number of newly affected EAP workers. The Department again estimated that the average wage with benefits and overhead costs for a mid-level human resource worker is $54.82 per hour (as explained above).

The Department estimated that it will take establishments an average of 75 minutes per affected worker to make the necessary adjustments. This is the same time estimate as used in the 2016 and 2019 rulemakings, as well as in the NPRM. Little applicable data were identified from which to estimate the amount of time required to make these adjustments. The estimated number of affected EAP workers in Year 1 due to the change in the standard salary level to $1,128 per week and the HCE level to $151,164 per year is 4.3 million (as discussed in section VII.B.7). However, because the compensation thresholds will undergo an initial update on July 1, 2024 and then an increase using the new methodologies 6 months later, employers may have additional adjustment costs when the standard salary level is initially updated to $844 per week and the HCE level is initially updated to $132,964.

Some employers may make two adjustments for affected workers—one at the initial update to the standard salary level and then again with the salary level adjustment 6 months later. To estimate the costs associated with multiple adjustments, the Department assumed that at the initial update, some employers could experience additional adjustment costs for the affected workers who will have their weekly earnings increased to $844 per week. In order to estimate the number of affected workers who would have their weekly earnings increased to $844 per week, the Department looked at EAP exempt workers earning at least $684 per week but less than $844 per week. Using the methodology laid out in the transfer analysis in section VII.C.4.iii, the Department then estimated the share of these workers who regularly work overtime and would remain exempt, because it is less expensive for the employer to pay the updated salary level than to pay overtime (described in that section as Type 4 workers). The Department estimated that there would be 27,692 workers who earn between $684 and $844 and would have their earnings increased at the initial update. The Department does not have data to determine how many employers would increase earnings twice for workers earnings between $684 and $844. For these workers, unless they are working large numbers of overtime hours, it is likely to be more economically beneficial for employers to make other changes in response to the rule instead of increasing their salary to $1,128 a week, such as limiting overtime hours worked. Despite this, in case there are limited cases in which workers do have their earnings increased twice, the Department has included these additional adjustment costs in the total adjustment cost estimate. Therefore, total estimated Year 1 adjustment costs would be $299.1 million ($54.82 × 1.25 hours × (4,337,469 + 27,692 workers)).

The Department used a time estimate per affected worker, rather than per establishment, because the distribution of affected workers across establishments is unknown. However, it may be helpful to present the total time estimate per establishment based on a range of affected workers. If an establishment has five affected workers, the time estimate for adjustment costs is 6.25 hours. If an establishment has 25 affected workers, the time estimate for adjustment costs is 31.25 hours. And if an establishment has 50 affected workers, the time estimate for adjustment costs is 62.5 hours.

A reduction in the cost to employers of determining employees' exemption status may partially offset adjustment costs. Currently, to determine whether

[353] The 2022 fully-loaded hourly wage was adjusted to 2023 using the CPI–U.

[354] 81 FR 32474; 84 FR 51266.

an employee is exempt, employers must apply the duties test to salaried workers who earn $684 or more per week. However, under the final rule, firms will no longer be required to apply the duties test to the 8.7 million employees earning above the current standard salary level of $684 and less than the new standard salary level of $1,128. While this will be a clear cost savings to employers for these employees, the Department did not estimate the potential size of this cost savings.

Some commenters representing employer interests stated that the Department underestimated adjustment costs. *See, e.g.,* NAHB; NSBA; PPWO. NAHB, for instance, stated that ''the Department's economic analysis,'' including its estimate of ''75 minutes per affected worker for adjustment,'' ''dramatically understate[d] the . . . cost burden on employers,'' and PPWO stated that adjustment costs (and regulatory familiarization and managerial costs) were ''all dramatically understated.'' SBA Advocacy and Seyfarth Shaw asserted that the Department underestimated adjustment costs for small businesses, with both commenters stating that smaller employers would be more likely than larger ones to hire outside assistance to make needed adjustments. *See also* NFIB (''The NPRM underestimates compliance costs for small businesses[.]''). Some commenters asserted that the Department failed to account for adjustment costs that employers would need to incur beyond the first year the rule is in effect, such as costs associated with determining whether an employee remains exempt, reclassifying newly-exempt employees as hourly, and making other adjustments to time and attendance systems, given that the earnings thresholds for exemption will be updated on a triennial basis. *See* PPWO; The 4As. Additionally, some commenters expressed particular concern with adjustment costs stemming from the proposed increase in the HCE compensation level, noting that for workers who were previously exempt under the HCE test but earn below the proposed HCE compensation level, employers would need to evaluate the worker's duties to determine whether they remain exempt under the standard test. *See, e.g.,* HR Policy Association; NAM; PPWO. NAM stated that ''[a]cross the manufacturing sector, the change in the HCE threshold may be as difficult and consequential as the proposed increases to the standard salary threshold.''

The Department is retaining its estimate of adjustment costs as 75 minutes per affected worker in the final rule. This estimate is consistent with the Department's estimate in the 2016 and 2019 rules.[355] The Department notes that the 75-minute-per-worker average time estimate is an assumption about the average across all workers, and it believes this estimate takes into account adjustment time for workers affected by the new standard salary level and the smaller portion of workers affected by the new HCE total compensation threshold. This estimate assumes that the time is focused on analyzing more complicated situations. For example, employers are likely to incur relatively low adjustment costs for some workers, such as the 69 percent of affected workers who work no overtime (described below as Type 1 workers). This leaves more time for employers to spend on adjustment costs for the 31 percent of affected workers who work overtime either occasionally or regularly. To demonstrate, if the aggregate time spent on adjustments (75 min × 4.37 million workers) was spread out over only workers who work overtime, then the time estimate is 4.0 hours per worker. Lastly, the Department did not receive any comments with data providing a different estimate for the Department to rely on.

Contrary to commenters that stated that the Department failed to take into account adjustment costs beyond the first year the rule is in effect, the Department's estimated adjustment costs include costs in all years for newly affected workers. The Department limits adjustment costs in projected years to newly affected workers because there is no need to ''adjust'' for workers who are already overtime eligible (due to a prior adjustment of the salary level) when the salary level is updated again. Table 26 provides adjustment (and other) cost projections in future years due to the updating mechanism.

iv. Managerial Costs

If an employee becomes nonexempt due to the changes in the salary levels, then firms may incur ongoing managerial costs because the employer may spend more time developing work schedules and closely monitoring an employee's hours to minimize or avoid paying that employee overtime. For example, the manager of a newly nonexempt worker may have to assess whether the marginal benefit of scheduling the worker for more than 40 hours exceeds the marginal cost of paying the overtime premium. Additionally, the manager may have to spend more time monitoring the employee's work and productivity since the marginal cost of employing the worker per hour has increased. Unlike regulatory familiarization and adjustment costs, which occur primarily in Year 1, managerial costs are incurred more uniformly every year.

The Department applied managerial costs to workers who (1) become nonexempt, overtime-protected and (2) either regularly work overtime or occasionally work overtime, but on a predictable basis—an estimated 911,000 workers (*see* Table 13 and accompanying explanation). Consistent with its approach in its 2019 rule and the NPRM, the Department assumed that management would spend an additional ten minutes per week scheduling and monitoring each affected worker expected to become nonexempt, overtime-eligible as a result of this rule, and whose hours would be adjusted.

As discussed in detail below, most affected workers do not currently work overtime, and there is no reason to expect their hours worked to change when their status changes from exempt to nonexempt. For that group of workers, management will have little or no need to increase their monitoring of hours worked; therefore, these workers are not included in the managerial cost calculation. Under these assumptions, the additional managerial hours worked per week will be 151,800 hours ((10 minutes ÷ 60 minutes) × 911,000 workers).

The median hourly wage in 2022 for a manager was $51.62.[356] Together with a 45 percent benefits rate and a 17 percent overhead cost, this totals $86.82 per hour in 2023 dollars.[357] Thus, the estimated Year 1 managerial costs total $685.5 million (151,835 hours per week × 52 weeks[358] × $86.82/hour). Although

[355] *See* 84 FR 51267; 81 FR 32475.

[356] OEWS 2022. Available at: *https://www.bls.gov/oes/current/oes110000.htm*. This may be an overestimate of the wage rate for managers who monitor workers' hours because (1) it includes very highly paid employees such as CEOs, and (2) some lower-level supervisors are not counted as managers in the data.

[357] The benefits ratio is derived from BLS' 2022 Employer Costs for Employee Compensation data using variables CMU1020000000000D and CMU1030000000000D. The fully-loaded hourly wage rate was inflated to 2023 dollars using the BLS CPI–U.

[358] Fifty-two weeks may be an overestimate of the amount of time that an employer would incur management costs in Year 1. For affected workers who earn below $1,128, but at least $844, their employers may not incur additional managerial costs until January 1, 2025 if they decide to wait to make changes in response to the rule. Therefore, these managerial costs would not occur for the full 52 weeks of the year. Because the Department does not know when employers would make changes in response to the rule, this estimate of 52 weeks is used for the entire population.

the exact magnitude will vary each year with the number of affected EAP workers, the Department anticipates that employers would incur managerial costs annually.

Some commenters expressed concerns that the regulation will increase managerial costs, with some specifically asserting that the Department's estimate was too low, *see, e.g.,* PPWO, SBA Advocacy, NCFC, IEC. Commenter concerns with managerial costs were often tied to the additional costs they asserted would result from tracking the work hours of newly nonexempt employees. *See, e.g.,* 16 Republication Representatives; APLU. Commenters specifically asserted tracking hours of currently exempt employees would increase human resources paperwork and technology costs for their companies. *See, e.g.,* The Chamber of Commerce for Greater Philadelphia; John C. Campbell Folk School.

The Department continues to believe that 10 minutes per worker per week is an appropriate managerial cost estimate. Currently, EAP exempt employees account for about 24 percent of total employment; as such, the Department expects that many employers of EAP exempt workers also employ nonexempt workers. Those employers already have in place recordkeeping systems and standard operating procedures for ensuring employees only work overtime under employer-prescribed circumstances. Thus, such systems generally do not need to be created or acquired for managing formerly exempt EAP employees. The Department also notes that under the FLSA recordkeeping regulations in part 516, employers determine how to make and keep an accurate record of hours worked by employees. For example, employers may tell their workers to write their own time records and any timekeeping plan is acceptable if it is complete and accurate. Additionally, if the nonexempt employee works a fixed schedule, *e.g.,* 9:00 a.m.–5:30 p.m. Monday–Friday, the employer may keep a record showing the exact schedule of daily and weekly hours and merely indicate exceptions to that schedule.[359] The Department believes its estimate, which tracks the approach taken in its 2019 rule, accurately predicts management costs, including costs firms may incur for monitoring and managing the hours of formerly exempt employees.

v. Other Potential Costs

In addition to the costs discussed above, commenters raised other potential costs that could not be quantified. These potential costs are discussed qualitatively below.

(a) Reduced Scheduling Flexibility

Several commenters claim that this rule would restrict employee workplace flexibility, such as remote work and flexible scheduling. *See, e.g.,* HR Policy Association; NAM; NRF; SBA; Chamber. For example, the Chamber stated, ''workers will lose their ability to work from home and the flexibility that they have enjoyed in salaried positions, particularly since the COVID–19 pandemic changed the face of the American workplace in 2020.'' However, commenters did not provide any specific evidence to support this claim. The Department notes that even those workers that are paid on an hourly basis can still take advantage of workplace flexibilities such as remote work. According to the CPS data, of all workers who reported working at home any time in the past week, 74.2 percent of them were categorized as hourly workers.

To the extent that some employers spend more time monitoring nonexempt workers' hours than exempt workers' hours, some employers could respond to this rule by limiting the ability of newly nonexempt workers to adjust their schedules. However, employers can continue to offer flexible schedules and require workers to monitor their own hours and to follow the employers' timekeeping rules. Additionally, some exempt workers already monitor their hours for billing purposes and so monitoring their hours as newly nonexempt workers should not be unduly burdensome. A study by Lonnie Golden found, using data from the General Social Survey (GSS), that ''[i]n general, salaried workers at the lower (less than $50,000) income levels don't have noticeably greater levels of work flexibility that they would 'lose' if they become more like their hourly counterparts.'' [360] Because there is little data or literature on these potential costs, the Department did not quantify potential costs regarding scheduling flexibility.

Organizations such as the American Beverage Licensees and educational institutions in CUPA–HR and APLU, also asserted that the rule would reduce employer flexibility to allocate work hours based on schedules that include non-traditional work hours. The Hinton Rural Life Center said that the rule would make it financially unfeasible for nonexempt employees to attend specific activities such as ''overnight training sessions or marketing events.'' NCFC stated that because of the increased attention that must be paid to the hours worked by nonexempt employees, they are likely to be at a competitive disadvantage with exempt employees in the same role. Under this assumption, they asserted that ''many training opportunities'' would now require additional compensation if ''those opportunities would put the nonexempt employee into an overtime situation,'' and therefore ''access to those opportunities may be limited'' for nonexempt employees. The Department notes that if an employer believes that training opportunities are sufficiently important, it can ensure employees attend the trainings during their 40-hour workweek or pay the overtime premium where training attendance causes the employee to work over 40 hours in a workweek. Given this, and because there is no data and literature to quantify any potential costs to workers, the Department did not quantify these costs.

(b) Preference for Salaried Status

Many commenters contended that the employers of some of the workers who will become nonexempt as a result of the rule could change their pay basis to hourly status despite the employee preferring to remain salaried. *See, e.g.,* AHLA; NSBA; SIGMA. Some commenters, such as SIGMA, stated that conversion of employees to hourly status that will negatively affect morale, as employees may perceive the change as a demotion or a loss of status because of, among other reasons, the lost flexibility associated with salaried status. Conversely, commenters such as the Coalition of State AGs and the Family Caregiving Coalition asserted that the proposed rule would increase employee satisfaction and retention, improve work-life balance, reduce stress and health problems, and make jobs more attractive to qualified applicants primarily because employees will now be compensated for hours worked beyond a standard workweek. Notably, a strong majority of the individual commenters who said they would be personally affected by the proposed rule expressed support for the rule.

If a worker does prefer to be salaried rather than hourly, then the employer changing them from salaried to hourly may impact the worker. However, the Department believes that for most

[359] *See* Fact Sheet #21: Recordkeeping Requirements under the Fair Labor Standards Act, available at: *https://www.dol.gov/agencies/whd/fact-sheets/21-flsa-recordkeeping.*

[360] Golden, L. (2014). Flexibility and Overtime Among Hourly and Salaried Workers. Economic Policy Institute. *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2597174.*

employees their feelings of importance and worth come not from their FLSA exemption status, but from the increased pay, flexibility, fringe benefits, and job responsibilities that traditionally have accompanied exempt status, and that these factors are not incompatible with overtime eligibility. And while research has shown that salaried workers (who are not synonymous with exempt workers, but whose status is correlated with exempt status) are more likely than hourly workers to receive certain benefits, as discussed below, such research generally does not control for differences between salaried and hourly workers such as education, job title, or earnings.

(c) Reduction in Employer-Provided Benefits

Several commenters stated that in response to the proposed salary level employers would likely decrease employee benefits. *See, e.g.,* PPWO; Rachel Greszler. These and similar comments were mostly general statements, often listing types of benefits employees may lose. Others stated that employees would lose benefits due to being reclassified as hourly workers. *See, e.g.,* Independent Women's Forum (IWF); NRF. Some commenters stated that these employees would have reductions in their ability to earn bonuses or other types of incentive payments, but these commenters generally did not discuss the net impact on these employees' earnings. *See, e.g.,* NRF. These comments did not provide information that would allow the Department to estimate the purported impact of the final rule on employee benefits.

Research has shown that salaried workers are more likely than hourly workers to receive benefits such as paid vacation time and health insurance [361] and are more satisfied with their benefits.[362] However, this literature generally does not control for differences between salaried and hourly workers such as education, job title, or earnings; therefore, this correlation is not necessarily attributable to hourly status.

If workers become nonexempt and the employer chooses to pay them on an hourly rather than salary basis, this may result in the employer reducing the workers' benefits. These newly nonexempt workers may continue to be paid a salary, as long as that salary is equivalent to a base wage at least equal to the minimum wage rate for every hour worked, and the employee receives a 50 percent premium on that employee's regular rate for any overtime hours each week.[363] Similarly, employers may continue to provide these workers with the same level of benefits as before, whether paid on an hourly or salary basis. Lastly, the nature of the market mechanism may be such that employers cannot reduce benefits without risking workers leaving, resulting in turnover costs to employers. The Department did not quantify potential costs regarding reduction in workers' benefits.

(d) Increased Prices

Several commenters such as AAHOA, the Chamber, CUPA–HR, Indiana Chamber of Commerce, NAHB, and the National Association of Wholesaler-Distributors stated that the regulation will result in increased prices due to increased employee salaries and other costs to employers. Some of these commenters assert that employers increasing their workers' salaries to maintain their exempt status would induce a general price increase if anticipated wage increases do not result in productivity increases. *See, e.g.,* Chamber; NAW. NAHB conducted a survey among its members about the proposal, and 50 percent of survey respondents stated that finalizing the salary level as proposed would lead them to raise home prices, while 25 percent of respondents stated that the change would make some projects unprofitable.

The Department acknowledges that, as discussed in the transfers section below, businesses may be able to help mitigate increased labor costs following this rulemaking by rebalancing the hours that employees are working. Businesses that are unable to rebalance these hours and do incur increased labor costs might pass along these increased labor costs to consumers through higher prices for goods and services. However, because costs and transfers will be, on average, small relative to payroll and revenues, the Department does not expect the rule to have a significant effect on prices. The Department estimated that, on average, costs and transfers make up less than 0.04 percent of payroll and 0.006 percent of revenues, although for specific industries and firms this percentage may be larger (*see* Table 24). Therefore, any potential change in prices related to costs and transfers from this rulemaking would be modest, and the Department notes that commenter predictions (such as those in the NAHB survey described above) reflect speculation about what will occur in the future and thus may not reflect actual economic responses by employers. Further, any significant price increases would not represent a separate category of effects from those estimated in this economic analysis. Rather, such price increases (where they occur) would be the channel through which consumers, rather than employers or employees, bear rule-induced costs (including transfers).

While economic theory suggests that an increase in labor costs in excess of productivity gains would lead to increases in prices, much of the empirical literature has found that wage inflation does not predict price inflation.[364] For example, Peneva et al. (2015) explore the relationship between labor costs and price inflation between 1965 and 2012, finding that the influence of labor costs on prices has decreased over the past several decades and have made a relatively small contribution to price inflation in recent years.[365]

(e) Reduced Services

Some commenters expressed concern that, by reducing the number of exempt employees, this rulemaking will negatively impact the amount or quality of services that employers can provide. *See, e.g.,* ANCOR; Boy Scouts of America; Catholic Charities USA; YMCA. The National Association of Counties raised similar concerns with respect to county governments. A number of colleges, universities, and other higher-education stakeholders, such as APLU and CUPA–HR, similarly asserted that the proposed rule would negatively affect support services for students. The Department appreciates that employers in some industries have

[361] Lambert, S.J. (2007). Making a Difference for Hourly Employees. In A. Booth, & A.C. Crouter, *Work-Life Policies that Make a Real Difference for Individuals, Families, and Communities.* Washington, DC: Urban Institute Press.

[362] Balkin, D.B., & Griffeth, R.W. (1993). The Determinants of Employee Benefits Satisfaction. *Journal of Business and Psychology,* 7(3), 323–339.

[363] 29 CFR 778.113–114.

[364] Church, J.D. and Akin, B. (2017). ''Examining price transmission across labor compensation costs, consumer prices, and finished-goods prices,'' *Monthly Labor Review,* U.S. Bureau of Labor Statistics; Emery, K. & Chang, C. (1996). Do Wages Help Predict Inflation?, Federal Reserve Bank of Dallas, Economic Review First Quarter 1996. *https://www.dallasfed.org/~/media/documents/research/er/1996/er9601a.pdf*; Jonsson, M. & Palmqvist, S. (2004). Do Higher Wages Cause Inflation? Sveriges Riksbank Working Paper Series 159. *http://archive.riksbank.se/Upload/WorkingPapers/WP_159.pdf.*

[365] Pevena, E.V. and Rudd, J.B. (2015). ''The Passthrough of Labor Costs to Price Inflation,'' Finance and Economics Discussion Series 2015–042. Washington: Board of Governors of the Federal Reserve System. *https://dx.doi.org/10.17016/FEDS.2015.042.*

less flexibility than others to account for new labor costs and that the services provided by such employers could be negatively affected. However, the Department believes the effect of the rule on public services will be small. The Department acknowledges that some newly nonexempt employees who currently work overtime providing public services may see a reduction in hours as an effect of the rulemaking. But if the services are in demand, the Department believes additional workers may be hired, as funding availability allows, to make up some of these hours, and productivity increases may offset some reduction in services. In addition, the Department expects some employers will adjust base wages downward to some degree so that even after paying the overtime premium, overall pay and hours of work for many employees will be relatively minimally impacted. Additionally, many nonprofits are noncovered enterprises because when determining enterprise coverage only revenue derived from business operations, not charitable activities, is included.

(f) Reduced Profits

Some commenters asserted that the rule would lead to decreased profits. *See e.g.,* Quad Cities Chamber of Commerce, ESEI, DT-Trak Consulting. The Department acknowledges that the increased employer costs and transfer payments as a result of this rule may reduce the profits of business firms, although (1) some firms may offset some of these costs and transfers by making payroll adjustments, and (2) some firms may mitigate their reduced profits due to these costs and transfers through increased prices. Because costs and transfers are, on average, small relative to payroll revenues, the Department does not expect this rulemaking to have a significant effect on profits.

(g) Hiring Costs

To the extent that firms respond to this rule by reducing overtime hours, they may do so by spreading hours to other workers, including current workers employed for fewer than 40 hours per week by that employer, current workers who remain exempt, and newly hired workers. If new workers are hired to absorb these transferred hours, then the associated hiring costs would be a cost of this rule. (However, new employees would likely only be hired if their wages, onboarding costs, and training costs are less than the cost of overtime pay for the newly nonexempt workers.) The Department does not know how many new employees would be hired and thus did not estimate this cost.

(h) Hours-Related Worker Effects

Some employer representatives highlighted the possibility that some workers might work more hours as a consequence of this rulemaking. For example, Construction Industry Roundtable commented that employers responding to the increased salary level might ''require the remaining exempt employees to absorb some of the duties of the newly non-exempt employees—which would be viewed as an unfair burden by the remaining exempt employees who are at or near capacity already.'' *See also* SIGMA (providing similar statements).

The Department acknowledges that for some affected workers, if their employers respond to the rule by increasing their salary to keep their exemption status, the change may also be accompanied by an increase in assigned hours. Additionally, some employers might respond to this regulation by reducing the overtime hours of affected workers and transferring those hours to other workers who remain exempt. The Department believes that while some workers may see an increase in hours, others may see their hours decline (discussed further in the Benefits section below).

(i) Wage Compression

Some commenters contended that the update to the salary threshold in this rule would lead to wage compression. For example, PPWO stated that the Department did not account for this potential cost, stating, ''Where employees below the proposed salary minimum have their salaries raised to meet the new minimum, employees above the new minimum will likewise need to have their salaries raised to account for the relative value of the work being performed.'' *See also, e.g.,* Seyfarth Shaw.

However, as discussed in section VII.C.4.iii.f., the Department estimates that only 2.2 percent of affected workers will have their earnings increased to the updated salary level. Thus, in the overwhelming majority of cases wage compression concerns should not arise. The Department recognizes that there may be some cases in which employers that raise the pay of affected employees to the new salary level will also choose to increase the earnings of more highly paid employees to avoid wage compression, but the Department does not have data to estimate this impact.

4. Transfers

i. Overview

Transfer payments occur when income is redistributed from one party to another. The Department has quantified two transfers from employers to employees that will result from the rule: (1) transfers to ensure compliance with the FLSA minimum wage provision; and (2) transfers to ensure compliance with the FLSA overtime pay provision. Transfers in Year 1 due to the minimum wage provision were estimated to be $87.5 million. The increase in the HCE compensation level does not affect minimum wage transfers because workers eligible for the HCE exemption earn well above the minimum wage. The Department estimates that transfers due to the applicability of the FLSA's overtime pay provision will be $1.4 billion: $1.2 billion from the increased standard salary level and $255.6 million from the increased HCE compensation level. Total Year 1 transfers are estimated at $1.5 billion (Table 10).

Table 10—Total Annual Change in Earnings for Affected EAP Workers by Provision, Year 1 (Millions)

Provision	Total	Standard Salary Level	HCE Compensation Level
Total	$1,509.2	$1,253.6	$255.6
Minimum wage only	$87.5	$87.5	--
Overtime pay only [a]	$1,421.7	$1,166.1	$255.6

Because the overtime premium depends on the employee's regular rate of pay, the estimates of minimum wage transfers and overtime transfers are linked. This can be considered a two-step approach. The Department first identified affected EAP workers with an implicit regular hourly wage lower than the minimum wage, and then calculated the wage increase necessary to reach the minimum wage. Then, the Department estimated overtime payments.

ii. Transfers Due to the Minimum Wage Provision

For this analysis, the hourly rate of pay was calculated as usual weekly earnings divided by usual weekly hours worked. To earn less than the Federal or most state minimum wages, this set of workers must work many hours per week. For example, a worker paid $684 per week must work 94.3 hours per week to earn less than the Federal minimum wage of $7.25 per hour ($684 ÷ $7.25 = 94.3).[366] The applicable minimum wage is the higher of the Federal minimum wage and the state minimum wage as of January 1, 2023. Most affected EAP workers already receive at least the minimum wage; only an estimated 0.5 percent (19,900 in total) earn an implicit hourly rate of pay less than the Federal minimum wage. The Department estimated transfers due to payment of the minimum wage by calculating the change in earnings if wages rose to the minimum wage for workers who become nonexempt.[367]

In response to an increase in the regular rate of pay to the minimum wage, employers may reduce the workers' hours. In theory, since the quantity of labor hours demanded is inversely related to wages, a higher mandated wage would, all things being equal, result in fewer hours of labor demanded. However, the weight of the empirical evidence finds that increases in the minimum wage that are similar in magnitude to what would be caused by this regulatory provision have caused little or no significant job loss.[368] Thus, in the case of this regulation, the Department believes that any disemployment effect due to the minimum wage provision will be negligible. This is partially due to the small number of workers affected by this provision. According to the Wolfson and Belman (2016) meta-analysis cited above, the consensus range for labor demand elasticity was −0.05 to −0.12. However for Year 1 of this analysis, the Department estimated the potential disemployment effects (*i.e.,* the estimated reduction in hours) of the transfer attributed to the minimum wage by multiplying the percent change in the regular rate of pay by a labor demand elasticity of −0.2 (years 2–10 use a long run elasticity of −0.4).[369] [370] The Department chose this labor demand elasticity because it was used in the 2019 final rule and is consistent with the labor demand elasticity estimates used when estimating other transfers further below.

At the new standard salary level, the Department estimated that 19,900 affected EAP workers will, on average, see an hourly wage increase of $1.57, work 2.1 fewer hours per week and receive an increase in weekly earnings of $84.73 as a result of coverage by the minimum wage provisions (Table 11). The total change in weekly earnings due to the payment of the minimum wage was estimated to be $1.7 million per week ($84.73 × 19,900) or $87.5 million in Year 1.

Table 11—Minimum Wage Only: Mean Hourly Wages, Usual Weekly Hours and Weekly Earnings for Affected EAP Workers, Year 1

Time Period	Hourly Wage [a]	Usual Weekly Hours	Usual Weekly Earnings	Total Weekly Transfer (1,000s)
Before rule	$12.85	65.8	$827.66	--
After rule	$14.42	63.6	$912.39	--
Change	$1.57	-2.1	$84.73	$1,683

Note: Pooled data for 2021 – 2023 adjusted to reflect 2023.
[a] The applicable minimum wage is the higher of the Federal minimum wage and the state minimum wage.

iii. Transfers Due to the Overtime Pay Provision

(a) Introduction

The FLSA requires covered employers to pay an overtime premium to nonexempt covered workers who work in excess of 40 hours per week. For workers who become nonexempt, the rulemaking will result in a transfer of income to the affected workers, increasing the marginal cost of labor, which employers may try to offset by adjusting the wages and/or hours of affected workers. The size of the transfer will depend largely on how employers choose to respond to the updated salary levels. Employers may respond by: (1) paying overtime premiums to affected workers; (2) reducing overtime hours of affected workers and potentially transferring some of these hours to other workers; (3) reducing the regular rate of pay for affected workers working

[366] The Federal minimum wage has not increased since 2009. Workers in states with minimum wages higher than the Federal minimum wage could earn less than the state minimum wage working fewer hours.

[367] Because these workers' hourly wages will be set at the minimum wage after this rule, their employers will not be able to adjust their wages downward to offset part of the cost of paying the overtime pay premium (which will be discussed in the following section). Therefore, these workers will generally receive larger transfers attributed to the overtime pay provision than other workers.

[368] Wolfson, Paul J. and Belman, Dale, 15 Years of Research on U.S. Employment and the Minimum Wage (December 10, 2016). Tuck School of Business Working Paper No. 2705499. *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2705499.* Dube, Arindrajit, Impacts of Minimum Wages: Review of the International Evidence (November 2019). *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/844350/impacts_of_minimum_wages_review_of_the_international_evidence_Arindrajit_Dube_web.pdf.*

[369] Labor demand elasticity is the percentage change in labor hours demanded in response to a one percent change in wages.

[370] This elasticity estimate represents a short run demand elasticity for general labor, and is based on the Department's analysis of Lichter, A., Peichl, A. & Siegloch, A. (2014). The Own-Wage Elasticity of Labor Demand: A Meta-Regression Analysis. IZA DP No. 7958.

overtime (provided that the reduced rates still exceed the minimum wage); (4) increasing affected workers' salaries to the updated salary or compensation level to preserve their exempt status; or (5) using some combination of these responses. How employers will respond depends on many factors, including the relative costs of each of these alternatives. In turn, the relative costs of each of these alternatives are a function of workers' earnings and hours worked.

(b) Literature on Employer Adjustments

Two conceptual models are useful for thinking about how employers may respond to when certain employees become eligible for overtime: (1) the ''fixed-wage'' or ''labor demand'' model, and (2) the ''fixed-job'' or ''employment contract'' model.[371] These models make different assumptions about the demand for overtime hours and the structure of the employment agreement, which result in different implications for predicting employer responses.

The fixed-wage model assumes that the standard hourly wage is independent of the statutory overtime premium. Under the fixed-wage model, a transition of workers from overtime exempt to overtime nonexempt would cause a reduction in overtime hours for affected workers, an increase in the prevalence of a 40-hour workweek among affected workers, and an increase in the earnings of affected workers who continue to work overtime.

In contrast, the fixed-job model assumes that the standard hourly wage is affected by the statutory overtime premium. Thus, employers can neutralize any transition of workers from overtime exempt to overtime nonexempt by reducing the standard hourly wage of affected workers so that their weekly earnings and hours worked are unchanged, except when minimum wage laws prevent employers from lowering the standard hourly wage below the minimum wage. Under the fixed-job model, a transition of workers from overtime exempt to overtime nonexempt would have different effects on minimum-wage workers and above-minimum-wage workers. Similar to the fixed-wage model, minimum-wage workers would experience a reduction in overtime hours, an increase in the prevalence of a 40-hour workweek at a given employer (though not necessarily overall), and an increase in earnings for the portion of minimum-wage workers who continue to work overtime for a given employer. Unlike the fixed-wage model, however, above-minimum-wage workers would experience no change.

The Department conducted a literature review to evaluate studies of how labor markets adjust to a change in the requirement to pay overtime. These studies are generally supportive of the fixed-job model of labor market adjustment, in that wages adjust to offset the requirement to pay an overtime premium as predicted by the fixed-job model, but do not adjust enough to completely offset the overtime premium as predicted by the model.

As in the 2016 and 2019 rules, the Department believes the two most important papers in this literature are the studies by Trejo (1991) and Barkume (2010). Analyzing the economic effects of the overtime pay provisions of the FLSA, Trejo (1991) found ''the data analyzed here suggest the wage adjustments occur to mitigate the purely demand-driven effects predicted by the fixed-wage model, but these adjustments are not large enough to neutralize the overtime pay regulations completely.'' Trejo noted, ''In accordance with the fixed job model, the overtime law appears to have a greater impact on minimum-wage workers.'' He also stated, ''[T]he finding that overtime-pay coverage status systematically influences the hours-of-work distribution for nonminimum-wage workers is supportive of the fixed-wage model. No significant differences in weekly earnings were discovered between the covered and non-covered sectors, which is consistent with the fixed-job model.'' However, ''overtime pay compliance is higher for union than for nonunion workers, a result that is more easily reconciled with the fixed wage model.'' Trejo's findings are supportive of the fixed-wage model whose adjustment is incomplete largely due to the minimum-wage requirement.[372]

A second paper by Trejo (2003) took a different approach to testing the consistency of the fixed-wage adjustment models with overtime coverage and data on hours worked.[373] In this paper, he examined time-series data on employee hours by industry. After controlling for underlying trends in hours worked over 20 years, he found changes in overtime coverage had no impact on the prevalence of overtime hours worked. This result supports the fixed-job model. Unlike the 1991 paper, however, he did not examine impacts of overtime coverage on employees' weekly or hourly earnings, so this finding in support of the fixed-job model only analyzes one implication of the model.

Barkume (2010) built on the analytic method used in Trejo (1991).[374] However, Barkume observed that Trejo did not account for ''quasi-fixed'' employment costs (*e.g.,* benefits) that do not vary with hours worked, and therefore affect employers' decisions on overtime hours worked. After incorporating these quasi-fixed costs in the model, Barkume found results consistent with those of Trejo (1991): ''though wage rates in otherwise similar jobs declined with greater overtime hours, they were not enough to prevent the FLSA overtime provisions from increasing labor costs.'' Barkume also determined that the 1991 model did not account for evidence that in the absence of regulation some employers may voluntarily pay workers some overtime premium to entice them to work longer hours, to compensate workers for unexpected changes in their schedules, or as a result of collective bargaining. Barkume found that how much wages and hours worked adjusted in response to the overtime pay requirement depended on what overtime pay would be in absence of regulation.

In addition, Bell and Hart (2003) examined the standard hourly wage, average hourly earnings (including overtime), the overtime premium, and overtime hours worked in Britain.[375] Unlike the United States, Britain does not have national labor laws regulating overtime compensation. Bell and Hart found that after accounting for overtime, average hourly earnings are generally uniform in an industry because firms paying below-market level straight-time wages tend to pay above-market overtime premiums and firms paying above-market level straight-time wages tend to pay below-market overtime premiums. Bell and Hart concluded ''this is consistent with a model in which workers and firms enter into an implicit contract that specifies total hours at a constant, market-determined, hourly wage rate. Their research is also consistent with studies showing that employers may pay overtime premiums either in the absence of a regulatory

[371] *See* Trejo, S.J. (1991). The Effects of Overtime Pay Regulation on Worker Compensation. *American Economic Review,* 81(4), 719–740, and Barkume, A. (2010). The Structure of Labor Costs with Overtime Work in U.S. Jobs. *Industrial and Labor Relations Review,* 64(1), 128–142.

[372] Trejo, S. J. (1991). The Effects of Overtime Pay Regulation on Worker Compensation. *American Economic Review,* 81(4), 719–740.

[373] Trejo, S. J. (2003). Does the Statutory Overtime Premium Discourage Long Workweeks? Industrial and Labor Relations Review, 56(3), 375–392.

[374] Barkume, A. (2010). The Structure of Labor Costs with Overtime Work in U.S. Jobs. *Industrial and Labor Relations Review,* 64(1), 128–142.

[375] Bell, D. N. F. and Hart, R. A. (2003). Wages, Hours, and Overtime Premia: Evidence from the British Labor Market, *Industrial and Labor Relations Review,* 56(3), 470–480.

mandate (*e.g.,* Britain), or when the mandate exists but the requirements are not met (*e.g.,* United States).[376]

On balance, consistent with its 2016 and 2019 rulemakings, the Department finds strong support for the fixed-job model as the best approximation for the likely effects of a transition of above-minimum-wage workers from overtime exempt to overtime nonexempt and the fixed-wage model as the best approximation of the likely effects of a transition of minimum-wage workers from overtime exempt to overtime nonexempt. In addition, the studies suggest that although observed wage adjustment patterns are consistent with the fixed-job model, this evidence also suggests that the actual wage adjustment might, especially in the short run, be less than 100 percent as predicted by the fixed-job model. Thus, the hybrid model used in this analysis may be described as an incomplete fixed-job adjustment model.

To determine the magnitude of the adjustment, the Department accounted for the following findings. Earlier research had demonstrated that in the absence of regulation some employers may voluntarily pay workers some overtime premium to entice them to work longer hours, to compensate workers for unexpected changes in their schedules, or as a result of collective bargaining.[377] Barkume (2010) found that the measured adjustment of wages and hours to overtime premium requirements depended on what overtime premium might be paid in absence of any requirement to do so. Thus, when Barkume assumed that workers would receive an average voluntary overtime pay premium of 28 percent in the absence of an overtime pay regulation, which is the average overtime premium that Bell and Hart (2003) found British employers paid in the absence of any overtime regulations, the straight-time hourly wage adjusted downward by 80 percent of the amount that would occur with the fixed-job model.[378] When Barkume assumed workers would receive no voluntary overtime pay premium in the absence of an overtime pay regulation, the results were more consistent with Trejo's (1991) findings that the adjustment was a smaller percentage. The Department modeled an adjustment process between these two findings. Although it seemed reasonable that some premium was paid for overtime in the absence of regulation, Barkume's assumption of a 28 percent initial overtime premium is likely too high for the salaried workers potentially affected by a change in the salary and compensation level requirements for the EAP exemptions because this assumption is based on a study of workers in Britain. British workers were likely paid a larger voluntary overtime premium than American workers because Britain did not have a required overtime pay regulation and so collective bargaining played a larger role in implementing overtime pay.[379] In the sections that follow, the Department uses a method between these two papers to model transfers.

(c) Comments Regarding Transfers

Many commenters representing employer interests indicated that employers would respond to the changes proposed in the NPRM by making a variety of adjustments to wages, hours worked, or both. Some commenters responded with results from surveys of their constituents. Although these surveys may be helpful as background information, they generally cannot be used in a quantitative analysis due to issues such as insufficient or uncertain sample sizes, missing sampling methodology, and missing magnitudes. For example, NAHB referenced results from a survey of an unknown number of its members, asserting that 38 percent of respondents indicated they would respond to the proposed increase in the salary level by ''[m]inimiz[ing] overtime hours.'' The Department agrees that firms may reduce the hours of some workers and has included this in the quantitative analysis below; however, the modeling question is to what degree employers will adjust hours.[380] As discussed below, the Department estimates that employers will reduce hours for Type 2B and Type 3 workers, which together make up 21% of all affected workers. The Department's model is based on worker-specific adjustments and does not assume that a firm would respond the same way for all affected workers that they employ. Moreover, such surveys were often sector-specific, making it difficult to extrapolate economy-wide trends, because the distribution of affected workers varies across sectors. Also, these surveys were often based not on actual economic responses, but rather on expressions of intentions. *See, e.g.,* AHLA; ANCOR; NAIS and NBOA; NDA.

Despite the inability to incorporate these survey results into the analysis, select results are presented here. For instance, according to AHLA, of the members it surveyed, ''70% anticipat[ed] reclassifying workers, 60% anticipat[ed] reducing hours and career development opportunities to reduce potential overtime costs, and 51% anticipat[ed] position consolidation.'' ANCOR found that ''approximately 61 percent of [its constituents] would employ a mitigation strategy of converting currently exempt salaried workers to hourly workers,'' ''[f]ifty-six percent . . . would increase the salary of full-time exempt workers to meet the projected threshold,'' ''49 percent . . . would prohibit or significantly restrict'' permitted overtime, and ''33 percent indicated the necessity of reducing salaried full-time employees.'' NAIS and NBOA stated that 13 percent of schools that responded to its survey said they would ''raise salaries of those exempt employees who do not meet the new threshold,'' 27 percent said they would ''convert employees to non-exempt and limit hours where possible,'' 11 percent said they would ''convert employees to non-exempt and pay overtime if hours worked are over 40 in a week'' and ''47% of schools said they will enact some combination of the available options.'' NAHB stated that, if the proposed salary threshold were implemented, 38 percent of respondents reported they would ''[m]inimize overtime hours,'' as noted above; 24 percent would ''[r]aise salaries above the threshold''; and 9 percent would ''[r]educe salaries to compensate for overtime'' (among other changes). And NDA stated that 66 percent of respondents ''said they would have to reclassify exempt employees as hourly employees and restructure jobs if DOL raised the minimum salary threshold'' as proposed in the NPRM.

Regarding the transfer calculations in the NPRM, SBA Advocacy expressed concern about the Department's

[376] Hart, R. A. and Yue, M. (2000). Why Do Firms Pay an Overtime Premium? IZA Discussion Paper No. 163.

[377] Barzel, Y. (1973). The Determination of Daily Hours and Wages. *The Quarterly Journal of Economics,* 87(2), 220–238, demonstrated that modest fluctuations in labor demand could justify substantial overtime premiums in the employment contract model. Hart, R. A. and Yue, M. (2000). Why Do Firms Pay an Overtime Premium? IZA Discussion Paper No. 163, showed that establishing an overtime premium in an employment contract can reduce inefficiencies.

[378] Barkume, A. (2010). The Structure of Labor Costs with Overtime Work in U.S. Jobs. *Industrial and Labor Relations Review,* 64(1), 128–142.

[379] Bell, D. N. F. and Hart, R. A. (2003). Wages, Hours, and Overtime Premia: Evidence from the British Labor Market, *Industrial and Labor Relations Review,* 56(3), 470–480.

[380] Illustrating the limitations of commenter-provided surveys for this quantitative analysis, the responses to NAHB's survey have inconsistencies that make them hard to interpret. For example, concerning the 2019 rule, NAHB reported that 94 percent of respondents stated that the rule's increase in the salary level to $35,568 did not affect anyone on their payroll. Nevertheless, of the same respondents, 20% stated that they responded to the 2019 rule by minimizing overtime hours and 18% stated that they raised salaries above the threshold.

estimates that affected small business establishments would have, on average, $360 to $2,683 in additional payroll costs in the first year of the proposed rule. SBA Advocacy stated that ''an Arkansas restaurant with four locations stated it would cost almost $200,000 to increase manager salaries to make them compliant,'' and that ''small amusement businesses reported estimated salary increases for their businesses'' ranging from $57,000 to $250,000. It also provided hypothetical examples of potential salary increases that restaurants in two states would need to make to comply with the proposed rule based on various assumptions, including different salaries and amounts of overtime performed. These anecdotal reports and hypothetical examples do not have any information on the actual amount of overtime work being performed by newly nonexempt workers at these businesses. The Department expects that businesses that would be faced with large increases in payroll costs if they were to increase salaries to the new threshold would instead find other responses more economically beneficial, such as limiting the number of overtime hours worked by workers who become nonexempt or paying such workers the overtime premium for hours in excess of 40 per week. Furthermore, this comment does not explain what methodological approach the Department should use to estimate transfers; what error(s), if any, the Department made in its transfer estimate in its NPRM; or how much the Department underestimated such transfers.

Some commenters indicated that employers may follow the fixed-job model rather than the incomplete fixed-job model used by the Department in the NPRM. *See, e.g.,* AFPI; Americans for Prosperity. AFPI, for instance, stated that ''[r]esearch shows employers primarily respond to expanded overtime eligibility by reducing base earnings to reflect expected overtime—leaving total earnings unchanged.'' Americans for Prosperity similarly asserted that ''[o]ver time, the natural response of business enterprises of all types to the higher wage costs occasioned by the proposed rule will be an adjustment in base pay and fringe benefits lower so that total compensation (base pay, benefits, overtime) does not rise.'' [381]

The Oxford Economics report included with NRF's comment pointed to a study by Quach (2022),[382] which analyzed the effects of the rescinded 2016 rule and the 2019 rule, along with the impact of state-level increases to the overtime exemption threshold. According to Oxford Economics, ''Quach finds evidence that overtime coverage decreases employment and increases earnings polarization'' and ''strong evidence of employee reclassifications from salaried to hourly status[.]'' The Department notes that the revised 2024 version of the working paper did not find that increasing overtime exemption thresholds decreases employment. In fact, when summarizing his findings, he says, ''I estimate that expansions in overtime coverage actually have little effect on employment.'' He also notes, ''while the DOL accurately predicted that average weekly earnings would rise, they calculated an income effect of only 0.7%, whereas I show that earnings increased by nearly twice that amount for salaried workers.'' While the Department also reviewed the 2022 study, as discussed further below, it has not incorporated this study into its analysis as it has multiple limitations, including a reliance on a non-representative selection of employers, which makes it inappropriate as a model of aggregate effects across the economy. The Oxford Economics report also claimed that the Department's analysis in the NPRM demonstrated ''a tendency to assume that which workers are paid on a salaried basis is determined by an exogenous occupational structure and to ignore the role that the DOL's overtime regulations themselves play in determining this.''

The Department's review of the literature cited above supports a result between the fixed-job model and the fixed-wage model and thus the results were modeled accordingly. Specifically, the Department believes the incomplete fixed-job model is most appropriate and consistent with the literature. Therefore, the analysis has not been changed. The Department further notes that its estimates of transfers are informed by its projection that employers will respond to the final rule in many ways. If, for example, an employer simply pays each affected employee the overtime premium for each hour worked in excess of 40 hours per week, without making any adjustments to wages, hours, or duties, such an approach would maximize transfers from employers to employees. However, as discussed above, the Department believes that employers will respond to the final rule by adjusting wages, hours, and duties to minimize the cost of the rule. Accordingly, the actual amount of transfers will fall well short of the transfers that would result if employers simply paid each affected employee overtime premiums without adjusting wages, hours, or duties.

(d) Identifying Types of Affected Workers

The Department identified four types of workers whose work characteristics affect how it modeled employers' responses to the changes in both the standard salary level and HCE compensation level:

- *Type 1:* Workers who do not work overtime.
- *Type 2:* Workers who do not regularly work overtime but occasionally work overtime.
- *Type 3:* Workers who regularly work overtime and become overtime eligible (nonexempt).
- *Type 4:* Workers who regularly work overtime and remain exempt, because it is less expensive for the employer to pay the updated salary level than to pay overtime and incur additional managerial costs.

The Department began by identifying the number of workers in each type. After modeling employer adjustments, it estimated transfer payments. Type 3 and Type 4 workers were identified as those who regularly work overtime (CPS variable PEHRUSL1 greater than 40). To distinguish Type 3 workers from Type 4 workers, the Department first estimated each worker's weekly earnings if they became nonexempt, to which it added weekly managerial costs for each affected worker of $14.47 ($86.82 per hour × (10 minutes ÷ 60 minutes)).[383] Then, the Department identified as Type 4 those workers whose expected nonexempt earnings plus weekly managerial costs exceeds the updated standard salary level, and, conversely, as Type 3 those whose expected nonexempt earnings plus

[381] In support, AFPI and Americans for Prosperity both cited to reports regarding the NPRM for the 2016 rule. *See* James Sherk, *Salaried Overtime Requirements: Employers Will Offset Them with Lower Pay,* Heritage Foundation Backgrounder No. 3031, July 2, 2015. *https://thf_media.s3.amazonaws.com/2015/pdf/BG3031.pdf* (cited by AFPI); Donald J. Boudreaux & Liya Palagashvili, *An Economic Analysis of Overtime Pay Regulations 17–21* (Apr. 2016), available at *https://www.mercatus.org/hayekprogram/research/working-papers/economic-analysis-overtime-pay-regulations* (cited by Americans for Prosperity).

[382] Simon Quach, *The Labor Market Effects of Expanding Overtime Coverage.* This is a working paper that was published in both 2022 and 2024. The 2024 version can be found linked on Simon Quach's website: *https://raw.githubusercontent.com/SimonQuach1/Papers/main/Quach_OT.pdf?token=AH2DVMEDLJGBAWFAVXXUNMDAYGGDQ.* The Department believes that Oxford Economics was citing to the 2022 version of the paper, which is Quach, S. (2022). The Labor Market Effects of Expanding Overtime Coverage. *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3608506.*

[383] *See* section VII.C.3.iv (managerial costs).

weekly managerial costs are less than the new standard salary. The Department assumed that firms will include incremental managerial costs in their determination of whether to treat an affected employee as a Type 3 or Type 4 worker because those costs are only incurred if the employee is a Type 3 worker.

Identifying Type 2 workers involved two steps. First, using CPS MORG data, the Department identified those who do not usually work overtime but did work overtime in the survey week (the week referred to in the CPS questionnaire, variable PEHRACT1 greater than 40). Next, the Department supplemented the CPS data with data from the Survey of Income and Program Participation (SIPP) to look at likelihood of working some overtime during the year. Based on 2021 data, the most recent available, the Department found that 31.3 percent of non-hourly workers worked overtime at some point in a year. Therefore, the Department classified a share of workers who reported they do not usually work overtime, and did not work overtime in the reference week, as Type 2 workers such that a total of approximately 31.3 percent of affected workers were Type 2, 3, or 4. Type 2 workers are subdivided into Types 2A and 2B later in the analysis (Table 12).

Table 12—Types of Affected Workers

Type of Worker	Percent of Total
Type 1	69%
Type 2A	8%
Type 2B	8%
Type 3	13%
Type 4	2%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

*Type 1: Workers who do not work overtime and gain overtime protection.

*Type 2: Workers who work occasional overtime and gain overtime protection.

- Type 2A: Those who work unexpected overtime hours.
- Type 2B: Those who work expected overtime.

*Type 3: Workers who work regular overtime and gain overtime protection.

*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary or compensation level).

(e) Modeling Changes in Wages and Hours

The incomplete fixed-job model predicts that employers will adjust wages of regular overtime workers but not to the full extent indicated by the fixed-job model, and thus some employees will receive a small increase in weekly earnings due to overtime pay coverage. The Department used the average of two estimates of the incomplete fixed-job model adjustments to model impacts of this rule: [384]

- Trejo's (1991) estimate that the overtime-induced wage change is 40 percent of the adjustment toward the amount predicted by the fixed-job model, assuming an initial zero overtime pay premium, and
- Barkume's (2010) estimate that the wage change is 80 percent of the predicted adjustment assuming an initial 28 percent overtime pay premium.

This is approximately equivalent to assuming that salaried overtime workers implicitly receive the equivalent of a 14 percent overtime premium in the absence of regulation (the midpoint between 0 and 28 percent).

Modeling changes in hourly wages, hours, and earnings for Type 1 and Type 4 workers was relatively straightforward. Type 1 affected EAP workers will become overtime-eligible, but because they do not work overtime, they will see no change in their wages, hours, or weekly earnings. Type 4 workers will remain exempt because their earnings will be raised to at least the updated EAP level (either the standard salary level or HCE compensation level). These workers' earnings will increase by the difference between their current earnings and the amount necessary to satisfy the new salary or compensation level. It is possible employers will increase these workers' hours in response to paying them a higher salary, but the Department did not have enough information to model this potential change.[385]

Modeling changes in wages, hours, and earnings for Type 2 and Type 3 workers was more complex. The Department distinguished those who regularly work overtime (Type 3 workers) from those who occasionally work overtime (Type 2 workers) because employer adjustment to the rule may differ accordingly. Employers are more likely to adjust hours worked and wages for regular overtime workers because their hours are predictable. Conversely, in response to a transient, perhaps unpredicted, shift in market demand for the good or service such employers provide, employers are more likely to pay for occasional overtime rather than adjust hours worked and pay.

[384] Both studies considered a population that included hourly workers. Evidence is not available on how the adjustment towards the fixed-job model differs between salaried and hourly workers. The fixed-job model may be more likely to hold for salaried workers than for hourly workers since salaried workers directly observe their weekly total earnings, not their implicit equivalent hourly wage. Thus, applying the partial adjustment to the fixed-job model as estimated by these studies may overestimate the transfers from employers to salaried workers.

[385] Cherry, Monica, ''Are Salaried Workers Compensated for Overtime Hours?'' *Journal of Labor Research* 25(3): 485–494, September 2004, found that exempt full-time salaried employees earn more when they work more hours, but her results do not lend themselves to the quantification of the effect *on* hours of an increase in earnings.

The Department treated Type 2 affected workers in two ways due to the uncertainty of the nature of these occasional overtime hours. The Department assumed that 50 percent of these occasional overtime workers worked *unexpected* overtime hours (Type 2A) and the other 50 percent worked *expected* overtime (Type 2B). Workers were randomly assigned to these two groups. Workers with *expected* occasional overtime hours were treated like Type 3 affected workers (incomplete fixed-job model adjustments). Workers with unexpected occasional overtime hours were assumed to receive a 50 percent pay premium for the overtime hours worked and receive no change in base wage or hours (full overtime premium model).[386] When modeling Type 2 workers' hour and wage adjustments, the Department treated those identified as Type 2 using the CPS data as representative of all Type 2 workers.[387] The Department estimated employer adjustments and transfers assuming that the patterns observed in the CPS reference week are representative of an average week in the year. Thus, the Department assumes total transfers for the year are equal to 52 times the transfers estimated for a representative week for which the Department has CPS data. However, these transfers are spread over a larger group including those who occasionally work overtime but did not do so in the CPS reference week.[388]

Since employers will pay more for the same number of labor hours, for Type 2 and Type 3 EAP workers, the quantity of labor hours demanded by employers will decrease. The reduction in hours is calculated using the elasticity of labor demand with respect to wages. The Department used a short-term demand elasticity of −0.20 to estimate the percentage decrease in hours worked in Year 1 and a long-term elasticity of −0.4 to estimate the percentage decrease in hours worked in Years 2–10. These elasticity estimates are based on the Department's analysis of Lichter et al. (2014).[389] [390] Brown and Hamermesh (2019) estimated the elasticity of overtime hours for EAP-exempt workers.[391] This estimate is based on a difference-in-differences in hours for two groups of workers between two time periods. However, some groups of workers are incorrectly defined, so the Department has not used these estimates.[392]

For Type 3 affected workers, and the 50 percent of Type 2 affected workers who worked expected overtime, the Department estimated adjusted total hours worked after making wage adjustments using the incomplete fixed-job model. To estimate adjusted hours worked, the Department set the percent change in total hours worked equal to the percent change in average wages multiplied by the wage elasticity of labor demand.[393] Figure 4 is a flow chart summarizing the four types of affected EAP workers. Also shown are the effects on exempt status, weekly earnings, and hours worked for each type of affected worker.

[386] The Department uses the term ''full overtime premium'' to describe the adjustment process as modeled. The full overtime premium model is a special case of the general fixed-wage model in that the Department assumes the demand for labor under these circumstances is completely inelastic. That is, employers make no changes to employees' hours in response to these temporary, unanticipated changes in demand.

[387] As explained in the previous section, to estimate the population of Type 2 workers, the Department supplemented workers who report working overtime in the CPS reference week with some workers who do not work overtime in the reference week to reflect the fact that different workers work occasional overtime in different weeks.

[388] If a different week was chosen as the survey week, then some of these workers would not have worked overtime. However, because the data are representative of both the population and all twelve months in a year, the Department believes the share of Type 2 workers identified in the CPS data in the given week is representative of an average week in the year.

[389] Lichter, A., Peichl, A. & Siegloch, A. (2014). The Own-Wage Elasticity of Labor Demand: A Meta-Regression Analysis. IZA DP No. 7958.

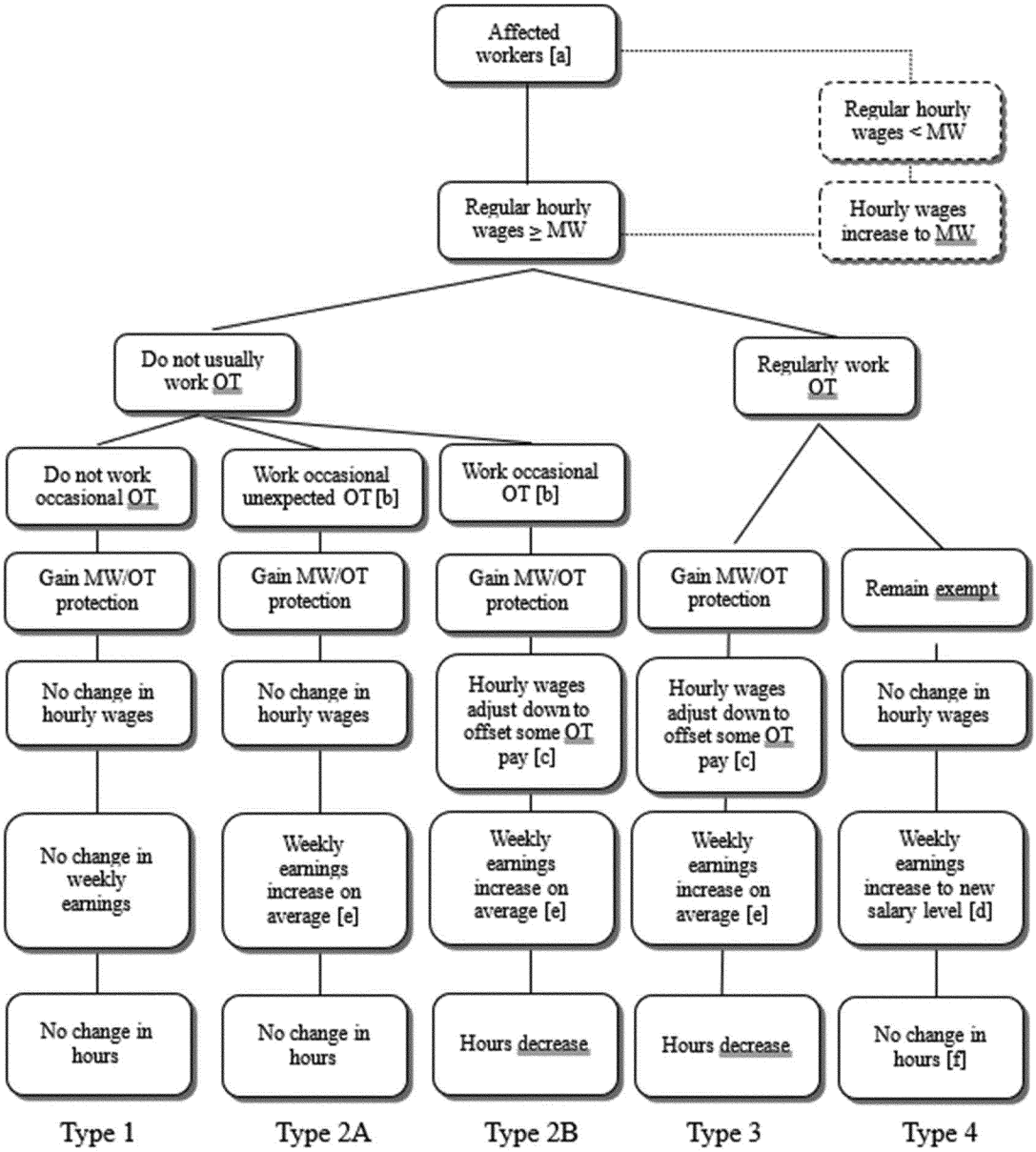
[390] Some researchers have estimated larger impacts on the number of overtime hours worked. For example, Hamermesh and Trejo (2000) conclude the price elasticity of demand for overtime hours is at least −0.5. The Department decided to use a general measure of elasticity applied to the average change in wages since the increase in the overtime wage is somewhat offset by a decrease in the non-overtime wage as indicated in the fixed-job model. Hamermesh, D. and S. Trejo. (2000)). The Demand for Hours of Labor: Direct Evidence from California. *The Review of Economics and Statistics,* 82(1), 38–47.

[391] Brown, Charles C., and Daniel S. Hamermesh. (2019). ''Wages and Hours Laws: What Do We Know? What Can Be Done?'' RSF: The Russell Sage Foundation Journal of the Social Sciences 5(5): 68–87. DOI: 10.7758/RSF.2019.5.5.04.

[392] For example, the authors defined the ''non-exempt 1987–1989'' group as workers earning above $223 but below $455 during this period. Because the salary level for the long test was $155 or $170 and was $250 for the short test, *see* section VII.A.1 (Table 1), some of these workers would be exempt.

[393] In this equation, the only unknown is adjusted total hours worked. Since adjusted total hours worked is in the denominator of the left side of the equation and is also in the numerator of the right side of the equation, solving for adjusted total hours worked requires solving a quadratic equation.

Figure 4—Flow Chart of the Rule's Effect on Earnings and Hours Worked



[a] Those who are exempt under the current EAP exemptions and will gain minimum wage and overtime protection or receive a raise to the increased salary or compensation level.
[b] The Department used two methods to identify occasional overtime workers. The first includes workers who report they usually work 40 hours or fewer per week (identified with variable PEHRUSL1 in CPS MORG), but in the reference week worked more than 40 hours (variable PEHRACT1 in CPS MORG). The second includes reclassifying some additional workers who usually work 40 hours or fewer per week, and in the reference week worked 40 hours or fewer, to match the proportion of workers measured in other data sets who work overtime at any point in the year.
[c] The amount wages are adjusted downwards depends on whether the fixed-job model or the fixed-wage model holds. The Department's primary method uses a combination of the two. Employers reduce the regular hourly wage rate somewhat in response to overtime pay requirements, but the wage is not reduced enough to keep total compensation constant.
[d] Based on hourly wage and weekly hours it is more cost efficient for the employer to increase the worker's weekly salary to the updated salary level than to pay overtime pay.
[e] On average, the Department's modeling of regulatory effects yields a result in which employees' overall weekly earnings will increase despite a small decrease in average hours worked. In some limited cases, employers might decrease employees' hours enough to cause those employees' weekly earnings to decrease.
[f] The Department assumed hours would not change; however, it is possible employers will increase these workers' hours in response to paying them a higher salary or to avoid paying overtime premiums to newly nonexempt coworkers.

(f) Estimated Number of and Effects on Affected EAP Workers

The Department estimated the rule will affect 4.3 million workers (Table 13), of which 3.0 million are Type 1 workers (68.7 percent of all affected EAP workers), 704,000 were estimated to be Type 2 workers (16.2 percent), 558,800 were Type 3 workers (12.9 percent), and 94,100 were estimated to be Type 4 workers (2.2 percent).

Table 13—Affected EAP Workers by Type (1,000s), Year 1

EAP Test	Total	No Overtime (T1)	Occasional Overtime (T2)	Regular Overtime	
				Newly Nonexempt (T3)	Remain Exempt (T4)
Standard salary level	4,044.6	2,778.7	691.3	486.7	87.9
HCE compensation level	292.9	201.4	13.2	72.1	6.2
Total	4,337.5	2,980.2	704.4	558.8	94.1

Note: Pooled CPS data for 2021 – 2023 adjusted to reflect 2023.
*Type 1: Workers who do not work overtime and gain overtime protection.
*Type 2: Workers who work occasional overtime and gain overtime protection.
*Type 3: Workers who work regular overtime and gain overtime protection.
*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary level).

The rule will affect some affected workers' hourly wages, hours, and weekly earnings. Predicted changes in implicit wage rates are outlined in Table 14, changes in hours in Table 15, and changes in weekly earnings in Table 16. How these will change depends on the type of worker, but on average the Department projects that weekly earnings will be unchanged or increase while hours worked will be unchanged or decrease.

Type 1 workers will have no change in wages, hours, or earnings due to the overtime pay provision because these workers do not work overtime.[394]

[394] It is possible that these workers may experience an increase in hours and weekly earnings because of transfers of hours from other newly nonexempt workers who do usually work overtime. Due to the high level of uncertainty in

Continued

For Type 2A workers, the Department assumed employers will be unable to adjust the hours or regular rate of pay for these occasional overtime workers whose overtime is irregularly scheduled and unpredictable. These workers will receive a 50 percent premium on their regular hourly wage for each hour worked in excess of 40 hours per week, and so average weekly earnings would increase.[395]

For Type 3 workers and Type 2B workers (the 50 percent of Type 2 workers who regularly work occasional overtime, an estimated 969,100 workers), the Department used the incomplete fixed-job model to estimate changes in the regular rate of pay. These workers will see a decrease in their average regular hourly wage and a small decrease in hours. However, because these workers will receive a 50 percent premium on their regular hourly wage for each hour worked in excess of 40 hours per week, their average weekly earnings will increase. The reduction in hours is relatively small and is due to a decrease in labor demand from the increase in the average hourly wage as predicted by the incomplete fixed-job model (Table 15).

Type 4 workers' implicit hourly rates of pay and weekly earnings will increase to meet the updated standard salary level or HCE annual compensation level. Type 4 workers' hours may increase to offset the additional earnings, but due to lack of data, the Department assumed hours would not change.

Table 14—Average Regular Rate of Pay by Type of Affected EAP Worker, Year 1

Time Period	Total	No Overtime (T1)	Occasional Overtime (T2)	Regular Overtime	
				Newly Nonexempt (T3)	Remain Exempt (T4)
Standard Salary Level					
Before rule	$24.26	$25.23	$24.61	$18.85	$20.62
After rule	$24.14	$25.23	$24.49	$17.90	$21.21
Change ($)	-$0.12	$0.00	-$0.12	-$0.95	$0.59
Change (%)	-0.5%	0.0%	-0.5%	-5.0%	2.9%
HCE Compensation Level					
Before rule	$57.97	$61.80	$59.78	$47.44	$52.13
After rule	$57.25	$61.80	$58.09	$44.74	$52.92
Change ($)	-$0.72	$0.00	-$1.69	-$2.70	$0.78
Change (%)	-1.2%	0.0%	-2.8%	-5.7%	1.5%

Note: Pooled CPS data for 2021 – 2023 adjusted to reflect 2023.
*Type 1: Workers who do not work overtime and gain overtime protection.
*Type 2: Workers who work occasional overtime and gain overtime protection.
*Type 3: Workers who work regular overtime and gain overtime protection.
*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary level).

employers' responses regarding the transfer of hours, the Department did not have credible evidence to support an estimation of the number of hours transferred to other workers.

[395] Type 2 workers will not see increases in regular earnings to the new salary or compensation levels (as Type 4 workers do) even if their new earnings in this week exceed those new levels. This is because the estimated new earnings only reflect their earnings in those weeks when overtime is worked; their earnings in typical weeks when they do not work overtime do not exceed the salary or compensation level.

Table 15—Average Weekly Hours by Type of Affected EAP Worker, Year 1

Time Period	Total	No Overtime Worked (T1)	Occasional OT (T2)	Regular OT	
				Newly Nonexempt (T3)	Remain Exempt (T4)
Standard Salary Level [a]					
Before rule	41.0	38.9	40.7	50.4	54.7
After rule	40.9	38.9	40.7	50.0	54.7
Change (hours)	-0.1	0.0	0.0	-0.4	0.0
Change (%)	-0.1%	0.0%	-0.1%	-0.8%	0.0%
HCE Compensation Level [a]					
Before rule	42.7	39.4	44.7	50.5	56.4
After rule	42.6	39.4	44.6	50.2	56.4
Change (hours)	-0.1	0.0	-0.1	-0.3	0.0
Change (%)	-0.2%	0.0%	-0.3%	-0.6%	0.0%

Note: Pooled CPS data for 2021 – 2023 adjusted to reflect 2023.

[a] Usual hours for Types 1, 3, and 4 but actual hours for Type 2 workers identified in the CPS MORG.

*Type 1: Workers who do not work overtime and gain overtime protection.

*Type 2: Workers who work occasional overtime and gain overtime protection.

*Type 3: Workers who work regular overtime and gain overtime protection.

*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary level).

Table 16—Average Weekly Earnings by Type of Affected EAP Worker, Year 1

Time Period	Total	No Overtime (T1)	Occasional Overtime (T2)	Regular Overtime	
				Newly Nonexempt (T3)	Remain Exempt (T4)
Standard Salary Level [a]					
Before rule	$947.71	$936.67	$982.87	$934.77	$1,091.89
After rule	$953.67	$936.67	$994.47	$961.31	$1,128.00
Change ($)	$5.96	$0.00	$11.60	$26.53	$36.11
Change (%)	0.6%	0.0%	1.2%	2.8%	3.3%
HCE Compensation Level [a]					
Before rule	$2,397.46	$2,375.43	$2,683.04	$2,366.73	$2,864.13
After rule	$2,414.25	$2,375.43	$2,719.10	$2,424.68	$2,907.00
Change ($)	$16.79	$0.00	$36.06	$57.94	$42.87
Change (%)	0.7%	0.0%	1.3%	2.4%	1.5%

Note: Pooled CPS data for 2021 – 2023 adjusted to reflect 2023.

[a] The mean of the hourly wage multiplied by the mean of the hours does not necessarily equal the mean of the weekly earnings because the product of two averages is not necessarily equal to the average of the product.

*Type 1: Workers who do not work overtime and gain overtime protection.

*Type 2: Workers who work occasional overtime and gain overtime protection.

*Type 3: Workers who work regular overtime and gain overtime protection.

*Type 4: Workers who work regular overtime and remain exempt (*i.e.*, earnings increase to the updated salary level).

At the new standard salary level, the average weekly earnings of affected workers will increase $5.96 (0.6 percent), from $947.71 to $953.67. Multiplying the average change of $5.96 by the 4.0 million EAP workers affected by the combination of the initial update and the subsequent application of the new standard salary level and 52 weeks equals an increase in earnings of $1.3 billion in the first year. For workers affected by the change in the HCE compensation level, average weekly earnings will increase by $16.79. When multiplied by 292,900 affected workers and 52 weeks, the national increase will be $255.6 million in the first year. Thus, total Year 1 transfer payments attributable to this rule will equal $1.5 billion.

The Department is only aware of one paper that modeled the impacts of the 2019 rule's increases in the salary and compensation levels. Quach (2024) [396] used administrative payroll data from May 2008 to July 2021 to estimate the impacts of the rescinded 2016 rule and the 2019 rule on employment, earnings, and salary status.[397] The paper has not been published in a peer-reviewed journal and has significant limitations, including that its use of administrative payroll data from ADP means that the findings are not representative as ADP customers do not represent a random sample of the workplace.

In terms of its findings, concerning employment, the author found that expansions in overtime coverage actually had little effect on employment. He also found that average weekly earnings rose by about 1.4% for salaried workers, and found no evidence that firms reduced base pays in response to changes in the overtime threshold. Concerning salary status, he found that approximately 2.6% of affected workers are re-classified from salaried to hourly status. The Department has not adjusted its methodology in response to this paper given the concerns listed above.

Additionally, it can be informative to look at papers which predict the impact of rulemakings. For example, Rohwedder and Wenger (2015) analyzed the effects of increasing the standard salary level from the then baseline level of $455 per week.[398] They compared hourly and salaried workers in the CPS using quantile treatment effects. This methodology estimates the effect of a worker becoming nonexempt by comparing similar workers who are hourly and salaried. They found no statistically significant change in hours or wages on average. However, their point estimates, averaged across all affected workers, show small increases in earnings and decreases in hours, similar to the Department's analysis. For example, using a salary level of $750, they estimated weekly earnings may increase between $2 and $22 and weekly hours may decrease by approximately 0.4 hours.

[396] Quach, S. (2024). The Labor Market Effects of Expanding Overtime Coverage. *https://raw.githubusercontent.com/SimonQuach1/Papers/main/Quach_OT.pdf?token=AH2DVMEDLJGBAWFAVXXUNMDAYGGDQ.*

[397] The Department notes that the effective date of the 2019 final rule was in January 2020, so using data from this month may not fully capture the effects of the 2019 rule.

[398] Rohwedder, S. and Wenger, J.B. (2015). The Fair Labor Standards Act: Worker Misclassification and the Hours and Earnings Effects of Expanded Coverage. RAND Labor and Population.

iv. Potential Transfers Not Quantified

This rule could lead to additional transfers that the Department is unable to quantify. For example, in response to this rule, some employers may decrease the hours of newly nonexempt workers who usually work overtime. These hours may be transferred to other workers, such as non-overtime workers and exempt workers who are not affected by the rule. Depending on how these hours are transferred, it could lead to either a reduction or increase in earnings for other workers. Employers may also offset increased labor costs by reducing bonuses or benefits instead of reducing base wages or hours worked. If this occurs, an employee's overall compensation may not be affected.

The rule could also reduce reliance on social assistance programs for some workers who may receive a transfer of income resulting from this rule. For low-income workers, this transfer could result in a reduced need for social assistance programs such as Medicaid, the Earned Income Tax Credit (EITC), the Supplemental Nutrition Assistance Program (SNAP), the Temporary Assistance for Needy Families (TANF) program, the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and free or reduced-priced school meals. A worker earning the current salary level of $684 per week earns $35,568 annually, which is roughly equivalent to the Federal poverty level for a family of five and makes the family eligible for multiple social assistance programs.[399] Thus, transferring income to these workers could reduce eligibility for government social assistance programs. This could lead to an increase or a reduction in a family's total resources, depending on the relative size of the increase in earnings and the value of the decrease in assistance. Regardless, reduced eligibility for social assistance programs would reduce government expenditures at the Federal, State, and/or local level.

5. Benefits and Cost Savings

The Department expects that this rule could lead to multiple benefits, which were discussed qualitatively in the NPRM. These potential benefits and commenter feedback about them are addressed below.

The revised salary level will strengthen the overtime protection of salaried, white-collar employees who do not pass the standard duties test and who earn between the current salary standard salary level and the new standard salary level. These employees are nonexempt but, because they satisfy the current salary level threshold, employers must apply the duties test to determine their exemption status. At the new salary level, the number of white-collar salaried employees who earn between the current and the new salary levels and fail the duties test would decrease by 4.7 million. Because these nonexempt employees no longer meet the salary level, employers will be able to determine their exemption status based solely on the salary test. If any of these employers previously spent significant time evaluating the duties of these workers to determine exemption status, the change to determining exemption status based on the salary level could lead to some cost savings. Also, as many commenters observed, the new salary level will strengthen the right to overtime pay for nonexempt workers who earn between the current and new standard salary levels. *See, e.g.,* Coalition of State AGs; Coalition of Gender Justice and Civil Rights Organizations; Washington Dept. of Labor & Industries. Similarly, to the extent that some of these 4.7 million employees are currently misclassified as exempt, the new salary level will make it more clear for workers and employers that such workers are not EAP exempt.[400] Thus, this aspect of the rule is responsive to commenter concerns that the current salary level is too low to prevent the misclassification of salaried employees who fail the duties test. *See e.g.,* AFSCME; EPI; NELP; Sanford Heisler Sharp.

Commenters disagreed over whether the proposed rule would improve or hinder the productivity of affected workers. Some commenters, such as the AFL–CIO, agreed with the analysis provided in the NPRM that this rulemaking could increase productivity ''by reducing turnover, incentivizing workers to work harder, and increasing marginal productivity as fewer hours are worked.'' In contrast, a number of employer representatives asserted that the rule would hinder worker productivity. For example, PPWO asserted that affected workers who become nonexempt ''will now need to account for their time in a way they have not had to previously, and in a way that their exempt co-workers do not.'' *See also, e.g.,* AFPI.

The Department continues to believe that the rule could potentially lead to increased worker productivity if workers receive an increase in compensation. Increased productivity could occur through numerous channels, such as employee retention and level of effort. A strand of economic research, commonly referred to as ''efficiency wage'' theory, considers how an increase in compensation may be met with greater productivity.[401] Efficiency wages may elicit greater effort on the part of workers, making them more effective on the job.[402] Other research on increases in the minimum wage have demonstrated a positive relationship between increased compensation and worker productivity. For example, Kim and Jang (2019) showed that wage raises increase productivity for up to two years after the wage increase.[403] They found that in both full and limited-service restaurants productivity increased due to improved worker morale after a wage increase. Additionally, research demonstrates a correlation between increased earnings and reduced employee turnover.[404] [405] Reducing turnover, in turn, may increase productivity because longer-tenured employees have more firm-specific skills and knowledge and thus could be more productive and require less

[399] Department of Health and Human Services (2023). Federal Poverty Level. *https://www.healthcare.gov/glossary/Federal-poverty-level-fpl/.*

[400] *See* Rohwedder, S. and Wenger, J.B. (2015). The Fair Labor Standards Act: Worker Misclassification and the Hours and Earnings Effects of Expanded Coverage. RAND Labor and Population. RAND conducted a survey to identify the number of workers who may have failed the standards duties test and yet are classified as EAP exempt. The survey, a special module to the American Life Panel, asked respondents: (1) their hours worked, (2) whether they are paid on an hourly or salary basis, (3) their typical earnings, (4) whether they perform certain job responsibilities that are treated as proxies for whether they would justify exempt status, and (5) whether they receive any overtime pay. Using these data, Rohwedder and Wenger found that ''11.5 percent of salaried workers were classified as exempt by their employer although they did not meet the criteria for being so.'' This survey was conducted when the salary level was $455. The exact percentage may no longer be applicable, but the concern that in some instances the duties test may be misapplied remains.

[401] Akerlof, G.A. (1982). Labor Contracts as Partial Gift Exchange. The Quarterly Journal of Economics, 97(4), 543–569.

[402] Another model of efficiency wages, which is less applicable here, is the adverse selection model in which higher wages raise the quality of the pool of applicants.

[403] Kim, H.S., & Jang, S. (2019). Minimum Wage Increase and Firm Productivity: Evidence from the Restaurant Industry. Tourism Management 71, 378–388. *https://doi.org/10.1016/j.tourman.2018.10.029.*

[404] Howes, Candace. (2005). Living Wages and Retention of Homecare Workers in San Francisco. *Industrial Relations,* 44(1), 139–163. Dube, A., Lester, T.W., & Reich, M.. (2014). Minimum Wage Shocks, Employment Flows and Labor Market Frictions. IRLE Working Paper #149–13.

[405] This literature tends to focus on changes in earnings for a specific sector or subset of the labor force. The impact on turnover when earnings increase across sectors (as would be the case with this regulation) may be smaller.

supervision and training.[406] Reduced turnover could also reduce firms' hiring and training costs. As a result, even though marginal labor costs rise, they may rise by less than the amount of the wage change because the higher wages may be offset by increased productivity and reduced hiring costs for firms.

This rulemaking could also result in an increase in personal time for some affected workers. Worker advocacy organizations and individual commenters asserted that employees would generally enjoy more personal time as a consequence of the rule. For example, SEIU commented that ''[w]hen workers are exempted from overtime pay protections, it disincentivizes employers from being efficient with [employees'] time.'' Due to the increase in marginal cost for overtime hours for newly overtime-eligible workers, employers could demand fewer hours from some of the workers affected by this rulemaking. If these workers' pay remains the same, they could benefit from increased personal time and improved work-life balance. Empirical evidence shows that workers in the United States typically work more than workers in other comparatively wealthy countries.[407] Workers in executive, administrative, and professional occupations tend to work longer hours.[408] They also have the highest percentage of workers who would prefer to work fewer hours compared to other occupational categories.[409] Therefore, the Department believes that this rule may result in reduced time spent working overtime for a group of workers, some of whom may prefer such an outcome.

6. Sensitivity Analysis of Transfer Payments

Because the Department cannot predict employers' precise reactions to the rule, the Department calculated bounds on the size of the estimated transfers from employers to workers, relative to the primary estimates in this RIA. For the upper bound, the Department assumed that the full overtime premium model is more likely to occur than in the primary model. For the lower bound, the Department assumed that the complete fixed-job model is more likely to occur than in the primary model. Based on these assumptions, estimated transfers may range from $631.1 million to $2.9 billion, with the primary estimate equal to $1.5 billion.

For a reasonable upper bound on transfer payments, the Department assumed that all occasional overtime workers and half of regular overtime workers would receive the full overtime premium (*i.e.,* such workers will work the same number of hours but be paid 1.5 times their implicit initial hourly wage for all overtime hours) (Table 17). The full overtime premium model is a special case of the fixed-wage model where there is no change in hours. For the other half of regular overtime workers, the Department assumed in the upper-bound method that they would have their implicit hourly wage adjusted as predicted by the incomplete fixed-job model (wage rates fall and hours are reduced but total earnings continue to increase, as in the primary method). In the primary model, the Department assumed that only 50 percent of occasional overtime workers and no regular overtime workers would receive the full overtime premium.

The plausible lower bound on transfer payments also depends on whether employees work regular overtime or occasional overtime. For those who regularly work overtime hours and half of those who work occasional overtime, the Department assumed the employees' wages would fully adjust as predicted by the fixed-job model.[410] For the other half of employees with occasional overtime hours, the lower bound assumes they would be paid one and one-half times their implicit hourly wage for overtime hours worked (full overtime premium).

[406] Argote, L., Insko, C. A., Yovetich, N., & Romero, A. A. (1995). Group Learning Curves: The Effects of Turnover and Task Complexity on Group Performance. *Journal of Applied Social Psychology,* 25(6), 512–529. Shaw, J. D. (2011). Turnover Rates and Organizational Performance: Review, Critique, and Research Agenda. *Organizational Psychology Review,* 1(3), 187–213.

[407] For more information, see OECD series, average annual hours actually worked per worker, available at: *https://stats.oecd.org/index.aspx?DataSetCode=ANHRS.*

[408] Boushey, H. and Ansel, B. (2016). Overworked America, The economic causes and consequences of long work hours. Washington Center for Equitable Growth. *https://equitablegrowth.org/research-paper/overworked-america/?longform=true.*

[409] Hamermesh, D.S., Kawaguchi, D., Lee, J. (2014). Does Labor Legislation Benefit Workers? Well-Being after an Hours Reduction. IZA DP No. 8077.

Golden, L., & Gebreselassie, T. (2007). Overemployment Mismatches: The Preference for Fewer Work Hours. *Monthly Labor Review,* 130(4), 18–37.

Hamermesh, D.S. (2014). Not Enough Time? *American Economist,* 59(2).

[410] The straight-time wage adjusts to a level that keeps weekly earnings constant when overtime hours are paid at 1.5 times the straight-time wage. In cases where adjusting the straight-time wage results in a wage less than the minimum wage, the straight-time wage is set to the minimum wage.

Table 17—Summary of the Assumptions Used to Calculate the Lower Estimate, Primary Estimate, and Upper Estimate of Transfers

Lower Transfer Estimate	Primary Estimate	Upper Transfer Estimate
Occasional Overtime Workers (Type 2)		
50% fixed-job model 50% full overtime premium	50% incomplete fixed-job model 50% full overtime premium	100% full overtime premium
Regular Overtime Workers (Type 3)		
100% fixed-job model	100% incomplete fixed-job model	50% incomplete fixed-job model 50% full overtime premium

* Full overtime premium model: Regular rate of pay equals the implicit hourly wage prior to the regulation (with no adjustments); workers are paid 1.5 times this base wage for the same number of overtime hours worked prior to the regulation.
* Fixed-job model: Base wages are set at the higher of: (1) a rate such that total earnings and hours remain the same before and after the regulation; thus the base wage falls, and workers are paid 1.5 times the new base wage for overtime hours (the fixed-job model) or (2) the minimum wage.
* Incomplete fixed-job model: Regular rates of pay are partially adjusted to the wage implied by the fixed-job model.

7. Effects by Regions and Industries

This section compares the number of affected workers, costs, and transfers across regions and industries. Although impacts will be more pronounced in some regions or industries, the Department has concluded that in no region or industry are the costs overly burdensome. The proportion of total costs and transfers in each region will be fairly consistent with the proportion of total workers in each region. Affected workers are overrepresented in some industries, but costs and transfers will still be manageable as a share of payroll and of total revenue (*See* Table 21 for regions and Table 24 for industries).

The Department also compared costs and transfers relative to total payrolls and revenues. This provides a common method of assessing the relative effects of the rule on different regions or industries, and the magnitude of adjustments the rule may require on the part of enterprises in each region or industry. The relative costs and transfers expressed as a percentage of payroll are particularly useful measures of the relative size of adjustment faced by organizations in a region or industry because they benchmark against the cost category directly associated with the labor force. Average estimated costs and transfers from this rule are very small relative to current payroll or current revenue—less than a tenth of a percent of payroll and of revenue in each region and in each industry.

Salaries vary across the U.S. geographically. To ensure the new standard salary level would not be too high in any region of the country, the Department has used only wages in the lowest-wage region, the South,[411] to set the salary level. However, because wages are lower in the South and the Midwest[412] than the Northeast[413] and the West,[414] impacts may be larger in these two lower-wage regions. This section considers impacts across the four Census regions to ensure the impacts in the lower-wage regions would be manageable. The South has by far the most affected workers (1.9 million), though it also has the most workers of any Census region (Table 18). As a share of potentially affected workers in the region, the South will have somewhat more affected workers relative to other regions (17.9 percent are affected compared with 11.0 to 15.4 percent in other regions). However, as a share of all workers in the region, the South will not be particularly affected relative to other regions (3.5 percent are affected compared with 2.3 to 3.0 percent in other regions).

Table 18—Potentially Affected and Affected Workers, by Region, Year 1

[411] The South Census region is comprised of the following states: Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia.

[412] The Midwest Census region is comprised of the following states: Kansas, Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin.

[413] The Northeast Census region is comprised of the following states: Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont.

[414] The West Census region is comprised of the following states: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming.

Region	Workers Subject to FLSA (Millions)	Potentially Affected Workers (Millions) [a]	Affected Workers (Millions) [b]	Affected Workers as a Precent of Potentially Affected Workers	Affected Workers as a Percent of All Workers
All	143.7	29.7	4.3	14.6%	3.0%
Northeast	25.5	6.0	0.7	12.3%	2.9%
Midwest	31.1	6.1	0.9	15.4%	3.0%
South	53.2	10.5	1.9	17.9%	3.5%
West	33.8	7.2	0.8	11.0%	2.3%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[a] EAP exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.

[b] Currently EAP exempt workers who will be entitled to overtime protection under the updated earnings levels or whose weekly earnings will increase to the new earnings levels to remain exempt.

Total transfers in the first year were estimated to be $1.5 billion (Table 19). As expected, the transfers in the South will be the largest portion because the largest number of affected workers would be in the South. However, transfers per affected worker will be less in the South than in other Census regions. Annual transfers per affected worker will be $291 in the South, and between $346 and $462 in other regions.

Table 19—Annual Transfers by Region, Year 1

Region	Total Annual Change in Earnings (Millions)	Annual Transfer Per Affected Worker	Annual Transfers per Entity	Percent of Total Transfers by Region
All	$1,509.2	$348	$183	100.0%
Northeast	$256.4	$346	$172	17.0%
Midwest	$343.6	$368	$202	22.8%
South	$543.6	$291	$181	36.0%
West	$365.6	$462	$178	24.2%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

Table 20—Annual Costs by Region, Year 1

Region	Total Direct Costs (Millions)	Total Direct Costs per Entity	Percent of Total Direct Costs by Region
All	$1,436.2	$174	100.0%
Northeast	$240.7	$162	16.8%
Midwest	$323.5	$190	22.5%
South	$581.7	$194	40.5%
West	$1,436.2	$174	100.0%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

Direct employer costs are composed of regulatory familiarization costs, adjustment costs, and managerial costs. The Department estimates that total direct employer costs will be the highest in the South ($581.7 million) and lowest in the Northeast ($240.7 million). Transfers and direct employer costs in each region, as a percentage of the total transfers and direct costs, would range from 16.9 percent in the Northeast to 38.2 percent in the South. These proportions are almost the same as the proportions of the total workforce in each region: 17.8 percent in the Northeast and 37.0 percent in the South. Costs and transfers per establishment would be slightly higher in the Midwest ($392) than on average, but still small (Table 21).

Another way to compare the relative effects of this rule by region is to consider the transfers and costs as a proportion of payroll and revenues (Table 21).[415] Nationally, employer costs and transfers will be approximately 0.031 percent of payroll. By region, direct employer costs and transfers as a percent of payroll will be approximately the same (between 0.025 and 0.036 percent of payroll). Employer costs and transfers as a percent of revenue will be 0.006 percent nationally and range between 0.005 and 0.006 percent in each region.

Table 21—Annual Transfers and Costs as Percent of Payroll and of Revenue by Region, Year 1

Region	Transfers and Costs per Entity	Payroll (Billions) [a]	Revenue (Billions) [a]	Costs and Transfers	
				As Percent of Payroll	As Percent of Revenue
All	$358	$9,471	$50,655	0.031%	0.006%
Northeast	$334	$2,010	$9,902	0.025%	0.005%
Midwest	$392	$1,947	$11,276	0.034%	0.006%
South	$375	$3,137	$17,812	0.036%	0.006%
West	$320	$2,377	$11,666	0.028%	0.006%

[a] Payroll and revenue data exclude the Federal Government.

Sources: Costs and transfers based on pooled CPS data for 2021-2023 adjusted to reflect 2023. Private sector payroll and revenue data from 2017 SUSB. State and local payroll and revenue data from State and Local Government Finances 2020. Inflated to $2023 using GDP deflator.

Impacts may be more pronounced in some industries. In particular, lower-wage industries where more workers may earn between $684 and the new salary level may be impacted more. Additionally, industries where EAP workers are more prevalent may experience larger impacts. To gauge the effect of the rule on industries, the Department estimated affected workers, costs, and transfers for the 13 major industry groups. The Department also compared estimates of combined costs and transfers as a percent of payroll and revenue across industries.

Table 22 presents the number of affected workers by industry. The industry with the most affected workers is professional and business services (827,400). The industry with the largest share of workers affected is financial activities (5.7 percent). This is because the financial activities industry is heavily composed of salaried white-collar workers. As a share of potentially affected workers, the industry with the highest share affected is leisure and hospitality (24.3 percent), followed by agriculture, forestry, fishing, & hunting (22.8 percent).

[415] The Department uses 2017 data here because although payroll data are available for more recent years, the most recent revenue data are for 2017.

Table 22—Potentially Affected and Affected Workers, by Industry, Year 1

Industry	Workers Subject to FLSA (1,000s)	Potentially Affected Workers (1,000s) [a]	Affected Workers (1,000s) [b]	Affected Workers as a Percent of Potentially Affected Workers	Affected Workers as a Percent of All Workers
All	143,677.6	29,746.7	4,337.5	14.6%	3.0%
Agriculture, forestry, fishing, & hunting	1,312.6	58.5	13.3	22.8%	1.0%
Mining	587.4	156.6	18.5	11.8%	3.1%
Construction	9,305.3	1,266.9	184.6	14.6%	2.0%
Manufacturing	15,521.5	4,062.0	350.6	8.6%	2.3%
Wholesale trade	3,164.1	852.5	112.3	13.2%	3.5%
Retail trade	15,649.0	1,966.1	377.4	19.2%	2.4%
Transportation & utilities	8,902.5	1,072.9	152.9	14.3%	1.7%
Information	2,711.7	1,082.4	132.4	12.2%	4.9%
Financial activities	9,925.6	4,349.8	564.5	13.0%	5.7%
Professional & business services	17,462.0	7,126.2	827.4	11.6%	4.7%
Education	14,294.5	1,202.7	244.1	20.3%	1.7%
Healthcare & social services	21,025.7	3,745.2	740.2	19.8%	3.5%
Leisure & hospitality	12,529.3	940.3	228.5	24.3%	1.8%
Other services	5,532.2	761.7	163.5	21.5%	3.0%
Public administration	5,754.2	1,103.0	227.2	20.6%	3.9%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[a] EAP exempt workers who are white-collar, salaried, not eligible for another (non-EAP) overtime exemption, and not in a named occupation.

[b] Currently EAP exempt workers who will be entitled to overtime protection under the updated earnings levels or whose weekly earnings will increase to the new earnings levels to remain exempt.

Both transfers and costs will be the largest in the professional and business services industry because this industry is large and heavily composed of salaried white-collar workers (Table 23). Combined, in Year 1, these total $564.7 million and represent 19.2 percent of nationwide transfers and costs. Transfers and costs are also large in the healthcare and social services industry, at least partially due to the large size of this industry. However, transfers per affected worker will be relatively low in this industry, $229 in the first year compared with $348 nationally. A third industry with relatively large total transfers and costs is the retail trade industry.

Table 23—Annual Transfers and Costs by Industry, Year 1

Industry	Transfers (Millions)	Transfer Per Affected Worker	Direct Costs (Millions) [a]	Transfers and Costs (Millions)	Percent of Total Transfers and Costs by Industry
All	$1,509.2	$348	$1,435.7	$2,944.9	100.0%
Agriculture, forestry, fishing, & hunting	$2.4	$178	$4.3	$6.6	0.2%
Mining	$5.2	$284	$4.5	$9.8	0.3%
Construction	$63.5	$344	$87.5	$151.1	5.1%
Manufacturing	$142.9	$408	$101.4	$244.3	8.3%
Wholesale trade	$52.2	$465	$50.7	$102.9	3.5%
Retail trade	$192.8	$511	$166.9	$359.7	12.2%
Transportation & utilities	$59.8	$391	$50.7	$110.5	3.8%
Information	$49.7	$375	$35.8	$85.5	2.9%
Financial activities	$184.2	$326	$168.0	$352.2	12.0%
Professional & business services	$303.9	$367	$260.8	$564.7	19.2%
Education	$48.3	$198	$53.4	$101.6	3.5%
Healthcare & social services	$169.6	$229	$197.4	$367.0	12.5%
Leisure & hospitality	$138.6	$607	$121.3	$259.9	8.8%
Other services	$48.1	$294	$82.7	$130.8	4.4%
Public administration	$47.9	$211	$50.3	$98.2	3.3%

Sources: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[a] Regulatory familiarization costs exclude 10,440 establishments whose industry is "not classified."

To measure the impact on businesses, a comparison of transfers and costs to payroll, revenue, or profit is more helpful than looking at the absolute size of transfers and costs per industry. As a percent of payroll, transfers and costs would be highest in agriculture, forestry, fishing, and hunting; retail trade; leisure and hospitality; and education (Table 24). However, the magnitude of the relative shares will be small, representing less than 0.1 percent of payroll costs in all industries. The Department's estimates of transfers and costs as a percent of revenue by industry also indicated a very small effect of less than 0.03 percent of revenues in any industry. The industries with the largest transfers and costs as a percent of revenue will be education; leisure and hospitality; and professional and business services. Table 24 illustrates that the differences in costs and transfers relative to revenues will be quite small across industry groupings.

The overall magnitude of costs and transfers as a percentage of profits represents less than 1.0 percent of overall profits in each industry.[416] [417] By industry, the value of total costs and transfers as a percent of profits ranges from a low of 0.02 percent (wholesale trade) to a high of 0.62 percent (agriculture, forestry, fishing, and hunting). Benchmarking against profits is potentially helpful in the sense that it provides a measure of the rule's effect against returns to investment. However, this metric must be interpreted carefully as it does not account for differences across industries in risk-adjusted rates of return which are not readily available for this analysis. The ratio of costs and transfers to profits also does not reflect

[416] Internal Revenue Service. (2023). SOI Tax Stats—Corporation Income Tax Returns Complete Report (Publication 16). Available at: *https://www.irs.gov/statistics/soi-tax-stats-corporation-income-tax-returns-complete-report-publication-16.*

[417] Table 1 of the IRS report provides total receipts, net income, and deficits by industry. For each industry, the Department calculated the profit-to-revenue ratio as net income (column (7)) less any deficit (column (8)) divided by total receipts (column (3)). Profits were then calculated as revenues multiplied by profit-to-revenue ratios. Profits could not be used directly because they are limited to only active corporations.

differences in the firm-level adjustment to profit impacts reflecting cross-industry variation in market structure.[418]

Table 24—Annual Transfers, Total Costs, and Transfers and Costs as Percent of Payroll, Revenue, and Profit by Industry, Year 1

Industry	Costs and Transfers per Entity	Payroll (Billions) [a]	Revenue (Billions) [a]	Costs and Transfers As Percent of:		
				Payroll [a]	Revenue [a]	Profit [a]
All	$357.9	$9,470.5	$50,655.8	0.031%	0.006%	0.060%
Agriculture, forestry, fishing, & hunting	$284.9	$8.6	$42.5	0.077%	0.016%	0.617%
Mining	$424.2	$61.9	$493.6	0.016%	0.002%	[b]
Construction	$193.6	$488.1	$2,430.8	0.031%	0.006%	0.107%
Manufacturing	$863.3	$834.6	$6,755.6	0.029%	0.004%	0.034%
Wholesale trade	$263.3	$531.0	$10,656.1	0.019%	0.001%	0.022%
Retail trade	$346.9	$543.4	$5,980.4	0.066%	0.006%	0.186%
Transportation & utilities	$369.5	$382.2	$1,781.5	0.029%	0.006%	0.329%
Information	$527.6	$436.3	$1,927.0	0.020%	0.004%	0.027%
Financial activities	$376.7	$928.5	$6,091.6	0.038%	0.006%	0.027%
Professional & business services	$386.2	$1,956.4	$3,575.3	0.029%	0.016%	0.141%
Education	$911.2	$174.9	$501.7	0.058%	0.020%	0.316%
Healthcare & social services	$387.4	$1,217.5	$3,093.5	0.030%	0.012%	0.159%
Leisure & hospitality	$288.1	$438.6	$1,480.7	0.059%	0.018%	0.214%
Other services	$167.3	$221.2	$881.1	0.059%	0.015%	0.220%
Public administration	$1,089.8	$1,247.4	$4,964.4	0.008%	0.002%	[c]

Sources: Pooled CPS data for 2021-2023 adjusted to reflect 2023. Private sector payroll and revenue data from 2017 SUSB. State and local payroll and revenue data from State and Local Government Finances 2020 are used for the Public Administration industry. Profit-to-revenue data from the Internal Revenue Service 2019. Inflated to $2023 using GDP deflator.

[a] Payroll and revenue data exclude the Federal Government. Profit-to-revenue data limited to active corporations. Regulatory familiarization costs, payrolls, and revenues exclude 10,440 establishments whose industry is "not classified." Because transfer payments include all workers, the estimates of costs and transfers as a share of payroll or revenue are slightly overestimated.

[b] Profits were negative in this industry in this year.

[c] Profit is not applicable for public administration.

[418] In particular, a basic model of competitive product markets would predict that highly competitive industries with lower rates of return would adjust to increases in the marginal cost of labor arising from the rule through an overall, industry-level increase in prices and a reduction in quantity demanded based on the relative elasticities of supply and demand. Alternatively, more concentrated markets with higher rates of return would be more likely to adjust through some combination of price increases and profit reductions based on elasticities as well as interfirm pricing responses.

8. Regulatory Alternatives

The Department considered a range of alternatives before selecting its methods for setting the standard salary level and the HCE compensation level. As seen in Table 25, the Department has calculated the salary/compensation levels, the number of affected workers, and the associated costs and transfers for these alternative levels.

The Department is increasing the standard salary level using earnings for the 35th percentile of full-time salaried workers in the South Census Region, $1,128 per week. The alternative methods considered for setting the standard salary level are:

- *Alternative 1:* 2004/2019 method—$844 per week—20th percentile of earnings of nonhourly full-time workers in the South Census region and/or in the retail industry nationally.
- *Alternative 2:* Kantor long test method—$942 per week—10th percentile of earnings of likely exempt workers.
- *Alternative 3:* 2016 method—$1,196 per week—40th percentile of earnings of nonhourly full-time workers in the South Census region.
- *Alternative 4:* Kantor short test method—$1,404 per week—Kantor long test level multiplied by 149 percent (the historical average relationship between the long and short test levels).

The Department considered using the 2004 methodology (the 20th percentile of full-time salaried white-collar workers in the lowest-wage Census region (currently the South) and/or in retail nationally), which is currently $844 per week ($43,888 per year). This is also the methodology that the Department used in the 2019 rule.[419] However, the salary level produced by the 2004 methodology is below the current equivalent long test salary level ($942 per week), which the Department considers to be a key parameter for determining an appropriate salary level.

The Department also considered setting the standard salary level at the long test level ($942 per week or $48,984 per year). Doing so would ensure the initial screening function of the salary level by restoring overtime protections to those employees who were consistently excluded from the EAP exemption under each iteration of the regulations prior to 2019, either by the long test salary level itself, or under the 2004 rule salary level, which was set equivalent to the long test salary level.[420] However, as explained above, setting the standard salary level at the long test level would not address the impact of the change from a two-test to a one-test system.

The Department also considered setting the standard salary level at the 40th earnings percentile of salaried white-collar workers in the lowest-wage Census Region (currently the South) ($1,196 per week or $62,192 per year). However, the Department is concerned that this approach could be seen by courts as making salary level determinative of exemption status for too large a portion of employees, as this salary level would make the salary paid by the employer determinative of exemption status for more than half (55 percent) of white-collar employees who earn between the long and short test salary levels. The Department is also concerned that this approach would generate the same concerns that led to the district court decision invalidating the 2016 rule (which adopted the same methodology).

Finally, the Department considered setting the standard salary level at the current equivalent of the short test salary level ($1,404 per week or $73,008 per year). This would ensure that all employees who earn between the long and short test salary levels and perform substantial amounts of nonexempt work would be entitled to overtime compensation. However, by making exemption status for all employees who earn between the long and short test levels depend on the salary paid by the employer, this approach would prevent employers from being able to use the EAP exemption for employees earning between these salary levels who do not perform substantial amounts of nonexempt work and thus were historically exempt under the long test.

As described above, the Department is setting the HCE compensation level using earnings for the 85th percentile of all full-time salaried workers nationally, $151,164 per year. The Department also evaluated the following alternative methods to set the HCE compensation levels:

- *HCE alternative 1:* 2019 method[421]—$132,964 annually—80th percentile of earnings of nonhourly full-time workers nationally.
- *HCE alternative 2:* 2016 method[422]—$179,972 annually—90th percentile of earnings of nonhourly full-time workers nationally.

The Department believes that HCE alternative 1 does not produce a threshold high enough to reserve the HCE test for employees who would ''almost invariably pass the standard duties test.'' The Department also considered setting the HCE threshold at the 90th percentile; however, the Department is concerned that the resulting level ($179,972) would restrict the use of the HCE exemption for employers in low-wage regions and industries. The Department believes its proposal to adjust the HCE total annual compensation threshold to reflect the 85th percentile of earnings of nonhourly full-time workers nationally strikes the appropriate balance and ensures that the HCE test continues to serve its intended function as a streamlined alternative for employees who are highly likely to pass the standard duties test.

[419] 84 FR 51260.

[420] *See* section V.B.4.ii.

[421] *See* 84 FR 51250.

[422] *See* 81 FR 32429.

Table 25—Updated Standard Salary and HCE Compensation Levels and Alternatives, Affected EAP Workers, Costs, and Transfers, Year 1

Alternative	Salary Level	Affected EAP Workers (1,000s)	Year 1 Effects (Millions)	
			Adj. & Managerial Costs	Transfers
Standard Salary Level (Weekly)				
Alt. #1: 2004/2019 method [a]	$844	959	$202.3	$204.3
Alt #2: Kantor long test [b]	$942	1,806	$385.9	$432.0
Final rule: 35th pct South [c]	$1,128	4,045	$905.4	$1,253.6
Alt. #3: 2016 method - 40th pct South [d]	$1,196	4,993	$1,116.1	$1,642.9
Alt. #4: Kantor short test [e]	$1,404	7,961	$1,860.0	$3,035.1
HCE Compensation Level (Annually)				
HCE alt. #1: 2019 method - 80th pct [f]	$132,964	223	$58.7	$164.5
Final rule: 85th pct [g]	$151,164	293	$79.2	$255.6
HCE alt. #2: 2016 method - 90th pct [h]	$179,972	340	$97.6	$359.2

Note: Regulatory familiarization costs are excluded because they do not vary based on the selected values of the salary levels. Additionally, they cannot be disaggregated by exemption type (i.e., standard versus HCE). The Department did not receive comments on how to refine familiarization cost estimates in a manner that distinguishes among regulatory alternatives.

[a] 20th percentile earnings of nonhourly full-time workers in the South Census region or retail industry (excludes workers not subject to the FLSA, not subject to the salary level test, and in agriculture or transportation). Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[b] 10th percentile earnings of likely exempt workers. Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[c] 35th percentile of earnings of nonhourly full-time workers in the South Census region. CPS 2023. Available at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.

[d] 40th percentile of earnings of nonhourly full-time workers in the South Census region. CPS 2023 data. Available at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.

[e] Kantor short test is set as the long test level multiplied by 149 percent. This is the historical average relationship between the two levels.

[f] 80th percentile of earnings of nonhourly full-time workers nationally (excludes workers not subject to the FLSA, not subject to the salary level test, and in agriculture or transportation). Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[g] 85th percentile of earnings of nonhourly full-time workers nationally. CPS 2023 data. Available at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm.

[h] 90th percentile of earnings of nonhourly full-time workers nationally CPS 2023 data. Available at https://www.bls.gov/cps/research/nonhourly/earnings-nonhourly-workers.htm

9. Triennial Updates to the Standard Salary and Annual Compensation Thresholds

Between updates to the standard salary and HCE compensation levels, nominal wages typically increase, resulting in an increase in the number of workers qualifying for the EAP exemption, even if there has been no change in their real earnings. Thus, workers whom Congress intended to be covered by the minimum wage and overtime pay provisions of the FLSA may lose those protections. The mechanism the Department established in this rulemaking for updating the salary and compensation levels allows these thresholds to keep pace with changes in earnings and continue to serve as an effective dividing line between potentially exempt and nonexempt workers. Furthermore, the updating mechanism will provide employers more certainty in knowing that these levels will change by smaller amounts on a regular basis, rather than the more disruptive increases caused by much larger changes after longer, uncertain increments of time. This will allow firms to better predict short- and long-term costs and employment needs. In addition to the changes being made to the standard salary level and HCE compensation threshold, the Department is including in this rule a mechanism for updating the salary and compensation levels initially on July 1, 2024 and every 3 years thereafter to reflect current earnings.

i. Initial Update

As discussed in section IV, the new standard salary level and HCE total annual compensation threshold methodologies do not become applicable until approximately 8 months after publication of this final rule. Therefore, the initial update on July 1, 2024 will use the methodologies in place at the time of the update (*i.e.,* the 2019 rule methodologies), which results in a $844 per week standard salary level and a $132,964 HCE total annual compensation threshold. Consistent with the 2019 rule, the Department used pooled CPS data for the most recent 3 years (2021, 2022, 2023), adjusted to reflect 2023, for the initial updates to the standard salary and annual compensation thresholds.

As previously discussed, the Department's affected worker, cost, and transfer estimates for Year 1 have accounted for the initial update and the new standard salary and annual compensation thresholds that become applicable 6 months after the initial update. Just looking at the initial update, the Department estimated the initial update to the standard salary level will affect workers who earn between $684 and $844 per week. The Department estimates that this update will result in 959,000 affected workers. Of these affected workers, 68.7 percent of them do not work overtime. The Department estimated the Year 1 adjustment and managerial costs for just this update would be $202.3 million and transfer payments would be $204.3 million. For the initial update to the HCE total annual compensation threshold, the Department estimated that just the update would result in 223,000 affected workers, $58.7 million in adjustment and managerial costs, and $164.5 million in transfer payments in Year 1.

ii. Future Updates

The Department is establishing future updates to the standard salary level and HCE total annual compensation threshold with current earnings data beginning 3 years after the date of the initial update, and every 3 years thereafter, using the methodologies in place at the time of the updates. For purposes of this analysis, the Department assumes that the future triennial updates to the standard salary level will be based on the same methodology that the Department used to set the new standard salary level in this rule: the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South). Likewise, the Department assumes that future triennial updates to the HCE total annual compensation level will be based on the same methodology the Department used to set this earnings threshold in this rulemaking: the annualized weekly earnings of 85th percentile of full-time salaried workers nationally.

As previously discussed, future triennial updates will set the earnings thresholds using the most recent available 4 quarters of CPS data preceding the Department's notice with the updated thresholds. To estimate future thresholds in years when the salary and compensation levels will be updated, the Department used the historic geometric growth rate between 2012 and 2022 in (1) the 35th earnings percentile of full-time salaried workers in the South for the standard salary level and (2) the annualized weekly earnings of the 85th percentile of full-time salaried workers nationally for the HCE compensation level. For example, between 2012 and 2022, the annual growth rate in the 35th percentile of full-time salaried workers in the South has increased by 3.17 percent. To estimate the first future triennial update salary level of $1,239, the Department multiplied $1,128 by 1.0317 to the power of three. Figure 5 shows the projected future triennial update levels for the first 10 years. Note that these projections are illustrative estimates based on past wage growth; the actual level at the time of the update will depend on the wage growth that occurs between now and the update date. Figure 6 shows the standard salary levels in both nominal and 2023 dollars.

Figure 5—Projected Future Salary and Compensation Levels, Nominal Dollars

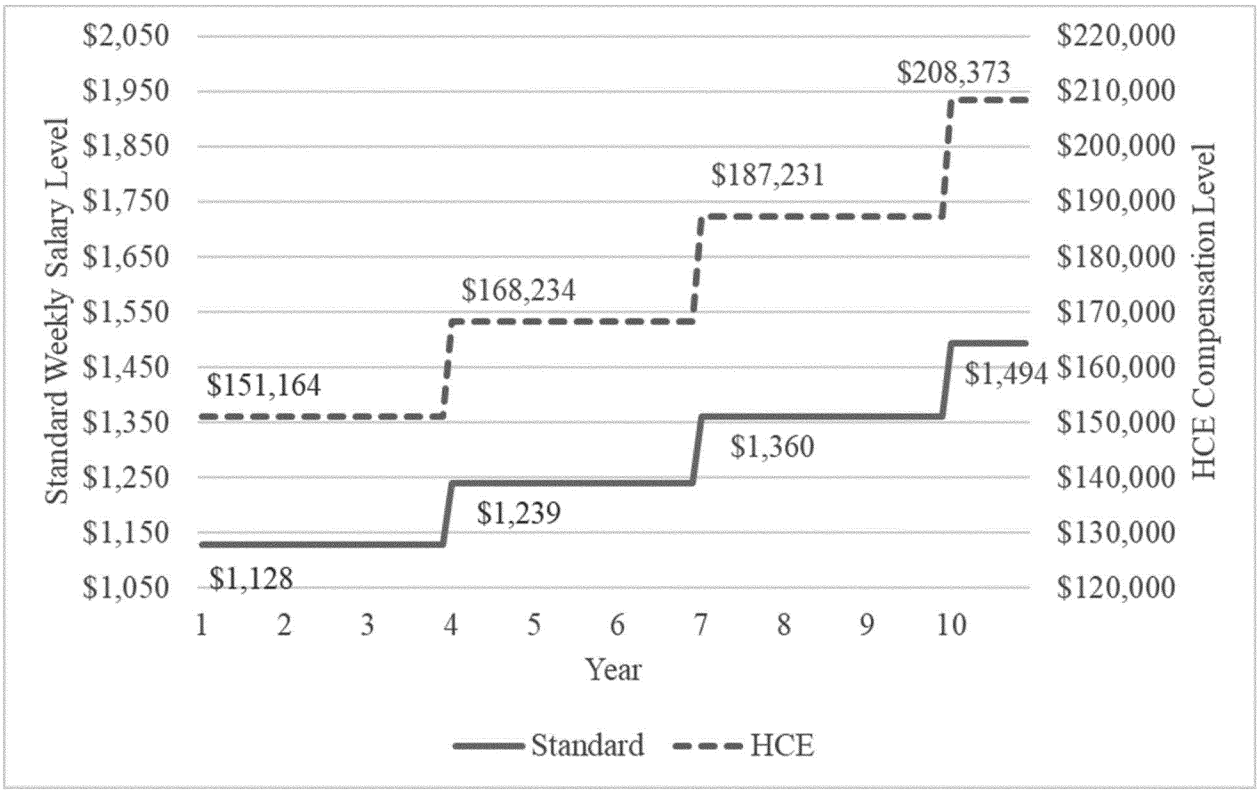
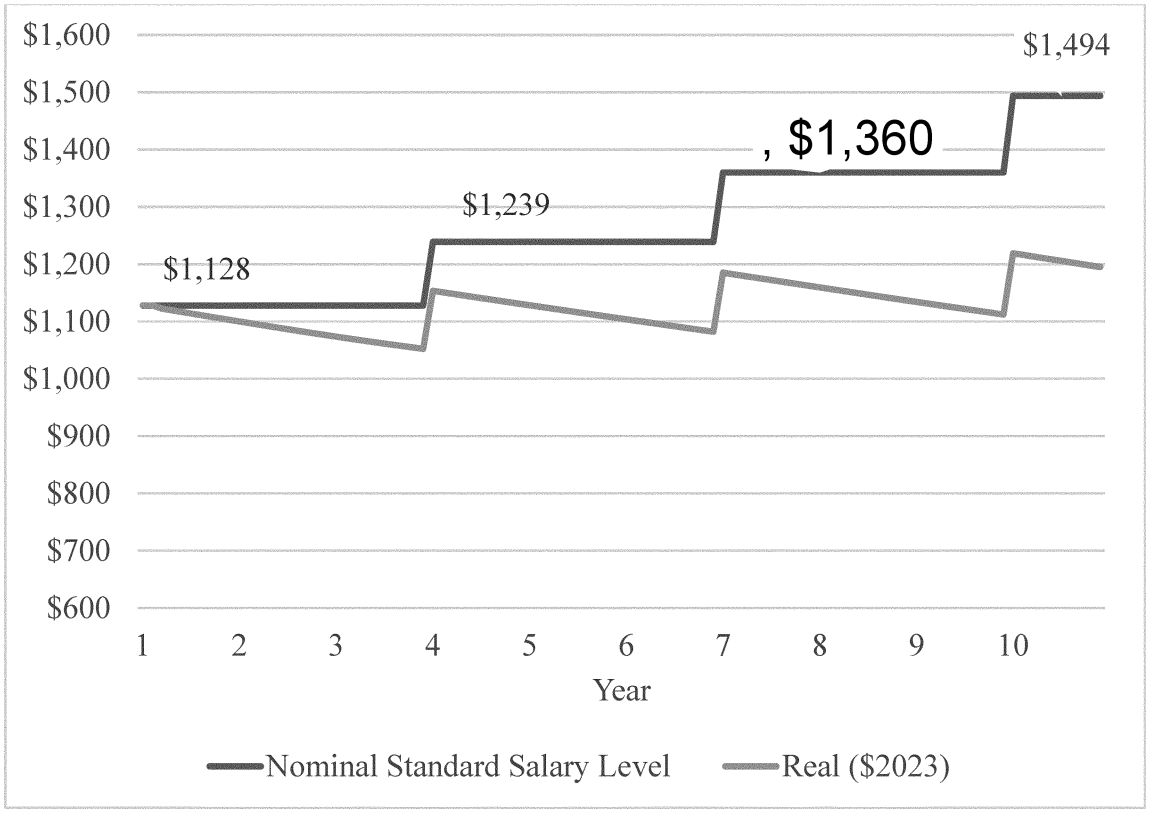


Figure 6—Projected Future Standard Salary Levels, Nominal and Real (Constant 2023 Dollars)



iii. Concerns With Use of Fixed Earnings Percentile as Updating Methodology

As discussed in detail in section V.A.3.iii, some commenters expressed concern that triennially updating the salary level using a fixed percentile of earnings would result in the salary levels growing at too quick a rate. *See, e.g.,* Chamber; National Lumber and Building Material Dealers Association; NRF; Seyfarth Shaw.

These commenters stated that updating the standard salary level using a fixed percentile of earnings of full-time salaried workers will cause some or all of the newly nonexempt workers to be converted to hourly status and thus removed from the data set, and earnings at the 35th percentile of salaried workers will quickly rise solely due to the exclusion of these hourly workers (an effect some commenters referred to as ''ratcheting''). Commenters asserted that this may cause growth in the 35th percentile of full-time salaried workers to no longer reflect prevailing economic conditions.

Claims that an updating mechanism using the fixed percentile approach will lead to the rapid escalation of the salary level are based primarily on the assumption that employers will respond to this rulemaking by converting newly nonexempt workers to hourly pay status. However, the Department believes these concerns are overstated because many affected EAP workers who are reclassified as nonexempt are likely to remain salaried as: (1) An analysis of the 2004 rule's salary level update did not indicate significant numbers of workers were converted to hourly pay; and (2) an analysis of updates in California's higher EAP exemption salary level (under state law) did not indicate significant numbers of workers were reclassified as hourly. In any event, the Department's modeling of the impact of updating shows that any potential ''ratcheting'' effect that may occur would be small, largely because newly nonexempt workers compose a small percentage of the pool of full-time nonhourly workers in the dataset used to establish the salary level.

The analyses discussed below are based on CPS MORG data. As acknowledged in the NPRM and above in section VII.B.5.i, salary status for CPS respondents cannot definitively be determined because workers who indicate they are paid on a salary basis or on some basis other than hourly are all classified as ''nonhourly.'' To consider the possibility this biases our results, the Department looked at the Panel Study of Income Dynamics (PSID). The PSID provides additional information concerning salaried versus other nonhourly workers. In the PSID, respondents are asked how they are paid on their main job and are asked for more detail if their response is in some way other than salaried or hourly.[423] The available responses include piecework, commission, self-employed/farmer/profits, and by the job/day/mile. None of these options are ones to which employers are likely to change their salaried workers. The share of workers who are not paid on either an hourly or salaried basis is relatively small, about 10 percent of workers in the PSID. Accordingly, grouping nonhourly workers with salaried workers does not negate the following comparisons and conclusions based on CPS data.

(a) Workers May Remain Salaried Even if Nonexempt

The Department disagrees with commenters that suggested that employers will likely (or automatically) convert large numbers of newly nonexempt employees to hourly pay status. In some instances such conversion may occur; for example, if an employee regularly works overtime and the employer is able to adjust his or her regular rate. However, for the majority of affected employees, there will be no incentive for employers to convert them to hourly pay because they do not work more than 40 hours in a workweek. Also, employers may have other incentives to maintain workers' salaried status; for example, they may offer salaried positions to attract talent. Some commenters representing employer interests highlighted that employees value job characteristics associated with salaried pay—such as earnings predictability—and so employers may pay nonexempt employees on a salary basis to preserve these benefits. Using the CPS MORG data pooled for 2021–2023 and projected to 2023, the Department estimated that 29.4 percent of white-collar workers earning below $684 per week are nonhourly; based on findings from the PSID, the Department believes most of these nonhourly workers are salaried. This data shows that even for some current nonexempt workers, employers are choosing to keep them as salaried instead of hourly. Furthermore, some nonhourly workers above the current salary threshold fail the duties test, and are therefore nonexempt, which is further evidence that employers already employ nonexempt workers who are paid on a salary basis.

(b) Previous Salary Level Updates Did Not Indicate a Significant Number of Workers Being Converted to Hourly

The ''ratcheting'' concerns raised in the comments are very similar to comments on this alleged effect that were received during the 2016 rulemaking. In that rule the Department analyzed employer responses to the 2004 rule and to a series of revisions to California's salary level test for exemption under state law in order to better estimate whether workers who become nonexempt are more likely to be paid on an hourly basis.[424] These analyses allow the identification of potential regulatory impact while controlling for time trends and a broad range of other relevant factors (education, occupation, industry, geographic location, etc.).

In the 2016 rule the Department analyzed the effect of the Federal 2004 salary level increase from $250 per week (short test salary level) to $455 (standard salary level) on the share of full-time, white-collar workers paid hourly. The analysis considered two types of differences: pre- versus post-rulemaking; and workers exempt before, but not after the rule compared to workers exempt both before and after the rule. As noted in the discussion of this analysis in the 2016 rule, if the salary level increase in the 2004 rule led employers to convert significant numbers of workers to hourly status (as commenters assert will result from the current rulemaking), then the Department would have expected to see a notable increase in the share of workers earning just below the new threshold at the time ($455) who are paid hourly relative to the share of workers earning just above the new threshold who are paid hourly. Instead, the Department found that between the first quarter of 2004 and the first quarter of 2005, the share of full-time white-collar workers who are paid hourly decreased marginally in the group of potentially affected workers (those earning $250 to $455), whereas in the group earning above the salary level (those earning more than $455 but less than $600) it increased by 2.6 percentage points. These results do not suggest that the 2004 salary level increase caused an increase in the share of workers paid hourly below the new threshold, and thus provide no evidence that salary level increases due to triennial updates will result in employers converting significant

[423] University of Michigan, Institute for Social Research. 2019 PSID. Data available at: *https://simba.isr.umich.edu/data/data.aspx.*

[424] *See* 81 FR 32441, 32507.

numbers of affected EAP workers to hourly pay status.

The Department did not replicate this analysis for the salary level increase in the 2019 final rule, because it would require comparing a quarter in 2019 before the effective date of the rule with a quarter in 2020 after the effective date. The economic effects of the COVID–19 pandemic would make it impossible to isolate the impact of the 2019 rule.

In the 2016 rule the Department also analyzed the effect of changes to California statutes that set exempt salary levels at a level equal to twice the state minimum wage for 40 hours worked per week. The analysis considered two types of differences: pre- versus post-rulemaking; workers exempt before, but not after the rule compared to workers exempt both before and after the rule; and California workers versus workers in other states where the salary level was not increased. The analysis of two updates found that the share of full-time white-collar workers in California being paid hourly decreased from 73.4 percent to 73.1 percent compared to an increase of 66.2 percent to 67.5 percent in states where the salary level did not change after the 2007–2008 update, while there was an increase from 72.0 percent to 74.0 percent in California compared to an increase of 68.2 to 69.4 percent in other states after the 2014 update.

The Department found no evidence that changes in the salary level for exemption resulted in a statistically significant increase in the percent of full-time white-collar workers paid on an hourly basis following either the 2004 rule or the California salary level updates.

(c) The Department's Modeling of Possible ''Ratcheting'' Indicates Effect Would Be Negligible

In a study referenced by PPWO, Edgeworth Economics estimated the impact that an updating mechanism using the fixed percentile approach would have on the salary level. They found that ''the DOL's automatic update mechanism would increase the salary threshold by approximately 9.1% to the current 40th percentile [which Edgeworth Economics estimated was equivalent to the 35th percentile of the resulting distribution after workers are reclassified] within three years even if there was not ANY wage growth.'' Their estimate was based on the assumption that all affected workers in the South Census Region who earn between $684 and $1,059 per week and who are expected to pass the duties test, which they estimate to be 1.4 million, would be reclassified to hourly employees, thus falling out of the distribution of workers that are part of the 35th percentile in the Census Region. However, as discussed above, the Department has found no evidence that previous changes in the salary level for exemption have resulted in a statistically significant increase in the percent of full-time white-collar workers paid on an hourly basis.

NRF submitted a 2023 study by Oxford Economics that also considered how converting salaried workers to hourly status could influence future triennial updates. The Oxford study states that DOL's updating methodology ''suffers from the same technical flaw as its NPRM analysis of the effects of the proposed regulation suffers from: the failure to model newly nonexempt affected workers losing salaried status.'' The study presents a visual analysis showing a share of workers who earn below the overtime threshold losing their salaried status, and a higher threshold for 2027 after this rule than in the scenario where there is no change to the standard salary level. Like Edgeworth Economics, Oxford Economics erroneously assumes that a large share of all affected workers will lose their salaried status. As discussed previously, the Department has found no evidence that previous changes in the salary level for exemption have resulted in a statistically significant increase in the percent of full-time white-collar workers paid on an hourly basis.

In 2016, the Department conducted a similar analysis, using what the Department believes are more realistic assumptions, and found a significantly smaller potential impact. The Department considered which affected workers are most likely to be converted from salaried to hourly pay as a result of that rulemaking. Type 4 workers, those whose salaries are increased to the new standard salary level, remain exempt and their method of pay will not change. Type 3 workers, who regularly work overtime and become nonexempt, and Type 2 workers, those who occasionally work overtime and become nonexempt, are the most likely to have their pay status changed. Type 1 workers (who, at the time, made up more than 60 percent of the affected workers) were assumed to not work overtime, and employers thus have little incentive to convert them to hourly pay. For this analysis, the Department assumed all Type 2 and Type 3 workers were converted to hourly status to generate a realistic upper bound of the magnitude of any possible ratcheting effect. The Department estimated that in 2026, after three updates over 10 years, the salary level as set in the final rule (based on weekly earnings of full-time salaried workers in the South) could be approximately 2.5 percent higher than expected due to this effect. This figure is significantly smaller than the estimates provided by the commenters. Furthermore, the Department believes its estimate is an overestimate because it assumed employers convert all Type 2 and Type 3 workers to hourly status, which, for the reasons discussed above and in section V.A.3.iii of the preamble, the Department believes is a highly unlikely outcome. The Department did not replicate this analysis for the salary level increase in the 2019 final rule, because the economic effects of the COVID–19 pandemic make it difficult to compare periods before and after the effective date of the 2019 final rule and isolate the effect of the rule.

10. Projections

The Department estimated that in Year 1, 4.3 million EAP workers will be affected, with about 292,900 of these attributable to the revised HCE compensation level (Table 26). In Year 10, the number of affected EAP workers was estimated to equal 6.0 million with 1.0 million attributable to the updated HCE compensation level. Average annualized costs are $802.9 million and transfers are $1.5 billion using a 7 percent real discount rate. These projections involved several steps.

1. Use past growth in the earnings distribution to estimate future salary and compensation levels (*see* section VII.C.9).

2. Predict workers' earnings, absent a change in the salary levels.

3. Compare workers' predicted earnings to the predicted salary and compensation levels to estimate affected workers.

4. Project future employment levels.

5. Estimate employer adjustments to hours and pay.

6. Calculate costs and transfers.

Figure 7—10-Year Projected Number of Affected Workers

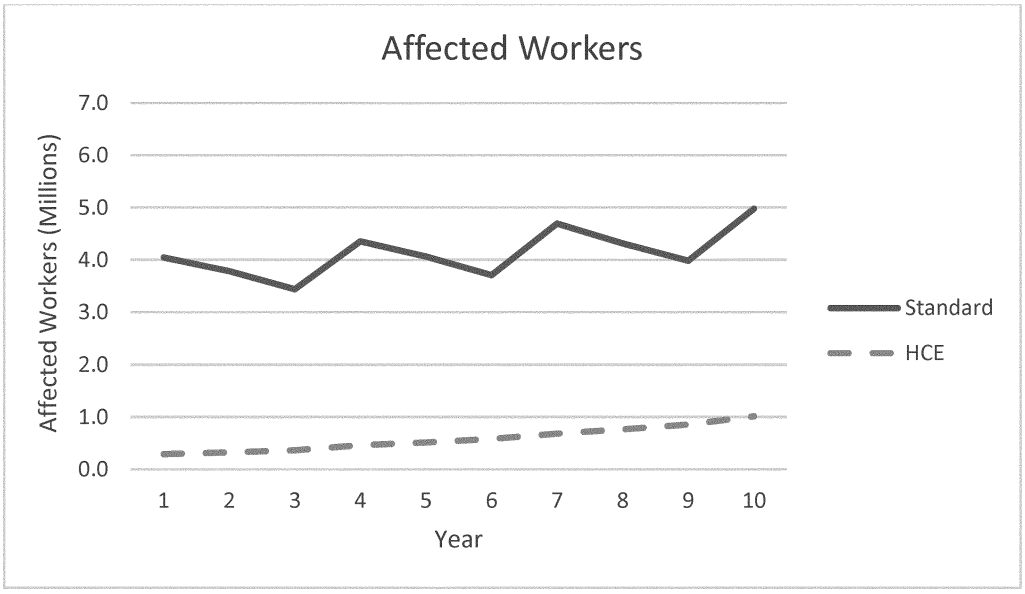


Figure 8—10-Year Projected Costs and Transfers (Millions $2023)

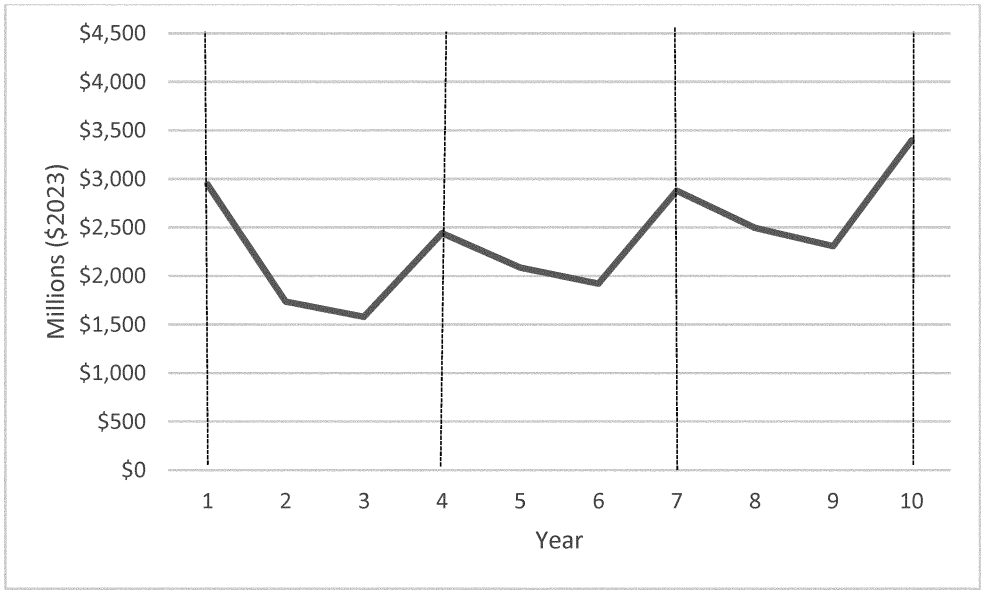


Table 26—Projected Costs and Transfers, Standard Salary and HCE Compensation Levels

Year	Affected EAP Workers (Millions)	Costs (Millions $2023)				Transfers (Millions $2023)		
		Regulatory Familiarization [a]	Adjustment [a]	Managerial	Total	Due to MW	Due to OT	Total
Year 1	4.3	$451.6	$299.1	$685.5	$1,436.2	$87.5	$1,421.7	$1,509.2
Year 2	4.1	$0.0	$9.4	$632.1	$641.5	$46.5	$1,047.8	$1,094.3
Year 3	3.8	$0.0	$8.9	$571.9	$580.8	$45.0	$953.7	$998.7
Year 4	4.8	$73.1	$14.2	$702.2	$789.5	$42.2	$1,609.4	$1,651.6
Year 5	4.6	$0.0	$8.7	$647.8	$656.5	$42.2	$1,386.5	$1,428.7
Year 6	4.3	$0.0	$9.5	$624.7	$634.2	$39.9	$1,246.0	$1,285.9
Year 7	5.4	$71.0	$18.6	$747.7	$837.2	$36.1	$2,005.6	$2,041.7
Year 8	5.1	$0.0	$9.6	$697.8	$707.4	$31.3	$1,757.3	$1,788.6
Year 9	4.8	$0.0	$9.0	$682.3	$691.3	$26.4	$1,590.1	$1,616.6
Year 10	6.0	$68.9	$20.9	$816.3	$906.1	$22.6	$2,467.5	$2,490.1
Annualized (3% real discount rate)	--	$71.8	$44.6	$677.6	$794.0	$43.2	$1,522.0	$1,565.2
Annualized (7% real discount rate)	--	$79.3	$50.0	$673.6	$802.9	$44.8	$1,489.3	$1,534.1

[a] Regulatory familiarization costs occur in years when the salary and compensation levels are updated. Adjustment costs occur in all years when there are newly affected workers.

The Department calculated workers' earnings in future years by applying the historical wage growth rate in the workers' industry-occupation to current earnings. The wage growth rate was calculated as the geometric growth rate in median wages using CPS MORG data for occupation-industry categories from 2011–2023.[425] The geometric growth rate is the constant annual growth rate that when compounded (applied to the first year's wage, then to the resulting second year's wage, etc.) yields the last historical year's wage. This rate only depends on the wage values in the first and last year.[426]

The geometric wage growth rates per industry-occupation combination were also calculated from the BLS' Occupational Employment and Wage Statistics (OEWS) survey for 2012 to 2022. In occupation-industry categories where the CPS MORG data had an insufficient number of observations to reliably calculate median wages, the Department used the growth rate in median wages calculated from the OEWS data.[427] Any remaining occupation-industry combinations without sufficient data in either data source were assigned the median of the growth rates in median wages from the CPS MORG data.

The Department compared workers' counter-factual earnings (*i.e.,* absent the rulemaking) to the predicted salary levels. If the counter-factual earnings are below the relevant salary level (*i.e.,* standard or HCE) then the worker is considered affected. In other words, in each year affected EAP workers were identified as those who would be exempt absent the rule change (*e.g.,* would earn at least $684 if exempt under standard salary level) but have projected earnings in the future year that are less than the relevant salary level. The projected number of affected workers also includes workers who were not EAP exempt in the base year but will become exempt in the absence of this rule in Years 2 through 10. For example, a worker who passes the standard duties test may earn less than $684 in Year 1 but between $684 and the new salary level in subsequent years; such a worker will be counted as an affected worker in those subsequent years. Additionally, the number of affected workers is not limited to newly affected workers. Workers who are affected in a given year may remain affected in subsequent years (*e.g.,* because they earn between $684 and $1,128 in years 1, 2, and 3), and continue to be counted as affected.

The projected number of affected workers also accounts for anticipated employment growth. Employment growth was estimated as the geometric annual growth rate based on the 10-year employment projection from BLS' National Employment Matrix (NEM) for 2022 to 2032 within an occupation-industry category.[428] [429] The Department applied these growth rates to the sample weights of the workers to estimate increased employment levels over time. This is because the Department cannot introduce new observations to the CPS MORG data to represent the newly employed.

For workers newly affected in Year 2 through Year 10, employers' wage and hour adjustments due to the rulemaking are generally estimated as described in section VII.C.4. The only difference is the hours adjustment now uses a long-run elasticity of labor demand of −0.4.[430] Employer adjustments are made in the first year the worker is affected and then applied to all future years in which the worker continues to be affected (unless the worker switches to a Type 4 worker). Workers' earnings in predicted years are earnings post employer adjustments, with overtime pay, and with ongoing wage growth based on historical growth rates (as described above).

The Department quantified three types of direct employer costs in the 10-year projections: (1) regulatory familiarization costs; (2) adjustment costs; and (3) managerial costs. Section VII.C.3 provides details on the methodology for estimating these costs. This section only discusses the aspects specific to projections. Projected costs and transfers were deflated to 2023 dollars using the Congressional Budget Office's projections for the CPI–U.[431]

Regulatory familiarization costs occur in years when the salary and compensation levels are updated. Thus, in addition to Year 1, some regulatory familiarization costs are expected to occur in Year 4, Year 7, and Year 10. The Department assumed 10 minutes per establishment for time to access and read the published notice in the **Federal Register** with the updated standard salary level and HCE compensation level. This average time estimate is low because the majority of establishments will not have newly affected workers, and while some firms may spend more than 10 minutes to read the new rule, many firms will spend no time. The time estimate has been increased from 5 minutes in the 2016 rulemaking. In each of these 3 years regulatory familiarization costs are between $68.9 and $73.1 million. Although start-up firms must become familiar with the FLSA, the difference between the time necessary for familiarization with the current part 541 exemptions and those exemptions as modified by this rulemaking is essentially zero. Therefore, projected regulatory familiarization costs for new entrants over the next 9 years are zero (although these new entrants will incur regulatory familiarization costs in years when the salary and compensation levels are updated).

Adjustment costs are a function of the number of newly affected EAP workers and would occur in any year in which workers are newly affected. Adjustment costs would be largest in Year 1, of moderate size in update years, and smaller in other years. Management costs would recur each year for all affected EAP workers whose hours are adjusted. Therefore, managerial costs increase in update years and then modestly decrease between updates since earnings growth will cause some workers to no longer be affected in those years.

[425] To maximize the number of observations used in calculating the median wage for each occupation-industry category, 3 years of data were pooled for each of the endpoint years. Specifically, data from 2011, 2012, and 2013 (converted to 2012 dollars) were used to calculate the 2012 median wage and data from 2021, 2022, and 2023 (converted to 2022 dollars) were used to calculate the 2022 median wage.

[426] The geometric growth rate may be a flawed measure if either or both of the endpoint years were atypical; however, in this instance these values seem typical. An alternative method would be to use the time series of median wage data to estimate the linear trend in the values and continue this to project future median wages. This method may be preferred if either or both of the endpoint years are outliers, since the trend will be less influenced by them. However, the linear trend may be flawed if there are outliers in the interim years. The Department chose to use the geometric mean because individual year fluctuations are difficult to predict and applying the geometric growth rate to each year provides a better estimate of the long-term growth in wages.

[427] To lessen small sample bias in the estimation of the median growth rate, this rate was only calculated using CPS MORG data when these data contained at least 10 observations in each time period.

[428] Bureau of Labor Statistics, Employment Projections Program. 2022–32 National Employment Matrix. *https://www.bls.gov/emp/ind-occ-matrix/matrix.xlsx.*

[429] An alternative method is to spread the total change in the level of employment over the ten years evenly (constant change in the number employed). The Department believes that on average employment is more likely to grow at a constant percentage rate rather than by a constant level (a decreasing percentage rate).

[430] Based on the Department's analysis of the following paper: Lichter, A., Peichl, A. & Siegloch, A. (2014). The Own-Wage Elasticity of Labor Demand: A Meta-Regression Analysis. IZA DP No. 7958.

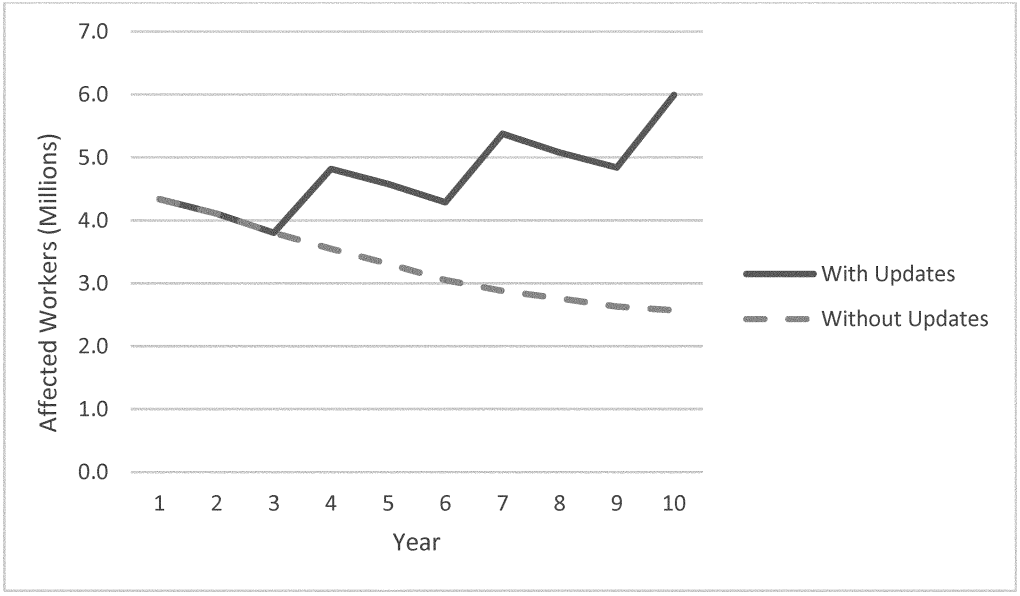
[431] Congressional Budget Office. 2023. The Budget and Economic Outlook: 2023 To 2033. *See https://www.cbo.gov/system/files/2023-02/58848-Outlook.pdf.*

The Department projected transfers from employers to employees due to the minimum wage provision and the overtime pay provision. Transfers to workers from employers due to the minimum wage provision would decline from $87.5 million in Year 1 to $22.6 million in Year 10 as increased earnings over time move workers' regular rates of pay above the minimum wage.[432] Transfers due to overtime pay should grow slightly over time because the number of affected workers would increase, although transfers fall in years between updates. Transfers to workers from employers due to the overtime pay provision would increase from $1.4 billion in Year 1 to $2.5 billion in Year 10.

The Department compared projected impacts with and without updating (Table 27). Projections without updating are shown so impacts of the initial increase and subsequent increases can be disaggregated. With triennial updating, the number of affected EAP workers would increase from 4.3 million to 6.0 million over 10 years. Conversely, in the absence of updating, the number of affected EAP workers is projected to decline from 4.3 million in Year 1 to 2.6 million in Year 10. As shown in Figure 9, the number of affected workers decreases from year to year between updates as the real value of the salary and compensation levels decrease, and then increases in update years.

Regarding costs, regulatory familiarization costs are lower without updating because, in the absence of updating, employers would not need to familiarize themselves with updated salary and compensation levels every 3 years. Adjustment costs and managerial costs are a function of the number of affected EAP workers and so will be higher with updating. Average annualized direct costs will be $802.9 million with updating and $615.6 million without updating. Transfers are also a function of the number of affected workers and hence are lower without updating. Average annualized transfers with a 7 percent real discount rate will be $1.5 billion with updating and $990 million without updating. Table 27 shows aggregated costs and transfers over the 10-year horizon.

Figure 9—10-Year Projected Number of Affected Workers, With and Without Updating



[432] State minimum wages above the Federal level as of January 1, 2023 were incorporated and used for projected years. Increases in minimum wages were not projected. If state or Federal minimum wages increase over the next 10 years, then estimated projected minimum wage transfers would be underestimated.

Table 27—Comparison of Projected Costs and Transfers With and Without Updating

Year	Affected EAP Workers (Millions)		Costs (Millions $2023)		Transfers (Millions $2023)	
	With Updates	Without Updates	With Updates	Without Updates	With Updates	Without Updates
Year 1	4.3	4.3	$1,436.2	$1,436.2	$1,509.2	$1,509.2
Year 2	4.1	4.1	$641.5	$641.5	$1,094.3	$1,094.3
Year 3	3.8	3.8	$580.8	$580.8	$998.7	$998.7
Year 4	4.8	3.5	$789.5	$526.2	$1,651.6	$937.2
Year 5	4.6	3.3	$656.5	$483.6	$1,428.7	$885.9
Year 6	4.3	3.1	$634.2	$448.6	$1,285.9	$863.8
Year 7	5.4	2.9	$837.2	$420.8	$2,041.7	$847.6
Year 8	5.1	2.8	$707.4	$404.4	$1,788.6	$801.4
Year 9	4.8	2.6	$691.3	$388.8	$1,616.6	$809.9
Year 10	6.0	2.6	$906.1	$380.1	$2,490.1	$809.7
Annualized (3% real discount rate)	--	--	$794.0	$590.0	$1,565.2	$970.2
Annualized (7% real discount rate)	--	--	$802.9	$615.6	$1,534.1	$989.5

VIII. Final Regulatory Flexibility Analysis (FRFA)

The Regulatory Flexibility Act of 1980 (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), hereafter jointly referred to as the RFA, requires that an agency prepare an initial regulatory flexibility analysis (IRFA) when proposing, and a final regulatory flexibility analysis (FRFA) when issuing, regulations that will have a significant economic impact on a substantial number of small entities. The Department has determined that this rulemaking is economically significant. This section (1) provides an overview of the objectives of this rule; (2) estimates the number of affected small entities and employees; (3) discusses reporting, recordkeeping, and other compliance requirements; (4) presents the steps the Department took to minimize the significant economic impact on small entities; and (5) declares that it is unaware of any relevant Federal rules that may duplicate, overlap, or conflict with this rule.

A. Objectives of, and Need for, the Final Rule

The FLSA requires covered employers to (1) pay employees who are covered and not exempt from the Act's requirements not less than the Federal minimum wage for all hours worked and overtime premium pay at a rate of not less than one and one-half times the employee's regular rate of pay for all hours worked over 40 in a workweek, and (2) make, keep, and preserve records of the persons employed by the employer and of the wages, hours, and other conditions and practices of employment. The FLSA provides exemptions from the Act's minimum wage and overtime pay provisions, including one for bona fide executive, administrative, and professional (EAP) employees, as those terms are ''defined and delimited'' by the Department.[433] The Department's regulations implementing this white-collar exemption are codified at 29 CFR part 541.

To qualify for the EAP exemption under the Department's regulations, the employee generally must meet three criteria: (1) the employee must be paid a predetermined and fixed salary that is not subject to reduction because of variations in the quality or quantity of work performed (the salary basis test); (2) the amount of salary paid must meet a minimum specified amount (the salary level test); and (3) the employee's job duties must primarily involve executive, administrative, or professional duties as defined by the regulations (the duties test). In 2004, the Department revised its regulations to include a highly compensated employee test with a higher salary threshold and a minimal

[433] 29 U.S.C. 213(a)(1).

duties test.[434] The Department has periodically updated the regulations governing the white-collar exemptions since the FLSA's enactment in 1938. Most recently, the 2019 rule updated the standard salary level test to $684 per week and the HCE compensation level to $107,432 annually.

The goal of this rulemaking is to set effective earnings thresholds to help define and delimit the FLSA's EAP exemption. To this end, the Department is finalizing its proposed change to the salary level. Specifically, the Department is adjusting the salary level by setting it equal to the 35th percentile of weekly earnings of full-time salaried workers in the lowest-wage Census Region (currently the South), based on the most recent year (2023) of Current Population Survey (CPS) data at the time of drafting. Using BLS 2023 data on percentiles of usual weekly earnings of nonhourly full-time workers, the standard salary level will be set at $1,128 per week. Additionally, to maintain the effectiveness of this test, the Department is finalizing an updating mechanism that will update the earnings thresholds to reflect current wage data on July 1, 2024 and every 3 years thereafter.

The Department's new salary level will, in combination with the standard duties test, better define and delimit which employees are employed in a bona fide EAP capacity in a one-test system. As explained in greater detail in sections III and V.B, setting the standard salary level at or below the long test salary level, as the 2004 and 2019 rules did, results in the exemption of lower-salaried employees who traditionally were entitled to overtime protection under the long test either because of their low salary or because they perform large amounts of nonexempt work, in effect significantly broadening the exemption compared to the two-test system. Setting the salary level at the low end of the historic range of short test salary levels, as the 2016 rule did, would have restored overtime protections to those employees who perform substantial amounts of nonexempt work and earned between the long test salary level and the low end of the short test salary range. However, it would also have resulted in denying employers the use of the exemption for lower-salaried employees who traditionally were not entitled to overtime compensation under the long test, which raised concerns that the Department was in effect narrowing the exemption. By setting a salary level above the equivalent of the long test salary level (using current data), the final rule will restore the right to overtime pay for salaried white-collar employees who prior to the 2019 rule were always considered nonexempt if they earned below the long test (or long test-equivalent) salary level. And it will ensure that fewer lower paid white-collar employees who perform significant amounts of nonexempt work are included in the exemption. At the same time, by setting it well below the equivalent of the short test salary level (using current data), the rule will allow employers to continue to use the exemption for many lower paid white-collar employees who were made exempt under the 2004 standard duties test. The new salary level will also more reasonably distribute between employees and their employers what the Department now understands to be the impact of the shift from a two-test to a one-test system on employees earning between the long and short test salary levels.

As the Department has previously noted, the amount paid to an employee is ''a valuable and easily applied index to the 'bona fide' character of the employment for which the exemption is claimed,'' as well as the ''principal[]'' ''delimiting requirement'' ''prevent[ing] abuse'' of the exemption.[435] Additionally, the salary level test facilitates application of the exemption by saving employees and employers from having to apply the more time-consuming duties analysis to a large group of employees who will not pass it. For these reasons, the salary level test has been a key part of how the Department defines and delimits the EAP exemption since the beginning of its rulemaking on the EAP exemption.[436] At the same time, the salary test's role in defining and delimiting the scope of the EAP exemption must allow for appropriate examination of employee duties.[437] Under the final rule, duties will continue to determine the exemption status for most salaried white-collar employees.

The Department is also adjusting the HCE total annual compensation requirement to the annualized weekly earnings for the 85th percentile of full-time salaried workers nationally ($151,164 using 2023 data). Though not as high a percentile as the HCE threshold initially adopted in 2004, which covered 93.7 percent of all full-time salaried workers,[438] the Department's new HCE threshold will ensure it continues to serve its intended function, because the HCE total annual compensation level will be high enough to exclude all but those employees at the very top of the economic ladder.

In its three most recent part 541 rulemakings, the Department has expressed its commitment to keeping the earnings thresholds up to date to ensure that they remain effective in helping differentiate between exempt and nonexempt employees. Long intervals between rulemakings have resulted in eroded earnings thresholds based on outdated earnings data that were ill-equipped to help identify bona fide EAP employees. In contrast, routine updates to the part 541 earnings thresholds to reflect wage growth will bring certainty and stability to employers and employees alike. Based on its long experience with updating the salary levels, the Department has determined that adopting a regulatory provision for regularly updating the salary levels, with an exception for pausing future updates under certain conditions, is the most viable and efficient way to ensure the EAP exemption earnings thresholds keep pace with changes in employee pay and thus remain effective in helping determine exemption status. Accordingly, the Department is including in this rule a mechanism for updating the salary and compensation levels, to reflect current wage data, on July 1, 2024 and every 3 years thereafter. As explained in greater detail in section V.A, employees and employers alike will benefit from the certainty and stability of regularly scheduled updates.

B. Response to Comment Filed by the Chief Counsel for Advocacy of the Small Business Administration

SBA Advocacy expressed similar concerns as those expressed by other small business commenters, based upon its meetings, roundtables, and other discussions regarding the NPRM. SBA Advocacy stated that it was concerned that the IRFA underestimated the compliance costs of the rule, the proposed rule would add to the current difficult business environment, the proposed rule would have significant impacts on small nonprofits, the IRFA did not account for non-financial costs to small entities and employees, and the IRFA did not consider less burdensome alternatives. SBA Advocacy recommended that the Department issue a supplemental RFA to reanalyze small entity impacts, adopt a lower standard salary level, update the standard salary level every four years through notice and comment rulemaking, publish a

[434] § 541.601.

[435] Stein Report at 19, 24; *see also* 81 FR 32422.

[436] *See* 84 FR 51237.

[437] *See id.* at 51238.

[438] *See* 69 FR 22169 (Table 3).

small entity compliance guide, provide more time for compliance, and add provisions to help small nonprofits comply. SBA Advocacy's comments and the Department's response to those comments are discussed in detail below.

SBA Advocacy reported that participants at its roundtables estimated first year costs would be much higher than the estimates in the IRFA, from $20,000 to over $200,000 in compliance costs per small entity. SBA Advocacy asserted that small businesses may have to hire outside staff to interpret and implement the rule and face high administrative and operational costs to schedule and track employee hours to minimize overtime costs. SBA Advocacy also stated that participants at their roundtables reported much higher payroll costs than the estimates provided by the Department in the IRFA. Advocacy further stated that the IRFA failed to estimate compliance costs by small entity size and revenue by presenting average impacts by industry.

The assumptions small businesses used to estimate first-year compliance costs ranging from $20,000 to $200,000 per entity were not described. However, the Department clearly outlined its methodology and assumptions used to estimate regulatory familiarization, adjustment, and management costs that it expects businesses, including small businesses, might incur. The Department disagrees that it underestimated small entity costs in the IRFA. First, this rulemaking is narrow in scope as it only makes changes relating to earnings thresholds in the part 541 regulations. The Department published final rules changing the salary thresholds in 2016 and 2019. The Department therefore expects that most businesses will not require significant time to become familiar with these regulations, or that they will require significant time from outside consultants. Furthermore, the Department expects that small entities will rely upon compliance assistance materials provided by the Department, including the small entity compliance guide that will be published, or industry associations to become familiar with the final rule.

Second, the Department estimates businesses will require an average of 75 minutes per employee to choose how to make adjustments for affected employees. The Department expects that employers will most likely need to spend little to no time making adjustments for many affected workers, such as the almost 70 percent of the employees who do not work overtime (Type 1 employees) and those whose salaries are well below the new standard salary level or only occasionally work overtime. If, for example, decisions can be quickly made for half of a business' affected employees, then that leaves two hours or more per employee for employers to consider how to respond with regard to employees requiring more consideration.

Third, the Department believes that most, if not all, entities have at least some nonexempt employees and, therefore, already have policies and systems in place for monitoring and recording their hours. The Department believes that applying those same policies and systems to the workers whose exemption status changes will, on average, not require more than 10 minutes per week per worker who works overtime in managerial time cost, as employers will rely on policies such as a policy against working overtime without express approval or a standard weekly schedule of assigned hours. The Department notes that nearly 70 percent of affected employees do not work overtime, and another 17 percent who do work overtime average about an hour of overtime per week; less than 15 percent of currently exempt employees average 10 or more hours of overtime per week. The Department therefore disagrees with SBA Advocacy that small entities will ''face vast administrative and operational costs to schedule and track employee hours to minimize overtime costs.'' Consistent with the approach taken in calculating managerial costs in the 2019 rule,[439] the Department believes that an average of 10 additional minutes per week managing the hours of each newly exempt worker who works overtime is appropriate.

SBA Advocacy bases its claim that the Department underestimated payroll costs on reports from ''[r]oundtable participants'' of ''much higher payroll costs,'' pointing to four businesses—''an Arkansas restaurant with four locations'' and three ''small amusement businesses''—which claimed they would need to increase manager salaries from $57,000 to $250,000 to comply with the rule. SBA Advocacy also provided hypothetical scenarios of potential salary increases that restaurant employers with currently exempt employees would need to incur to comply with the proposed rule based on various assumptions. As discussed in section VII.C.4.iii.c, these anecdotal reports and hypothetical examples do not have any information on the actual amount of overtime work being performed by employees who could become newly nonexempt under the new salary level. The Department expects that businesses that would be faced with large increases in payroll costs if they were to increase salaries to the new threshold would instead find other responses more economically feasible, such as limiting the number of overtime hours worked by nonexempt workers.

Moreover, as explained above, the majority of affected workers who work no overtime or minimal overtime will likely receive little additional pay as a result of the rule. While some employers might have to pay the overtime premium, when combined with the 85 percent of affected employees who will receive little or no overtime pay premium because they work little or no overtime, the average pay raise over all affected employees and their employers will be much smaller than the examples presented in SBA Advocacy's comment.

SBA Advocacy stated that small firms have expressed the sentiment that they would have to fire and not promote employees and limit hours worked as a result of the rule, after recent inflation, supply chain disruptions, shutdowns and tight labor markets that followed the COVID–19 pandemic. The Department acknowledges that the economic climate has been difficult to navigate since the start of 2020. However, most indications are that the economy has been returning to long run growth patterns with subsiding inflation. For example, a report by Van Nostrand and Sinclair (2023)[440] from the U.S. Department of the Treasury indicates that the United States has seen a strong GDP recovery and was on track during 2023 to recover to levels predicted before the pandemic. Similarly, reflecting improvements in inflation and personal incomes, the Survey of Consumers from the University of Michigan reported that consumer sentiment in January 2024 grew by 13 percent and reached its highest level since July 2021.[441] To the extent that labor markets remain tight, that might be a reflection of significant, potentially long-run changes in factors such as long run labor force participation rates.[442] Regardless,

[439] *See* 84 FR 51267.

[440] *Van Nostrand and Sinclair* (2023). The U.S. Economy in Global Context. U.S. Department of the Treasury. *https://home.treasury.gov/news/featured-stories/the-us-economy-in-global-context.*

[441] University of Michigan (2024). Surveys of Consumers. *http://www.sca.isr.umich.edu/.*

[442] Bognar et al. (2023) What Does Everything Besides the Unemployment Rate Tell Us About Labor Market Tightness?. Federal Reserve Bank of Chicago. *https://www.chicagofed.org/publications/chicago-fed-letter/2023/491.* Hornstein and Kudlyak (2022). The Pandemic's Impact on Unemployment

Continued

workers affected by this rule compose a relatively small part of the overall labor market and the increase in wages should be relatively small (*see e.g.*, estimated transfers per worker, Table 23). While small businesses may be more affected by labor market turmoil, the overall size of the impact of this rule on the economy would indicate that it is unlikely that the rule will have a significant impact on this market turmoil.

SBA Advocacy also stated that it believes that the Department underestimated the impact of the proposed rule on small nonprofit organizations, citing examples of small nonprofits that estimate costs above the one to three percent of revenue threshold, a measure for determining the economic impact on small entities from SBA Advocacy's RFA compliance guide. The Department disagrees that it underestimated the impact of this rule on small nonprofits. First, many nonprofits are non-covered enterprises because when determining enterprise coverage, only revenue derived from business operations, not charitable activities, is included. However, as discussed in section VII.B.3, the Department nonetheless included workers employed by enterprises that do not meet the enterprise coverage requirements in its estimate of workers subject to the FLSA, since there is no data set that would adequately inform an estimate of the size of this worker population in order to exclude them from these estimates. [443] Second, for the reasons stated above, the Department believes that expected costs and payroll impacts of the rule cited by SBA Advocacy and other commenters are overestimates, and that the Department's estimates are more accurate reflections of costs and impacts. The Department finds that even if all employees at a small entity, whether for-profit or nonprofit, are exempt—an unlikely scenario—then cost and increased payroll combined comprise about one percent of payroll per affected small entity, and therefore an even smaller percentage of revenues. *See* Table 32. SBA Advocacy cited concerns about the rule's effect on seasonal businesses raised by a representative from America Outdoors Association, which asserted that many affected employees in seasonal recreational businesses work nontraditional work schedules that would make it difficult to reclassify them as hourly workers, as well as a concern raised by a representative of the Independent Community Bankers Association of America that the rule could cause its members to reduce services in ''rural or less profitable areas.'' The Department reiterates that employers do not need to reclassify nonexempt workers as hourly employees; they merely need to pay an overtime premium for hours worked over 40 in a workweek. While there will be affected workers in the finance sector, the Department believes that costs and transfers for small entities in the finance sector will be manageable as a share of payroll and of total revenue.[444]

SBA Advocacy further stated that the IRFA ''does not consider the non-financial consequences to reclassify workers, such as the effect on worker flexibility, worker morale, and loss of benefits and career advancement.'' The Department addresses these and other possible impacts that cannot be quantified in sections V.B.4.v and VII.C.3.v. In addition, the Department believes that while individual experiences vary, the rule will benefit employees in a variety of ways (*e.g.,* through increased earnings and an increase in personal time for some affected workers).

Exempt workers may enjoy more scheduling flexibility because their hours are less likely to be monitored than nonexempt workers. If so, the final rule could impose costs on newly nonexempt, overtime-eligible workers by, for example, limiting their ability to adjust their schedules to meet personal and family obligations. However, employers can continue to offer flexible schedules and require workers to monitor their own hours and to follow the employers' timekeeping rules. Additionally, some exempt workers already monitor their hours for billing purposes. For these reasons, and because there is little data or literature on these costs, the Department did not quantify potential costs regarding scheduling flexibility. Further, a study by Lonnie Golden [445] using data from the General Social Survey (GSS) found that ''[i]n general, salaried workers at the lower (less than $50,000) income levels don't have noticeably greater levels of work flexibility that they would 'lose' if they became more like their hourly counterparts.''

Some of the workers who become nonexempt as a result of the final rule and whose pay is changed by their employer from salaried to hourly status may have preferred to remain salaried. As noted above in section VII.C.3.v, research has shown that salaried workers are more likely than hourly workers to receive benefits such as paid vacation time and health insurance,[446] and are more satisfied with their benefits.[447] Additionally, when employer demand for labor decreases, hourly workers tend to see their hours cut before salaried workers, making earnings for hourly workers less predictable.[448] However, this literature generally does not control for differences between salaried and hourly workers such as education, job title, or earnings; therefore, this correlation is not necessarily attributable to hourly status.

If workers are reclassified as hourly, and hourly workers have fewer benefits than salaried workers, reclassification could reduce workers' benefits. But the Department notes that these newly nonexempt workers may continue to be paid a salary, as long as that salary is equivalent to a base wage at least equal to the minimum wage rate for every hour worked, and the employee receives a 50 percent premium on that base wage for any overtime hours each week. Similarly, employers may continue to provide these workers with the same level of benefits as previously, whether paid on an hourly or salary basis. While reducing benefits may be one way for employers to offset payroll increases associated with this rule, as shown below, the Department estimates that costs and payroll increases for small, affected firms are less than 0.9 percent of payroll and less than 0.2 percent of estimated revenues. Therefore, the Department does anticipate that it will be necessarily for a significant number of employers to reduce employee benefits.

and Labor Force Participation Trends. Federal Reserve of Richmond Economic *https://www.richmondfed.org/publications/research/economic_brief/2022/eb_22-12*.

[443] Although not excluding such entities and associated workers only affects a small percentage of workers generally, it may have a larger effect (and result in a larger overestimate) for nonprofits, because revenue from charitable activities is not included when determining enterprise coverage. *See* section VII.B.3.

[444] *See* Table 32.

[445] Golden, L. (2014). Flexibility and Overtime Among Hourly and Salaried Workers. Economic Policy Institute. *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2597174*.

[446] Lambert, S.J. (2007). Making a Difference for Hourly Employees. In A. Booth, & A.C. Crouter, *Work-Life Policies that Make a Real Difference for Individuals, Families, and Communities.* Washington, DC: Urban Institute Press.

[447] Balkin, D.B., & Griffeth, R.W. (1993). The Determinants of Employee Benefits Satisfaction. *Journal of Business and Psychology,* 7(3), 323–339.

[448] Lambert, S.J., & Henly, J.R. (2009). *Scheduling in Hourly Jobs: Promising Practices for the Twenty-First Century Economy.* The Mobility Agenda. Lambert, S.J. (2007). Making a Difference for Hourly Employees. In A. Booth, & A.C. Crouter, *Work-Life Policies that Make a Real Difference for Individuals, Families, and Communities.* Washington, DC: Urban Institute Press.

Finally, it is unclear why career advancement will be inhibited. As noted above, *see* section VII.C.3.v., nothing in this rule requires employers to limit advancement opportunities for newly nonexempt workers. The Department notes that if an employer believes that career advancement opportunities such as training are sufficiently important, it can ensure employees attend the trainings during their 40-hour workweek or pay the overtime premium where training attendance causes the employee to work over 40 hours in a workweek.

SBA Advocacy stated that the IRFA was incomplete ''because it d[id] not analyze any regulatory alternatives that would minimize the impact of the rule for small businesses, such as lower salary levels.'' However, the Department considered several regulatory alternatives in the NPRM, describing both the alternatives it considered, which included lower (and higher) thresholds for the standard salary level and HCE total compensation requirement, and why it chose the earnings thresholds it proposed.[449] And it has considered and analyzed multiple regulatory alternatives, including lower (and higher) thresholds for the standard salary and HCE total compensation requirement, in this final rule as well.[450]

SBA Advocacy recommended that the Department issue a Supplemental Regulatory Flexibility Analysis to be published in the **Federal Register** for public comment addressing compliance costs in and after the first year, compliance costs by different sized small entities, the current business environment, impacts to small nonprofits, the non-financial consequences of the rule, and the impacts of adopting alternative salary thresholds on different sizes of small businesses. The Department disagrees with SBA Advocacy that this rulemaking should be delayed for this reason. The Department provided a fully robust and transparent analysis of estimated impacts on small entities in its IRFA, relying on largely the same methods and assumptions the Department employed in drafting the IFRA in its 2019 rulemaking.

As the Department stated in the IRFA, it is difficult to directly evaluate compliance cost impacts by entity size due to lack of data concerning the distribution of affected workers by entity size. There are fewer affected workers than there are small entities. Therefore, many small entities will employ zero affected workers; small entities that do employ affected workers may employ one affected worker, or have nearly all workers affected, and anywhere in between. The number of small entities that employ affected workers will be inversely related to the number of affected employees per entity; if small entities only employ one affected worker, more entities will be affected, and vice versa.

Therefore, the Department evaluated a range of potential impacts from lowest to highest depending on whether one or all employees are affected. Furthermore, the Department evaluated the impact of regulatory compliance costs plus increased wages as a percent of payroll. Payroll is largely proportionate to the number of employees at the firm; if one entity has 10 times as many employees as another, its payroll is likely to be 10 times larger. Similarly, if an entity has 10 times more affected employees than another firm, then it will likely incur 10 times more compliance cost and wage impacts. Finally, firms hire more workers to increase production and sales, so entity revenues will be a multiple of payroll, although that multiple might vary by industry. If compliance costs and increased wages comprise 2 percent of payroll, those costs will comprise less than 2 percent of revenues. Thus, regardless of the size of the small entity, regulatory impacts should fall within the range calculated by the Department.

The Department shows in Table 34 that with the exception of the accommodation and the food services and drinking places industries, if all employees at an entity are affected by the rule, compliance cost and increased wages comprise less than 1.5 percent of payroll and substantially less than 1 percent of revenues per affected small entity. Although compliance costs and increased wages might comprise 3.55 percent of payroll in the food services and drinking places industry, that is about 1.10 percent of revenues. Performing this analysis for different sized firms should not appreciably change these results.

SBA Advocacy also recommended adopting a lower standard salary level that considers the significant small business impacts of the rule. The comment proposed two alternatives: retain the current standard salary threshold, or ''adjust[ ] the standard salary threshold by a particular industry sector that will experience the greatest economic costs,'' noting that the 2019 standard salary level was based on earnings in both the lowest-wage Census region and the retail industry. The comment also stated that small entities at SBA Advocacy's roundtable recommended a gradual or phased increase in the standard salary threshold.

Although SBA Advocacy disagreed with the standard salary level selected by the Department, the salary level accounts for regions and industries likely to be most affected by the rule. As discussed above,[451] the Department is setting the final rule standard salary level using the lowest-wage Census Region, instead of a national level, ensuring the salary level is not driven by earnings in high- or even middle-wage regions of the country. The Department believes that using earnings data from the lowest-wage Census Region produces a salary level that accounts for differences across industries and regional labor markets. The Department thus believes that the standard salary level is appropriate for small businesses.

Consistent with the history of the part 541 regulations, the Department also declines to create a lower salary level requirement for employees employed at small entities, or to exclude such employees from the salary level test. As the Department has previously noted, while ''the FLSA itself does provide special treatment for small entities under some of its exemptions . . . the FLSA's statutory exemption for white-collar employees in section 13(a)(1) contains no special provision based on size of business.'' [452] In the 86-year history of the part 541 regulations defining the EAP exemption, the salary level requirements have never varied according to the size or revenue of the employer.[453]

SBA Advocacy recommended that updates to the standard salary threshold be made once every 4 years through a proposed rule with a notice and comment process for each update, as opposed to updating the standard salary level every three years through the proposed updating mechanism. The comment conveyed skepticism regarding the lawfulness of the Department's proposed updating mechanism asserting that the FLSA requires the Department to periodically issue regulations to set the standard salary level. The comment also expressed concern that the updating provision would drive wage inflation for salaried workers because employers

[449] *See* 88 FR 62217.

[450] *See* section VII.C.8.

[451] *See* sections V.B.4.iv, VII.C.2.

[452] *See* 81 FR 32526; 69 FR 22238.

[453] *See* Stein Report at 5–6 (rejecting proposals to set varying regional salary levels); *see also* 69 FR 22238 (stating that implementing differing salary levels based on business size industry-by-industry ''would present the same insurmountable challenges'' as adopting regional or population-based salary levels).

may raise the salaries of their newly nonexempt workers to keep them exempt or move them to hourly work to comply with the rule, thereby causing ''a self-perpetuating threshold, as the salary level of the 35th percentile would grow each iteration or three years.'' The comment reported small businesses at Advocacy's roundtable opposed the proposed updating mechanism ''because it creates steep and unpredictable changes to the EAP exemption and uncertainty for employers[,]'' and asserted that small entities have highlighted the administrative burdens of reclassifying workers and tracking employee hours. The comment also mentioned the concern from small construction and professional services businesses about difficulties setting price structures on long term federal and private contracts.

The Department disagrees with SBA Advocacy's skepticism regarding the lawfulness of the updating mechanism. As explained in section V.A.3.i, the Department is adopting an updating mechanism in this rulemaking after publishing a notice of the proposed rule and providing opportunity for stakeholders to comment in accordance with the appropriate notice and comment requirements. The Department has received and considered numerous comments on the proposed updating mechanism. Future updates under the triennial updating mechanism would simply reset the thresholds by applying current data to a standard already established by regulation. Therefore, the Department disagrees with the assertion that a notice and comment rulemaking must precede each future update made through the updating mechanism even where the methodology for setting the compensation levels and the mechanism for updating those levels would remain unchanged.

The Department also disagrees with the concern that the updating mechanism would result in rapid increases to the salary level solely because of employers' actions in response to the rule. This assertion is akin to the ones made by a number of other commenters that the updating mechanism tied to a fixed percentile would lead to the salary level being ratcheted upward over time due to the resulting actions of employers. As explained in detail in sections V.A.3.iii and VII.C.9, there is nothing to substantiate this assertion. On the contrary, the Department's analyses shows that employers' actions in response to the rule will not have the asserted impact on future updates. Rather, the updating mechanism will only ensure that the salary level continues to reflect prevailing economic conditions.

The Department also finds unpersuasive the assertion that the updating mechanism will lead to unpredictable changes and uncertainty for employers. Unlike irregular updates to the earnings thresholds, which may result in drastic changes to the thresholds, regular updates on a pre-determined interval and using an established methodology will produce more predictable and incremental changes. Through the updating mechanism, the Department will reset the standard salary level and total annual compensation threshold using the most recent, publicly available, BLS data on earnings for salaried workers. Therefore, employers will be able to track where the thresholds would fall on a quarterly basis by looking at the BLS data and can estimate the changes in the thresholds even before the Department publishes the notice with the adjusted thresholds in the **Federal Register**. The Department believes that, compared to the irregular updates of the past, employers will be better positioned to anticipate and prepare for future updates under the updating mechanism.

SBA Advocacy also referenced that the Department must publish a small entity compliance guide for this rule. Pursuant to its obligations under section 212 of SBREFA, the Department will publish a small entity compliance guide for this rule.

SBA Advocacy recommended the Department add provisions to help small nonprofits comply with the rule, due to difficulties renegotiating government grants and contracts. As explained in section II.D, issues directly related to the public financing available for certain employers that might be affected by this final rule are beyond the Department's authority to address. However, the Department intends to issue technical assistance to help employers comply with the FLSA.

Finally, SBA Advocacy recommended an extended effective date for the rule of at least 1 year or 18 months, as small entities indicated needing ''more time to understand and evaluate the rule, and possibly reclassify their workforce and budget for expenditures.'' As discussed in section IV, having considered commenter feedback in response to the NPRM, the Department has determined that a delayed applicability date is appropriate for the new standard salary level and the HCE total annual compensation threshold. Specifically, the new $1,128 per week standard salary level and $151,164 per year HCE total annual compensation threshold will not be applicable until approximately 8 months after publication of this final rule in the **Federal Register**. The Department will initially update those thresholds on July 1, 2024, by reapplying the methodologies used to set those thresholds in the 2019 rule, resulting in an initial salary level of $844 per week and an initial HCE total annual compensation threshold of $132,964 per year. Those initial thresholds will remain in effect until the higher thresholds become applicable.

C. Significant Issues Raised by Public Comments in Response to the Initial Regulatory Flexibility Analysis

Many of the issues raised by small businesses in the public comments received on the proposed rule are described in the preamble and RIA above, which are incorporated herein. Nevertheless, significant issues raised by representatives of small businesses are also addressed here.

Most of the comments received concerning small businesses centered on the burden that the proposed salary level would impose on small entities. Many such commenters emphasized that rule-related costs would detrimentally impact small businesses. *See, e.g.,* Amusement and Music Operators Association; Independent Women's Forum; NSBA. Some commenters specifically asserted that the Department underestimated compliance costs for small entities under the proposed rule. *See, e.g.,* ABC; The 4A's. For example, NFIB contended that the rule could cost small businesses more than large businesses because, among other reasons, small businesses often have fewer resources (such as administrative staff members, experienced human resources personnel, or regular access to legal counsel). Sixteen Members of the U.S. House of Representatives cited rule-related costs, combined with burdens facing small businesses, in urging the Department to withdraw its proposal. A number of small businesses specifically raised concerns about the impact of the proposed salary level on small entities in low-wage regions and industries. *See, e.g.,* Nebraska Bankers Association; National Restaurant Association. Other commenters, including the Job Creators Network Foundation, expressed concern that the rule would adversely impact small businesses by increasing inflation. Some small businesses, raising these and similar concerns, urged the Department to set a special salary level or create an exemption for small businesses. *See, e.g.,* Bowling Proprietors Association of America; WFCA. Opposition was not uniform,

however, as some small businesses supported the proposed rule. *See, e.g.* A Few Cool Hardware Stores; BA Auto Care; Well-Paid Maids.

For the reasons previously discussed in detail, the Department believes its cost estimates are appropriate and do not provide a basis for changing the methodology used to set the salary level or for abandoning this rulemaking altogether. The Department does not agree with those commenters who asserted that the proposal would be ruinous for small businesses. As shown later in this section, Department's upper bound estimate of the impact of this rule per small establishment (which assumed all employees in a small firm are affected by the new rule) shows that costs and payroll increases for small affected firms were less than 0.9 percent of payroll and less than 0.2 percent of estimated revenues. While the affect in some industries will be somewhat larger, these figures reinforce that this rule will not be unduly burdensome for small businesses. In addition, the Department believes that most, if not all, small businesses, like larger businesses, employ a mix of exempt and overtime-protected workers. As such, to the extent cost concerns are tied in part to small businesses reclassifying some employees who become nonexempt as hourly as a result of this rule, many employers will already have policies and systems in place for scheduling workers and monitoring overtime hours worked and the corresponding overtime premium pay. Such established procedures, and experience gained through fairly recent rulemakings to increase the earnings thresholds, may help mitigate concerns related to small businesses requiring substantial assistance from outside professionals to comply with this final rule. Additionally, the Department intends to publish compliance assistance materials, including a small entity compliance guide. Industry associations also typically become familiar with rulemakings such as this one and often provide compliance assistance to association members. As to inflationary concerns, as previously discussed, the Department does not expect its rule to lead to increased inflation on a national level.

The Department recognizes that many small employers operate in low-paying regions or industries, and the Department has historically accounted for small employers when setting the salary level.[454] This final rule is no exception, as the Department is setting the salary level using the lowest-wage Census Region. The Department declines to adopt special exceptions or lower salary levels for small businesses. As stated above and as the Department has emphasized in past rules, '''the FLSA's statutory exemption for white-collar employees in section 13(a)(1) contains no special provision based on size of business.' '' [455] In the 86-year history of the part 541 regulations defining the EAP exemption, the Department has never adopted special salary levels for small businesses. The Department continues to believe that implementing differing salary levels based on business size industry-by-industry would be inadvisable because, among other reasons, it ''would present the same insurmountable challenges'' as adopting regional or population-based salary levels.[456]

The Department received many comments in response to its proposed mechanism to update the standard salary and HCE total annual compensation requirements. As discussed in section V.A.3.i, some commenters asserted that the proposed updating mechanism would violate the RFA. Commenters, including Independent Electrical Contracts, RILA, and Seyfarth Shaw, commented that the RFA required the Department ''to undertake a detailed economic and cost analysis'' and that Department's proposed updating mechanism would bypass these requirements. The RFA requires a regulatory flexibility analysis to accompany any agency final rule promulgated under 5 U.S.C. 553.[457] In accordance with this requirement, this section estimates the costs of future triennial updates using the fixed percentile method. The RFA only requires that such analyses accompany rulemaking, and commenters did not cite any RFA provision that would require the Department to conduct a new regulatory flexibility analysis before each scheduled update to the salary and annual compensation thresholds.

Several commenters addressed the potential effects that the proposed updating mechanism could have on small entities. Small Business Majority expressed support for the proposed updating mechanism, asserting that ''[s]maller, predictable increases that are known well in advance will allow small business owners to be better prepared for any staffing or compensation changes they need to make.'' Business for a Fair Minimum Wage—whose members include many small business owners—commented that the proposed updating mechanism would keep the thresholds up to date and predictable for employers. In contrast, NFIB asserted that ''triennial updates would result in instability in labor and administrative costs for small businesses in perpetuity'' as small businesses would have to reconsider the classifications given to their employees every 3 years. The 4As similarly asserted that the updating mechanism imposes substantial ongoing expense on small agencies noting that ''[l]ike many small businesses, small agencies often outsource legal, payroll, and some HR functions to outside professionals.'' ASTA expressed concern that ''small business owners with limited resources to engage outside help, would have difficulty keeping abreast of salary level increases and could inadvertently find themselves out of compliance.''

As previously explained, the Department believes the updating mechanism adopted by this final rule will ensure greater certainty and predictability for the regulated community. For all future triennial updates, the Department will publish a notice with the revised salary and annual compensation thresholds not fewer than 150 days before the new thresholds are set to take effect. Moreover, businesses will be able to estimate the changes in the thresholds by looking at BLS data even before the Department publishes the notice with the adjusted thresholds. The Department believes that, compared to the irregular updates of the past, employers will be better positioned to anticipate and prepare for future updates under the updating mechanism. As noted in section V.A.3.ii, the alternative to Department's updating mechanism is not a permanent fixed earnings threshold, but instead larger changes to the threshold that would occur during irregular future updates. Since the updating mechanism will change the thresholds regularly and incrementally, and based on actual earnings of salaried workers, the Department predicts that employers will be in a better position to be able to adjust to the changes resulting from triennial updates.

The Department believes that the updating mechanism will ensure that the earnings thresholds for the EAP exemption will remain effective and up to date over time. The updating mechanism should benefit employers of

[454] *See, e.g.,* Weiss Report at 14–15 (setting the long test salary level for executive employees ''slightly lower than might be indicated by the data'' in part to avoid excluding ''large numbers of the executives of small establishments from the exemption'').

[455] *See* 81 FR 32526 (quoting 69 FR 22238).

[456] 69 FR 22238.

[457] *See* 5 U.S.C. 603–604.

all sizes going forward by avoiding the uncertainty and disruptiveness of larger increases that would likely occur as a result of irregular updates.

D. Estimate of the Number of Affected Small Entities

1. Definition of Small Entity

The RFA defines a ''small entity'' as (1) a small not-for-profit organization, (2) a small governmental jurisdiction, or (3) a small business. The Department used the entity size standards defined by SBA and in effect as of 2019, to classify entities as small or large.[458] The most recent size standards were released in 2022 and use the 2022 NAICS. However, because the data used by the Department to estimate the number of small entities uses the 2017 NAICS, the Department used the 2019 entity size standards instead of the 2022 standards.[459]

SBA establishes standards for 6-digit NAICS industry codes, and standard size cutoffs are typically based on either the average number of employees or average annual receipts. However, some exceptions exist, the most notable being that depository institutions (including credit unions, commercial banks, and non-commercial banks) are classified by total assets and small governmental jurisdictions are defined as areas with populations of less than 50,000.[460]

2. Number of Small Entities and Employees

The primary data source used to estimate the number of small entities and employment in these entities is the Statistics of U.S. Businesses (SUSB). Alternative sources were used for industries with asset thresholds (credit unions,[461] commercial banks and savings institutions,[462] agriculture [463]), and public administration.[464] The Department used 2017 data, when possible, to align with the use of 2017 SUSB data. Private households are excluded from the analysis due to lack of data.

For each industry, the SUSB 2017 tabulates employment, establishment, and firm counts by both enterprise employment size (*e.g.,* 0–4 employees, 5–9 employees) and receipt size (*e.g.,* less than $100,000, $100,000–$499,999).[465] Although more recent SUSB data are available, these data do not disaggregate entities by revenue sizes. The Department combined these data with the SBA size standards to estimate the proportion of firms and establishments in each industry that are considered small, and the proportion of workers employed by a small entity. The Department classified all firms and establishments and their employees in categories below the SBA cutoff as small.[466] If a cutoff fell in the middle of a category, the Department assumed a uniform distribution of employees across that bracket to determine what proportion of establishments should be classified as small.[467] The estimated share of establishments that were small in 2017 was applied to the more recent 2021 SUSB data on the number of small establishments to determine the number of small entities.[468]

The Department also estimated the number of small establishments and their employees by employer type (nonprofit, for-profit, government). This calculation is similar to the calculation of the number of establishments by industry but with different data. Instead of using data by industry, the Department used SUSB data by Legal Form of Organization for nonprofit and for-profit establishments. The estimated share of establishments that were calculated as small with the 2017 data was then applied to the 2021 SUSB counts. For governments, the Department used the number of governments reported in the 2017 Census of Governments.[469]

Table 28 presents the estimated number of establishments/governments and small establishments/governments in the U.S. (hereafter, referred to as ''entities'').[470] The numbers in the following tables are for Year 1; projected impacts are considered later. The Department found that of the 8.2 million entities, 80 percent (6.6 million) are small by SBA standards. These small entities employ 55.3 million workers, about 37 percent of workers (excluding self-employed, unpaid workers, and members of the armed forces). They also account for roughly 35 percent of total payroll ($3.7 trillion of $10.7 trillion).[471]

Although the Department used 6-digit NAICS to determine the number of small entities and the associated number of employees, the following tables aggregate findings to 27 industry categories. This was the most detailed level available while maintaining adequate sample sizes.[472] The Department started with the 51-industry breakdown and aggregated where necessary to obtain adequate sample sizes.

Table 28—Number of Entities and Employees by SBA Size Standards, by Industry and Employer Type

[458] *See https://data.sba.gov/dataset/small-business-size-standards/resource/d89a5f17-ab8e-4698-9031-dfeb34d0a773.*

[459] The SBA size standard changes in 2022 primarily adjusted the standards to the 2022 NAICS, these changes were not substantive. *https://www.govinfo.gov/content/pkg/FR-2022-09-29/pdf/2022-20513.pdf.*

[460] *See https://advocacy.sba.gov/resources/the-regulatory-flexibility-act/rfa-data-resources-for-federal-agencies/* for details.

[461] National Credit Union Association. (2018). 2018 Year End Statistics for Federally Insured Credit Unions. Available at: *https://www.cuna.org/advocacy/credit-union---economic-data/data---statistics/credit-union-profile-reports.html.*

[462] Federal Depository Insurance Corporation. (2018). Quarterly Financial Reports-Statistics On Depository Institutions (SDI). Available at: *https://www.fdic.gov/foia/ris/id-sdi/index.html.* Data are from 12/31/17.

[463] United States Department of Agriculture. (2019). 2017 Census of Agriculture: United States Summary and State Data: Volume 1, Geographic Area Series, Part 51. Available at: *https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/usv1.pdf.*

[464] Census of Governments. 2017. Available at: *https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html.*

[465] The SUSB defines employment as of March 12th.

[466] The Department's estimates of the numbers of affected small entities and affected workers who are employees of small entities includes entities not covered by the FLSA and thus are likely overestimates. The Department had no credible way to estimate which enterprises with annual revenues below $500,000 also did not engage in interstate commerce and hence are not subject to the FLSA.

[467] The Department assumed that the small entity share of credit card issuing and other depository credit intermediation institutions (which were not separately represented in FDIC asset data), is similar to that of commercial banking and savings institutions.

[468] Statistics of U.S. Businesses 2021, *https://www.census.gov/programs-surveys/susb.html.*

[469] Census of Governments 2017. Available at *https://www.census.gov/programs-surveys/cog.html.*

[470] SUSB reports data by ''enterprise'' size designations (a business organization consisting of one or more domestic establishments that were specified under common ownership or control). However, the number of enterprises is not reported for the size designations. Instead, SUSB reports the number of ''establishments'' (individual plants, regardless of ownership) and ''firms'' (a collection of establishments with a single owner within a given state and industry) associated with enterprises size categories. Therefore, numbers in this analysis are for the number of establishments associated with small enterprises, which may exceed the number of small enterprises. The Department based the analysis on the number of establishments rather than firms for a more conservative estimate (potential overestimate) of the number of small businesses.

[471] Since information is not available on employer size in the CPS MORG, respondents were randomly assigned as working in a small business based on the SUSB probability of employment in a small business by detailed Census industry. Annual payroll was estimated based on the CPS weekly earnings of workers by industry size.

[472] The Department required at least 15 affected workers (*i.e.,* observations) in small entities in Year 1.

Industry / Employer Type	Entities (1,000s)		Workers (1,000s) [a]		Annual Payroll (Billions)	
	Total	Small	Total	Small Business Employed	Total	Small
Total	8,238.7	6,588.6	147,798.7	55,279.6	$10,660.7	$3,743.6
Industry [b]						
Agriculture, forestry, fishing, and hunting	23.3	19.3	1,349.6	702.6	$66.0	$34.7
Mining	23.0	18.5	587.9	276.3	$62.3	$28.6
Construction	780.3	752.7	9,345.8	5,617.2	$646.7	$390.4
Manufacturing - durable goods	174.6	159.8	10,032.5	4,634.0	$824.9	$368.6
Manufacturing - non-durable goods	108.4	96.6	5,580.1	2,674.4	$435.0	$195.1
Wholesale trade	390.8	301.3	3,169.5	1,308.9	$250.8	$100.9
Retail trade	1,036.9	661.3	15,698.4	4,878.2	$815.6	$264.4
Transportation and warehousing	279.1	220.1	7,539.4	1,795.4	$476.5	$112.3
Utilities	19.9	8.0	1,463.3	309.9	$142.3	$27.2
Information	162.0	93.9	2,720.8	702.5	$283.3	$69.2
Finance	297.4	137.5	4,859.8	875.2	$533.1	$99.5
Insurance	181.5	139.9	2,801.6	641.1	$254.1	$58.0
Real estate and rental and leasing	456.2	353.3	2,359.8	1,212.3	$181.8	$93.5
Professional and technical services	962.5	858.7	12,003.4	5,320.8	$1,389.8	$598.3
Management, administrative and waste management services	499.5	411.0	5,622.8	2,406.6	$310.7	$121.8
Educational services	111.5	98.9	14,383.5	3,701.4	$998.1	$239.4
Hospitals	7.5	1.5	7,832.2	277.4	$649.1	$22.6
Health care services, except hospitals	751.4	579.3	10,476.2	4,565.8	$672.5	$288.7
Social assistance	188.7	152.8	3,121.3	1,739.0	$153.9	$82.7
Arts, entertainment, and recreation	156.1	142.3	2,656.0	1,296.1	$138.7	$66.7
Accommodation	70.8	59.4	1,190.0	466.8	$57.9	$22.6

Food services and drinking places	675.1	524.8	8,750.2	4,952.0	$294.8	$167.6
Repair and maintenance	220.0	202.3	1,736.5	1,253.6	$95.9	$68.8
Personal and laundry services	254.4	226.7	1,644.1	1,286.4	$71.7	$55.5
Membership associations and organizations	307.0	294.8	2,038.9	1,395.3	$143.6	$96.1
Public administration [c]	90.1	65.7	8,211.2	990.3	$692.2	$70.6
Employer Type						
Nonprofit, private	597.3	504.5	10,692.3	4,029.0	$796.6	$264.3
For profit, private	7,551.3	5,874.3	114,570.7	47,910.7	$8,169.1	$3,257.6
Government (state and local)	90.1	65.7	18,284.5	3,339.9	$1,296.3	$221.7

Note: Establishment data are from SUSB 2021; worker and payroll data from pooled CPS MORG data for 2021-2023 adjusted to reflect 2023.

[a] Excludes the self-employed, unpaid workers, and workers in private households.

[b] Summation across industries may not add to the totals reported due to suppressed values and some entities not reporting an industry.

[c] Entity number represents the total number of governments, including state and local. Data from Census of Governments, 2017.

Estimates are not limited to entities subject to the FLSA because the Department cannot estimate which enterprises do not meet the enterprise coverage requirements because of data limitations. Although not excluding such entities and associated workers only affects a small percentage of workers generally, it may have a larger effect (and result in a larger overestimate) for non-profits, because revenue from charitable activities is not included when determining enterprise coverage.

3. Number of Affected Small Entities and Employees

The calculation of the number of affected EAP workers was explained in detail in section VII.B. Here, the Department focuses on how these workers were allocated to either small or large entities. To estimate the probability that an exempt EAP worker in the CPS data is employed by a small entity, the Department assumed this probability is equal to the proportion of all workers employed by small entities in the corresponding industry. That is, if 50 percent of workers in an industry are employed in small entities, then on average small entities are expected to employ one out of every two exempt EAP workers in this industry.[473] The Department applied these probabilities to the population of exempt EAP workers to find the number of workers (total exempt EAP workers and total affected by the rule) that small entities employ. No data are available to determine whether small businesses (or small businesses in specific industries) are more or less likely than non-small businesses to employ exempt EAP workers or affected EAP workers. Therefore, the best assumption available is to assign the same rates to all small and non-small businesses.[474] [475]

The Department estimated that small entities employ 1.6 million of the 4.3 million affected workers (36.3 percent) (Table 29). This composes 2.8 percent of the 55.3 million workers that small entities employ. The sectors with the highest total number of affected workers employed by small entities are professional and technical services (281,000); health care services, except hospitals (140,000); and retail trade (125,000). The sectors with the largest percent of workers employed by small entities who are affected include:

[473] The Department used CPS microdata to estimate the number of affected workers. This was done individually for each observation in the relevant sample by randomly assigning them a small business status based on the best available estimate of the probability of a worker to be employed in a small business in their respective industry.

[474] A strand of literature indicates that small businesses tend to pay lower wages than larger businesses. This may imply that workers in small businesses are more likely to be affected than workers in large businesses; however, the literature does not make clear what the appropriate alternative rate for small businesses should be.

[475] Workers are designated as employed in a small business based on their industry of employment. The share of workers considered small in nonprofit, for profit, and government entities is therefore the weighted average of the shares for the industries that compose these categories.

insurance (7.0 percent); membership associations and organizations (5.7 percent); and professional and technical services (5.3 percent).

Table 29—Number of Affected Workers Employed by Small Entities, by Industry and Employer Type

Industry	Workers (1,000s)		Affected Workers (1,000s) [a]	
	Total	Small Business Employed	Total	Small Business Employed
Total	147,798.7	55,279.6	4,337.5	1,574.1
Industry				
Agriculture, forestry, fishing, and hunting	1,349.6	702.6	13.3	6.4
Mining	587.9	276.3	18.5	8.8
Construction	9,345.8	5,617.2	184.6	112.1
Manufacturing - durable goods	10,032.5	4,634.0	232.9	121.8
Manufacturing - non-durable goods	5,580.1	2,674.4	117.7	58.9
Wholesale trade	3,169.5	1,308.9	112.3	50.9

Retail trade	15,698.4	4,878.2	377.4	124.5
Transportation and warehousing	7,539.4	1,795.4	113.1	30.0
Utilities	1,463.3	309.9	39.8	7.5
Information	2,720.8	702.5	132.4	34.8
Finance	4,859.8	875.2	276.4	43.6
Insurance	2,801.6	641.1	198.6	45.1
Real estate and rental and leasing	2,359.8	1,212.3	89.4	51.3
Professional and technical services	12,003.4	5,320.8	676.3	280.7
Management, administrative and waste management services	5,622.8	2,406.6	151.1	47.5
Educational services	14,383.5	3,701.4	244.1	53.4
Hospitals	7,832.2	277.4	238.9	11.4
Health care services, except hospitals	10,476.2	4,565.8	347.0	140.1
Social assistance	3,121.3	1,739.0	154.2	91.4
Arts, entertainment, and recreation	2,656.0	1,296.1	118.3	64.6
Accommodation	1,190.0	466.8	26.6	12.3
Food services and drinking places	8,750.2	4,952.0	83.6	42.0
Repair and maintenance	1,736.5	1,253.6	21.5	16.1
Personal and laundry services	1,644.1	1,286.4	23.4	14.3
Membership associations and organizations	2,038.9	1,395.3	117.8	79.4
Public administration	8,211.2	990.3	227.2	25.2
Employer Type				
Nonprofit, private	10,692.3	4,029.0	461.3	201.3
For profit, private	114,570.7	47,910.7	3,392.5	1,310.8
Government (state and local)	18,284.5	3,339.9	483.6	62.1

Note: Worker data are from pooled CPS MORG data for 2021-2023 adjusted to reflect 2023.

[a] Estimation of affected workers employed by small entities was done at the most detailed industry level available. Therefore, at the more aggregated industry level shown in this table, the ratio of small business employed to total employed does not equal the ratio of affected small business employed to total affected for each industry, nor does it equal the ratio for the national total because relative industry size, employment, and small business employment differs from industry to industry.

Because no information is available on how affected workers would be distributed among small entities, the Department estimated a range of effects. At one end of this range, the Department assumed that each small entity employs no more than one affected worker, meaning that at most 1.6 million of the 6.6 million small entities will employ an affected worker. Thus, these assumptions provide an upper-end estimate of the number of affected small entities. (However, it provides a lower-end estimate of the effect per small entity because costs are spread over a larger number of entities; the impacts experienced by an entity would increase as the share of its workers that are affected increases.) For the purpose of estimating a lower-range number of affected small entities, the Department used the average size of a small entity as the typical size of an affected small entity, and assumed all workers are affected. This can be considered an approximation of all employees at an entity affected.[476] The average number

[476] This is not the true lower bound estimate of the number of affected entities. Strictly speaking, a true lower bound estimate of the number of affected

of employees in a small entity is the number of workers that small entities employ divided by the total number of small establishments in that industry. The number of affected employees at small businesses is then divided by this average number of employees to calculate 208,300 affected small entities.

Table 30 summarizes the estimated number of affected workers that small entities employ and the expected range for the number of affected small entities by industry. The Department estimated that the rule will affect 1.6 million workers who are employed by somewhere between 208,300 and 1.6 million small entities; this comprises from 3.2 percent to 23.9 percent of all small entities. It also means that from 5.0 million to 6.4 million small entities would incur no more than minimal regulatory familiarization costs (*i.e.,* 6.6 million minus 1.6 million equals 5.0 million; 6.6 million minus 208,300 equals 6.4 million, using rounded values). The table also presents the average number of affected employees per establishment using the method in which all employees at the establishment would be affected. For the other method, by definition, there would always be one affected employee per establishment. Also displayed is the average payroll per small establishment by industry (based on both affected and non-affected small entities), calculated by dividing total payroll of small businesses by the number of small businesses (Table 28) (applicable to both methods).

small entities would be calculated by assuming all employees in the largest small entity are affected. For example, if the SBA standard is that entities with 500 employees are ''small,'' and 1,350 affected workers are employed by small entities in that industry, then the smallest number of entities that could be affected in that industry (the true lower bound) would be three. However, because such an outcome appears implausible, the Department determined a more reasonable lower estimate would be based on average establishment size.

Table 30—Number of Small Affected Entities and Employees by Industry and Employer Type

Industry	Affected Workers in Small Entities (1,000s)	Number of Small Affected Entities (1,000s) [a]		Per Entity	
		One Affected Employee per Entity [b]	All Employees at Entity Affected [c]	Affected Employees [a]	Average Annual Payroll ($1,000s)
Total	1,574.1	1,574.1	208.3	7.6	$568.2
Industry					
Agriculture, forestry, fishing, and hunting	6.4	6.4	0.2	36.4	$1,796.9
Mining	8.8	8.8	0.6	15.0	$1,546.6
Construction	112.1	112.1	15.0	7.463	$518.6
Manufacturing - durable goods	121.8	121.8	4.2	29.0	$2,306.3
Manufacturing - non-durable goods	58.9	58.9	2.1	27.7	$2,020.1
Wholesale trade	50.9	50.9	11.7	4.3	$334.9
Retail trade	124.5	124.5	16.9	7.4	$399.7
Transportation and warehousing	30.0	30.0	3.7	8.2	$510.4
Utilities	7.5	7.5	0.2	38.9	$3,415.5
Information	34.8	34.8	4.7	7.5	$736.8
Finance	43.6	43.6	6.9	6.4	$723.6
Insurance	45.1	45.1	9.8	4.6	$415.0
Real estate and rental and leasing	51.3	51.3	15.0	3.4	$264.7
Professional and technical services	280.7	280.7	45.3	6.2	$696.8
Management, administrative and waste management services	47.5	47.5	8.1	5.9	$296.4
Educational services	53.4	53.4	1.4	37.4	$2,420.0
Hospitals	11.4	9.9 [d]	0.1	189.1	$15,377.1
Health care services, except hospitals	140.1	140.1	17.8	7.9	$498.4
Social assistance	91.4	91.4	8.0	11.4	$541.3

Arts, entertainment, and recreation	64.6	64.6	7.1	9.1	$468.5
Accommodation	12.3	12.3	1.6	7.9	$379.4
Food services and drinking places	42.0	42.0	4.5	9.4	$319.3
I Repair and maintenance	16.1	16.1	2.6	6.2	$340.1
Personal and laundry services	14.3	14.3	2.5	5.7	$244.8
Membership associations and organizations	79.4	79.4	16.8	4.7	$325.8
Public administration [e]	25.2	25.2	1.7	15.1	$1,075.1
Employer Type					
Nonprofit, private	201.3	201.3	25.2	8.0	$523.9
For profit, private	1,310.8	1,310.8	160.7	8.2	$554.5
Government (state and local)	62.1	62.1	1.2	50.8	$3,373.6

Note: Establishment data are from SUSB 2021; worker and payroll data from pooled CPS MORG data for 2021-2023 adjusted to reflect 2023.

[a] Estimation of both affected small entity employees and affected small entities was done at the most detailed industry level available. Therefore, the ratio of affected small entities employees to total small entity employees for each industry may not match the ratio of small affected entities to total small entities at the more aggregated industry level presented in the table, nor will it equal the ratio at the national level because relative industry size, employment, and small business employment differs from industry to industry.

[b] This method may overestimate the number of affected entities and therefore the ratio of affected workers to affected entities may be greater than 1-to-1. However, the Department addresses this issue by also calculating effects based on the assumption that 100 percent of workers at an entity are affected.

[c] For example, on average, a small entity in the construction industry employs 7.5 workers (5.6 million employees divided by 752,700 small entities). This method assumes if an entity is affected then all 7.5 workers are affected. Therefore, in the construction industry this method estimates there are 15,000 small affected entities (112,100 affected small entity workers divided by 7.5).

[d] Number of entities is smaller than number of affected employees; thus, total number of entities is ,reported.

[e] Entity number represents the total number of state and local governments.

4. Impacts to Affected Small Entities

For small entities, the Department estimated various types of effects, including regulatory familiarization costs, adjustment costs, managerial costs, and payroll increases borne by employers. The Department estimated a range for the number of affected small entities and the impacts they incur. While the upper and lower bounds are likely over- and under-estimates, respectively, of effects per small entity, the Department believes that this range of costs and payroll increases provides the most accurate characterization of the effects of the rule on small employers.[477] Furthermore, the smaller estimate of the number of affected entities (*i.e.,* where all employees at each affected employer are assumed to be affected) will result in the largest costs and payroll increases per entity as a percent of establishment payroll and revenue, and the Department expects that many, if not most, entities will incur smaller costs, payroll increases, and effects relative to entity size.

Parameters that are used in the small business cost analysis for Year 1 are provided in Table 31, along with summary data of the impacts.[478]

[477] As noted previously, these are not the true lower and upper bounds. The values presented are the highest and lowest estimates the Department believes are plausible.

[478] *See* section VII.C.3 for a more fulsome discussion on these costs.

Table 31—Overview of Parameters Used for Costs to Small Businesses and the Impacts on Small Businesses

Small Business Costs	Cost
Direct and Payroll Costs	
Average total cost per affected entity [a]	$4,544
Range of total costs per affected entity [a]	$1,767-$57,218
Average percent of revenue per affected entity	0.16%
Average percent of payroll per affected entity	0.80%
Direct Costs	
Regulatory familiarization	
Time (first year)	1 hour per entity
Time (update years)	10 minutes per entity
Hourly wage	$54.82
Adjustment	
Time (first year affected)	75 minutes per newly affected worker
Hourly wage	$54.82
Managerial	
Time (weekly)	10 minutes per affected worker whose hours change
Hourly wage	$86.82
Payroll Increases	
Average payroll increase per affected entity [a]	$2,773
Range of payroll increases per affected entity [a]	$674-$15,532

[a] Using the methodology where all employees at an affected small firm are affected. This assumption generates upper-end estimates. Lower-end cost estimates are significantly smaller.

The Department expects total direct employer costs will range from $368.7 million to $443.6 million for affected small entities (*i.e.,* those with affected employees) in the first year (an average cost of between $282 to $1,771 per entity) (Table 32). Small entities that do not employ affected workers will incur $274.9 million to $349.7 million in regulatory familiarization costs (an average cost of $54.82 per entity). The three industries with the highest costs (professional and technical services; health care services, except hospitals; and retail trade) account for about 35 percent of the costs. Hospitals are expected to incur the largest cost per establishment ($42,900 using the method where all employees are affected), although the costs are not expected to exceed 0.3 percent of payroll. The food services and drinking places industry is expected to experience the largest effect as a share of payroll (estimated direct costs compose 0.69 percent of average entity payroll).

Table 32—Year 1 Small Establishment Direct Costs, Total and per Establishment, by Industry and Employer Type

Industry	Direct Cost to Small Entities in Year 1 [a]					
	One Affected Employee			All Employees Affected		
	Total (Millions) [a]	Cost per Affected Entity	Percent of Annual Payroll	Total (Millions) [b]	Cost per Affected Entity	Percent of Annual Payroll
Total	$443.6	$282	0.05%	$368.7	$1,771	0.31%
Industry						
Agriculture, forestry, fishing, and hunting	$1.8	$281	0.02%	$1.5	$8,292	0.46%
Mining	$2.5	$281	0.02%	$2.0	$3,443	0.22%
Construction	$31.6	$282	0.05%	$26.3	$1,751	0.34%
Manufacturing - durable goods	$34.3	$282	0.01%	$27.9	$6,631	0.29%
Manufacturing - non-durable goods	$16.7	$283	0.01%	$13.5	$6,367	0.32%
Wholesale trade	$14.3	$281	0.08%	$12.2	$1,039	0.31%
Retail trade	$35.1	$282	0.07%	$29.2	$1,731	0.43%
Transportation and warehousing	$8.5	$282	0.06%	$7.0	$1,912	0.37%
Utilities	$2.1	$281	0.01%	$1.7	$8,876	0.26%
Information	$9.8	$281	0.04%	$8.1	$1,750	0.24%
Finance	$12.3	$281	0.04%	$10.3	$1,496	0.21%
Insurance	$12.7	$281	0.07%	$10.8	$1,093	0.26%
Real estate and rental and leasing	$14.5	$283	0.11%	$12.5	$839	0.32%
Professional and technical services	$79.1	$282	0.04%	$66.2	$1,460	0.21%
Management, administrative and waste management services	$13.5	$284	0.10%	$11.3	$1,394	0.47%
Educational services	$15.0	$281	0.01%	$12.2	$8,531	0.35%
Hospitals	$3.2	$281	0.00%	$2.6	$42,885	0.28%

Health care services, except hospitals	$39.5	$282	0.06%	$32.8	$1,842	0.37%
Social assistance	$25.7	$281	0.05%	$21.1	$2,633	0.49%
Arts, entertainment, and recreation	$18.2	$282	0.06%	$15.0	$2,120	0.45%
Accommodation	$3.5	$281	0.07%	$2.9	$1,834	0.48%
Food services and drinking places	$11.9	$282	0.09%	$9.8	$2,203	0.69%
Repair and maintenance	$4.5	$281	0.08%	$3.8	$1,459	0.43%
Personal and laundry services	$4.0	$282	0.12%	$3.4	$1,343	0.55%
Membership associations and organizations	$22.4	$282	0.09%	$18.9	$1,129	0.35%
Public administration	$7.1	$281	0.03%	$5.8	$3,471	0.32%
Employer Type						
Nonprofit, private	$54.4	$270	0.05%	$44.8	$1,777	0.34%
For profit, private	$394.4	$301	0.05%	$331.4	$2,062	0.37%
Government (state and local)	$17.5	$283	0.01%	$14.2	$11,633	0.34%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[a] Direct costs include regulatory familiarization, adjustment, and managerial costs.

[b] The range of costs per entity depends on the number of affected entities. The minimum assumes that each affected entity has one affected worker (therefore, the number of affected entities is equal to the number of affected workers). The maximum assumes the share of workers in small entities who are affected is also the share of small entity entities that are affected.

It is possible that the costs of the rule may be disproportionately large for small entities, especially because small entities often have limited human resources personnel on staff. However, the Department expects that small entities would rely on compliance assistance materials provided by the Department or industry associations to become familiar with the final rule. Additionally, the Department notes that the rule is narrow in scope because the changes all relate to the salary component of the part 541 regulations. Finally, the Department believes that most entities have at least some nonexempt employees and, therefore, already have policies and systems in place for monitoring and recording their hours. The Department believes that applying those same policies and systems to the workers whose exemption status changes will not be an unreasonable burden on small businesses.

Average weekly earnings for affected EAP workers in small entities are expected to increase by about $7.06 per week per affected worker, using the incomplete fixed-job model [479] described in section VII.C.4.iii.[480] This would lead to $577.5 million in additional annual wage payments to employees in small entities (less than 0.5 percent of aggregate affected establishment payroll; Table 33). The largest payroll increases per establishment are expected in utilities (up to $15,500 per entity); hospitals (up to $14,300 per entity); and manufacturing—durable goods (up to

[479] The incomplete fixed-job model reflects the Department's determination that an appropriate estimate of the impact on the implicit hourly rate of pay for regular overtime workers should be determined using the average of Barkume's and Trejo's two estimates of the incomplete fixed-job model adjustments: a wage change that is 40 percent of the adjustment toward the amount predicted by the fixed-job model, assuming an initial zero overtime pay premium, and a wage change that is 80 percent of the adjustment assuming an initial 28 percent overtime pay premium.

[480] This is an average increase for all affected workers (both standard test and HCE), and reconciles to the weighted average of individual salary changes discussed in the Transfers section.

$13,000 per entity). However, average payroll increases per entity would exceed one percent of average annual payroll in only two sectors: food services and drinking places (2.9 percent) and accommodation (1.1 percent).

Table 33—Year 1 Small Establishment Payroll Increases, Total and per Establishment, by Industry and Employer Type

Industry	Increased Payroll for Small Entities in Year 1 [a]				
	Total (Millions)	One Affected Employee		All Employees Affected	
		Per Entity	Percent of Annual Payroll	Per Entity	Percent of Annual Payroll
Total	$577.5	$367	0.06%	$2,773	0.49%
Industry					
Agriculture, forestry, fishing, and hunting	$1.2	$195	0.01%	$7,088	0.39%
Mining	$2.2	$256	0.02%	$3,828	0.25%
Construction	$43.6	$389	0.08%	$2,904	0.56%
Manufacturing - durable goods	$54.7	$449	0.02%	$13,027	0.56%
Manufacturing - non-durable goods	$21.9	$372	0.02%	$10,291	0.51%
Wholesale trade	$24.9	$489	0.15%	$2,123	0.63%
Retail trade	$66.2	$532	0.13%	$3,922	0.98%
Transportation and warehousing	$14.0	$468	0.09%	$3,815	0.75%
Utilities	$3.0	$399	0.01%	$15,532	0.45%
Information	$4.1	$116	0.02%	$871	0.12%
Finance	$12.0	$274	0.04%	$1,746	0.24%
Insurance	$6.6	$147	0.04%	$674	0.16%
Real estate and rental and leasing	$25.7	$500	0.19%	$1,716	0.65%

Professional and technical services	$116.8	$416	0.06%	$2,577	0.37%
Management, administrative and waste management services	$14.1	$296	0.10%	$1,733	0.58%
Educational services	$12.0	$225	0.01%	$8,434	0.35%
Hospitals	$0.9	$76	0.00%	$14,333	0.09%
Health care services, except hospitals	$30.6	$218	0.04%	$1,721	0.35%
Social assistance	$12.3	$135	0.02%	$1,534	0.28%
Arts, entertainment, and recreation	$28.8	$446	0.10%	$4,059	0.87%
Accommodation	$6.6	$533	0.14%	$4,189	1.10%
Food services and drinking places	$40.7	$968	0.30%	$9,136	2.86%
Repair and maintenance	$8.7	$539	0.16%	$3,341	0.98%
Personal and laundry services	$2.1	$148	0.06%	$841	0.34%
Membership associations and organizations	$19.4	$244	0.07%	$1,155	0.35%
Public administration	$4.6	$181	0.02%	$2,730	0.25%
Employer Type					
Nonprofit, private	$47.3	$235	0.04%	$1,879	0.36%
For profit, private	$511.4	$390	0.07%	$3,182	0.57%
Government (state and local)	$18.8	$302	0.01%	$15,371	0.46%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[a] Aggregate change in total annual payroll experienced by small entities under the updated salary levels after labor market adjustments. This amount represents the total amount of (wage) transfers from employers to employees.

Table 34 presents estimated first year direct costs and payroll increases combined per entity and the costs and payroll increases as a percent of average entity payroll. The Department presents only the results for the upper bound scenario where all workers employed by the entity are affected. Combined costs and payroll increases per establishment range from $1,800 in insurance to $57,200 in hospitals. Combined costs and payroll increases compose more than two percent of average annual payroll in one sector, food services and drinking places (3.6 percent).

However, comparing costs and payroll increases to payrolls overstates the effects on entities because payroll represents only a fraction of the financial resources available to an establishment. The Department approximated revenue per affected small establishment by calculating the ratio of small business revenues to payroll by industry from the 2017 SUSB data then multiplying that ratio by average small entity payroll.[481] Using this approximation of annual revenues as a benchmark, only one sector will have costs and payroll increases amounting to greater than one percent of revenues, food services and drinking places (1.1 percent).

[481] The Department used this estimate of revenue, instead of small business revenue reported directly from the 2017 SUSB so revenue aligned with payrolls in 2023.

Table 34—Year 1 Small Establishment Direct Costs and Payroll Increases, Total and per Entity, by Industry and Employer Type, Using All Employees in Entity Affected Method

Industry	Costs and Payroll Increases for Small Affected Entities, All Employees Affected			
	Total (Millions)	Per Entity [a]	Percent of Annual Payroll	Percent of Estimated Revenues [b]
Total	$946.3	$4,544	0.80%	0.16%
Industry				
Agriculture, forestry, fishing, and hunting	$2.7	$15,381	0.86%	0.17%
Mining	$4.3	$7,271	0.47%	0.07%
Construction	$69.9	$4,655	0.90%	0.21%
Manufacturing - durable goods	$82.6	$19,659	0.85%	0.18%
Manufacturing - non-durable goods	$35.4	$16,658	0.82%	0.11%
Wholesale trade	$37.1	$3,162	0.94%	0.07%
Retail trade	$95.4	$5,652	1.41%	0.14%
Transportation and warehousing	$21.1	$5,726	1.12%	0.26%
Utilities	$4.7	$24,409	0.71%	0.05%
Information	$12.2	$2,621	0.36%	0.11%
Finance	$22.2	$3,242	0.45%	0.13%
Insurance	$17.4	$1,767	0.43%	0.09%
Real estate and rental and leasing	$38.2	$2,554	0.97%	0.21%
Professional and technical services	$182.9	$4,038	0.58%	0.23%
Management, administrative and waste management services	$25.4	$3,127	1.06%	0.43%

Educational services	$24.2	$16,965	0.70%	0.29%
Hospitals	$3.5	$57,218	0.37%	0.16%
Health care services, except hospitals	$63.4	$3,564	0.72%	0.30%
Social assistance	$33.4	$4,167	0.77%	0.36%
Arts, entertainment, and recreation	$43.8	$6,179	1.32%	0.43%
Accommodation	$9.4	$6,023	1.59%	0.38%
Food services and drinking places	$50.5	$11,339	3.55%	1.11%
Repair and maintenance	$12.5	$4,800	1.41%	0.40%
Personal and laundry services	$5.5	$2,184	0.89%	0.31%
Membership associations and organizations	$38.3	$2,284	0.70%	0.17%
Public administration	$10.4	$6,201	0.58%	0.14%
Employer Type				
Nonprofit, private	$94.40	$3,570	1.00%	0.30%
For profit, private	$585.30	$3,532	1.00%	0.20%
Government (state and local)	$12.20	$9,264	0.60%	0.20%

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

[a] Total direct costs and transfers for small entities in which all employees are affected. Impacts to small entities in which one employee is affected will be a fraction of the impacts presented in this table.

[b] Revenues estimated by calculating the ratio of estimated small business revenues to payroll from the 2017 SUSB, and multiplying by payroll per small entity. For the public administration sector, the ratio was calculated using revenues and payroll from the 2017 Census of Governments.

5. Projected Effects to Affected Small Entities in Year 2 Through Year 10

To determine how small businesses would be affected in future years, the Department projected costs to small businesses for 9 years after Year 1 of the rule. Projected employment and earnings were calculated using the same methodology described in section VII.B.3. Affected employees in small firms follow a similar pattern to affected workers in all entities: the number decreases gradually between automatic update years, and then increases. There are 1.6 million affected workers in small entities in Year 1 and 2.2 million in Year 10. Table 35 reports affected workers in these 2 years only.

Table 35—Projected Number of Affected Workers in Small Entities, by Industry

Industry	Affected Workers in Small entities (1,000s)	
	Year 1	Year 10
Total	1,574.1	2,171.7
Agriculture, forestry, fishing, and hunting	6.4	8.8
Mining	8.8	10.6
Construction	112.1	159.7
Manufacturing - durable goods	121.8	169.8
Manufacturing - non-durable goods	58.9	79.7
Wholesale trade	50.9	70.5
Retail trade	124.5	148.4
Transportation and warehousing	30.0	47.1
Utilities	7.5	13.3
Information	34.8	40.7
Finance	43.6	58.7
Insurance	45.1	58.6
Real estate and rental and leasing	51.3	81.0
Professional and technical services	280.7	394.5
Management, administrative and waste management services	47.5	56.8
Educational services	53.4	80.9
Hospitals	11.4	16.3
Health care services, except hospitals	140.1	205.0
Social assistance	91.4	136.0
Arts, entertainment, and recreation	64.6	99.6
Accommodation	12.3	12.4
Food services and drinking places	42.0	52.4
Repair and maintenance	16.1	20.5
Personal and laundry services	14.3	17.5
Membership associations and organizations	79.4	98.7
Public administration	25.2	34.2

Note: Worker data are from Pooled CPS data for 2021-2023 adjusted to reflect 2023.

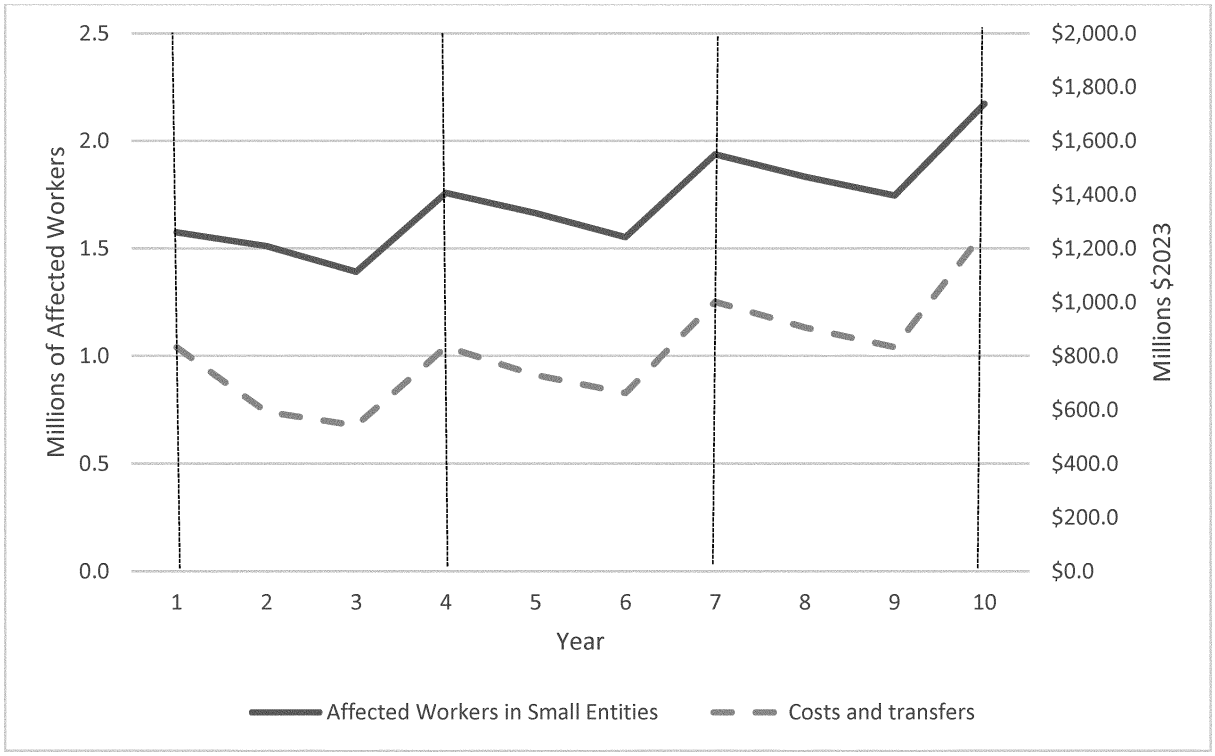
Direct costs and payroll increases for small entities vary by year but generally decrease between updates as the real value of the salary and compensation levels decrease and the number of affected workers consequently decreases. In updating years, costs will increase due to newly affected workers and some regulatory familiarization costs. Direct costs and payroll increases for small businesses will increase in Year 10 (an automatic update year) compared to Year 1, $946 million in Year 1 and $1.3 billion in Year 10 (Table 36 and Figure 10).

Table 36—Projected Direct Costs and Payroll Increases for Affected Small Entities, by Industry, Using All Employees in Entity Affected Method

Industry	Costs and Payroll Increases for Small Affected Entities, All Employees Affected (Millions $2023)	
	Year 1	Year 10
Total	$946.3	$1,263.5
Agriculture, forestry, fishing, and hunting	$2.7	$5.8
Mining	$4.3	$4.2
Construction	$69.9	$102.7
Manufacturing - durable goods	$82.6	$113.3
Manufacturing - non-durable goods	$35.4	$44.5
Wholesale trade	$37.1	$67.7
Retail trade	$95.4	$97.3
Transportation and warehousing	$21.1	$35.1
Utilities	$4.7	$5.5
Information	$12.2	$14.3
Finance	$22.2	$26.6
Insurance	$17.4	$16.7
Real estate and rental and leasing	$38.2	$54.7
Professional and technical services	$182.9	$236.7
Management, administrative and waste management services	$25.4	$41.1
Educational services	$24.2	$33.1
Hospitals	$3.5	$4.4
Health care services, except hospitals	$63.4	$94.0
Social assistance	$33.4	$41.3
Arts, entertainment, and recreation	$43.8	$65.3
Accommodation	$9.4	$7.9
Food services and drinking places	$50.5	$59.4
Repair and maintenance	$12.5	$16.9
Personal and laundry services	$5.5	$10.1
Membership associations and organizations	$38.3	$53.3
Public administration	$10.4	$11.7

Note: Pooled CPS data for 2021-2023 adjusted to reflect 2023.

Figure 10—10-Year Projected Number of Affected Workers in Small Entities, and Associated Costs and Payroll Increases



E. Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

The FLSA sets minimum wage, overtime pay, and recordkeeping requirements for employment subject to its provisions. Unless exempt, covered employees must be paid at least the minimum wage and not less than one and one-half times their regular rates of pay for overtime hours worked.

Pursuant to section 11(c) of the FLSA, the Department's regulations at part 516 require covered employers to maintain certain records about their employees. Bona fide EAP workers are subject to some of these recordkeeping requirements but are exempt from others related to pay and hours worked.[482] Thus, although this rulemaking does not introduce any new recordkeeping requirements, employers will need to keep some additional records for affected employees who become newly nonexempt if they do not presently record such information. As indicated in this analysis, this rule expands minimum wage and overtime pay coverage to 4.3 million affected EAP workers, of which 1.6 million are employed by a small entity. This will result in an increase in employer burden and was estimated in the PRA portion (section VI) of this rule.

F. Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities

This section describes the steps the agency has taken to minimize the economic impact on small entities, consistent with the stated objectives of the FLSA. It includes a statement of the factual, policy, and legal reasons for the selected standard and HCE levels adopted in the rule and why alternatives were rejected.

In this rule, the Department sets the standard salary level equal to the 35th percentile of earnings of full-time salaried workers in the lowest-wage Census Region (currently the South). Based on 2023 data, this results in a salary level of $1,128 per week. This approach will fully restore the salary level's screening function and, by setting the salary level above the long test salary level, ensure that fewer lower paid white-collar employees who perform significant amounts of nonexempt work are included in the exemption. At the same time, by setting it below the short test salary level, the new salary level allows employers to continue to use the exemption for many lower paid white-collar employees who were made exempt under the 2004 standard duties test. Thus, the Department believes that the new salary level will also more reasonably distribute between employees and their employers the impact of the shift from a two-test to a one-test system on employees earning between the long and short test salary levels. As in prior rulemakings, the Department is not establishing multiple salary levels based on region, industry, employer size, or any other factor, which stakeholders have generally agreed would significantly complicate the regulations.[483] Instead, the Department is setting the standard salary level using earnings data from the lowest-wage Census Region, in part to accommodate small employers and employers in low-wage industries.[484]

The Department is setting the HCE total annual compensation level equal to the 85th percentile of earnings of full-time salaried workers nationally ($151,164 annually based on 2023 data).

[482] *See* 29 CFR 516.3 (providing that employers need not maintain the records required by 29 CFR 516.2(a)(6) through (10) for their EAP workers).

[483] *See* 84 FR 51239; 81 FR 32411; 69 FR 22171.

[484] *See* 84 FR 51238; 81 FR 32527; 69 FR 22237.

The Department believes that this level avoids costs associated with evaluating, under the standard duties test, the exemption statuses of large numbers of highly-paid white-collar employees, many of whom would have remained exempt even under that test, while providing a meaningful and appropriate complement to the more lenient HCE duties test. While the threshold is higher than the HCE level adopted in the 2019 rule (which was set equal to the 80th percentile of earnings for salaried workers nationwide), the HCE threshold in this rule is lower than the HCE percentile adopted in the 2004 and 2016 rules, which covered 93.7 and 90 percent of salaried workers nationwide respectively. The Department further believes that nearly all of the highly-paid white-collar workers earning above this threshold ''would satisfy any duties test.'' [485]

1. Differing Compliance and Reporting Requirements for Small Entities

This rule provides no differing compliance requirements and reporting requirements for small entities. The Department strives to minimize respondent recordkeeping burden by requiring no specific form or order of records under the FLSA and its corresponding regulations. Moreover, employers normally maintain the records under usual or customary business practices.

2. Least Burdensome Option or Explanation Required

The Department believes it has chosen the most effective option that updates and clarifies the rule and results in the least burden. Among the options considered by the Department, the least restrictive option was using the 2004 methodology (the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census region, currently the South, and in retail nationally) to set the standard salary level, which was also the methodology used in the 2019 rule. As noted above, however, the salary level produced by the 2004 methodology is below the long test salary level, which the Department considers to be a key parameter for determining an appropriate salary level in a one-test system using the current standard duties test. Using the 2004 methodology thus does not address the Department's concerns discussed above under Objectives of, and Need for, the Rule.

Pursuant to section 603(c) of the RFA, the following alternatives are to be addressed:

i. Differing Compliance or Reporting Requirements That Take Into Account the Resources Available to Small Entities

The FLSA creates a level playing field for businesses by setting a floor below which employers may not pay their employees. To establish differing compliance or reporting requirements for small businesses would undermine this important purpose of the FLSA. The Department makes available a variety of resources to employers for understanding their obligations and achieving compliance. Therefore, the Department is not implementing differing compliance or reporting requirements for small businesses.

ii. The Clarification, Consolidation, or Simplification of Compliance and Reporting Requirements for Small Entities

This rule imposes no new reporting requirements. The Department makes available a variety of resources to employers for understanding their obligations and achieving compliance.

iii. The Use of Performance Rather Than Design Standards

Under this rule, employers may achieve compliance through a variety of means. Employers may elect to continue to claim the EAP exemption for affected employees by adjusting salary levels, hiring additional workers, spreading overtime hours to other employees, or compensating employees for overtime hours worked. The Department makes available a variety of resources to employers for understanding their obligations and achieving compliance.

iv. An Exemption From Coverage of the Rule, or any Part Thereof, for Such Small Entities

Creating an exemption from coverage of this rulemaking for businesses with as many as 500 employees, those defined as small businesses under SBA's size standards, is inconsistent with the FLSA, which applies to all employers that satisfy the enterprise coverage threshold or employ individually covered employees, regardless of employer size.[486]

IX. Unfunded Mandates Reform Act Analysis

The Unfunded Mandates Reform Act of 1995 (UMRA),[487] requires agencies to prepare a written statement for rulemaking that includes any Federal mandate that may result in increased expenditures by state, local, and tribal governments, in the aggregate, or by the private sector, of $200 million ($100 million in 1995 dollars adjusted for inflation to 2023) or more in at least one year. This statement must (1) identify the authorizing legislation; (2) present the estimated costs and benefits of the rule and, to the extent that such estimates are feasible and relevant, present its estimated effects on the national economy; (3) summarize and evaluate state, local, and tribal government input; and (4) identify reasonable alternatives and select, or explain the non-selection, of the least costly, most cost-effective, or least burdensome alternative. This rule contains unfunded mandates as described below.

A. Authorizing Legislation

This final rule is issued pursuant to section 13(a)(1) of the FLSA, 29 U.S.C. 213(a)(1). The section exempts from the FLSA's minimum wage and overtime pay requirements ''any employee employed in a bona fide executive, administrative, or professional capacity (including any employee employed in the capacity of academic administrative personnel or teacher in elementary or secondary schools), or in the capacity of outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary, subject to the provisions of [the Administrative Procedure Act] . . .).'' [488] The requirements of the exemption are contained in part 541 of the Department's regulations. Section 3(e) of the FLSA [489] defines ''employee'' to include most individuals employed by a state, political subdivision of a state, or interstate governmental agency. Section 3(x) of the FLSA [490] also defines public agencies to include the government of a state or political subdivision thereof, or any interstate governmental agency.

B. Costs and Benefits

For purposes of the UMRA, this rule includes a Federal mandate that is expected to result in increased expenditures by the private sector of more than $200 million in at least one year and result in increased expenditures by state, local and tribal governments, in the aggregate, of $200 million or more in at least one year. Based on the economic impact analysis of this final rule, the Department determined that Year 1 costs for state and local governments would total $197.7 million, of which $98.9 million are direct employer costs and $98.8

[485] *See* 84 FR 51250 (internal citation omitted).

[486] *See* 29 U.S.C. 203(s).

[487] 2 U.S.C. 1501 *et seq.*

[488] 29 U.S.C. 213(a)(1).

[489] 29 U.S.C. 203(e).

[490] 29 U.S.C. 203(x).

million are payroll increases (Table 37). In subsequent years, state and local governments may experience payroll increases of as much as $183.7 million (in year 10 of the rule).

The Department estimates that the final rule will result in Year 1 costs to the private sector of approximately $2.7 billion, of which $1.3 billion are direct employer costs and $1.4 billion are payroll increases.

Table 37—Summary of Year 1 Impacts by Type of Employer

Impact	Total	Private	Government [a]
Affected EAP Workers (1,000s)			
Number	4,337	3,854	475
Direct Employer Costs (Millions)			
Regulatory familiarization	$451.6	$446.7	$4.9
Adjustment	$299.1	$265.9	$32.6
Managerial	$685.5	$622.8	$61.4
Total direct costs	$1,436.2	$1,335.3	$98.9
Payroll Increases (Millions)			
From employers to workers	$1,509.2	$1,402.7	$98.8
Direct Employer Costs & Payroll Increases (Millions)			
From employers	$2,945.4	$2,738.0	$197.7

[a] Includes only state, local, and tribal governments.

UMRA requires agencies to estimate the effect of a regulation on the national economy if, at its discretion, such estimates are reasonably feasible and the effect is relevant and material.[491] However, OMB guidance on this requirement notes that such macroeconomic effects tend to be measurable in nationwide econometric models only if the economic effect of the regulation reaches 0.25 percent to 0.5 percent of GDP, or in the range of $68.4 billion to $136.8 billion (using 2023 GDP). A regulation with a smaller aggregate effect is not likely to have a measurable effect in macro-economic terms unless it is highly focused on a particular geographic region or economic sector, which is not the case with this rule.

The Department's RIA estimates that the total first-year costs (direct employer costs and payroll increases from employers to workers) of the final rule would be approximately $2.7 billion for private employers and $197.7 million for state and local governments. Given OMB's guidance, the Department has determined that a full macro-economic analysis is not likely to show any measurable effect on the economy. Therefore, these costs are compared to payroll costs and revenue to demonstrate the feasibility of adapting to these new rules.

Total first-year state and local government costs compose 0.02 percent of state and local government payrolls.[492] First-year state and local government costs compose 0.004 percent of state and local government revenues (projected 2023 revenues were estimated to be $5.0 trillion).[493] Effects of this magnitude will not result in significant disruptions to typical state and local governments. The $197.7 million in state and local government costs constitutes an average of approximately $2,200 for each of the approximately 90,126 state and local entities. The Department considers these costs to be quite small both in absolute terms and in relation to payroll and revenue.

Total first-year private sector costs compose 0.034 percent of private sector payrolls nationwide.[494] Total private sector first-year costs compose 0.006 percent of national private sector revenues (revenues in 2023 are projected to be $45.3 trillion).[495] The Department concludes that effects of this magnitude are affordable and will not result in significant disruptions to typical firms in any of the major industry categories.

C. Summary of State, Local, and Tribal Government Input

Prior to issuing the NPRM, the Department held a series of stakeholder listening sessions between March 8, 2022, and June 3, 2022 to gather input on its part 541 regulations. Stakeholders invited to participate in these listening sessions included representatives from labor unions; worker advocate groups; industry associations; small business associations; state and local governments; tribal governments; non-profits; and representatives from specific industries such as K–12 education, higher education, healthcare, retail, restaurant, manufacturing, and wholesale. Stakeholders were invited to share their input on issues including the appropriate EAP salary level, the costs and benefits of increasing the salary level to employers and employees, the methodology for updating the salary level and frequency of updates, and whether changes to the duties test are

[491] 2 U.S.C. 1532(a)(4).

[492] 2020 state and local government payrolls were $1.1 trillion, inflated to 2023 payroll costs of $1.2 trillion using the GDP deflator. State and Local Government Finances 2020. Available at *https://www.census.gov/data/datasets/2020/econ/local/public-use-datasets.html*.

[493] 2020 state and local revenues were $4.3 trillion, inflated to 2023 dollars using the GDP deflator. State and Local Government Finances 2020. Available at *https://www.census.gov/data/datasets/2020/econ/local/public-use-datasets.html*.

[494] Private sector payroll costs are projected to be $8.1 trillion in 2023 based on private sector payroll costs of $6.6 trillion in 2017, inflated to 2023 dollars using the GDP deflator. 2017 Economic Census of the United States.

[495] Private sector revenues in 2017 were $37.0 trillion using the 2017 Economic Census of the United States. This was inflated to 2023 dollars using the GDP deflator.

warranted. A listening session was held specifically for state and local governments on April 1, 2022, and a session for tribal governments was held on May 12, 2022. The input received at these listening sessions aided the Department in drafting its rule.

The Department received mixed feedback on the proposed rule from state, local, and tribal government commenters. Some state and local government stakeholders voiced strong support for the proposed rule. For example, the Coalition of State AGs supported the proposal, stating that the current salary level is too low and that the proposed updating mechanism ''is important for employers in our respective states to have predictability in their labor costs.'' The Washington State Department of Labor & Industries noted that it implemented a state EAP salary level through administrative rulemaking which is currently $1,302.40 per week ($67,724.80 annually), stating that ''the State of Washington considered many of the same factors'' as the Department to set its salary level. Commenting on behalf of 1.4 million members who are state and local government employees, AFSCME described the proposed salary level as ''a modest increase that will nevertheless benefit millions of workers.''

Other state and local government stakeholders voiced opposition to the proposed rule. The National Association of Counties asserted that the proposed threshold increases would have a disproportionate impact on small and rural county governments, emphasizing that practical and legal constraints limit the ability of county governments to raise revenues to account for added labor costs. Similarly, Ohio Township Association commented that ''[if] townships [do] not wish to raise taxes or residents reject a property tax levy for such purpose, the township will be forced to cut or eliminate services.'' *See also* Pennsylvania State Association of Township Supervisors (providing similar feedback). The Mississippi State Personnel Board asserted that the proposed rule could jeopardize Mississippi's use of telework to recruit and retain certain employees for the state government.

The Department received one comment from a tribal government stakeholder—Ho-Chuck Inc., a subsidiary of the Winnebago Tribe of Nebraska. Explaining that it operates various establishments in the gaming and retail industries, Ho-Chuck Inc. expressed concern about the magnitude of the Department's proposed increase to the standard salary level and of the NPRM's proposed 60-day effective date. Ho-Chuck Inc. requested the Department to consider a smaller increase, such as a 25 percent increase to the current $684 per week salary level (*i.e.,* $855 per week), with ''staggered increases over a period of 3 to 5 years to the higher amount.''

As discussed in this final rule,[496] the Department agrees with commenters such as the Coalition of State AGs that the updating mechanism's triennial updates to the earnings thresholds for exemption will provide greater certainty and predictability for the regulated community. The Department appreciates that some employers, such as state, local, and tribal governments, may have less flexibility than others to account for new labor costs, as well as that employers in low-wage industries, regions, and in non-metropolitan areas may be more affected because they typically pay lower wages and salaries. However, the Department believes that costs and transfers associated with this rule will be manageable for and will not result in significant disruptions to state, local, and tribal governments. The Department is setting the standard salary level using earnings data from the lowest-wage Census Region, in part to accommodate small employers and employers in low-wage sectors and regions. As discussed earlier in this section, the Department estimates that total first-year costs for state and local governments comprise 0.02 percent of state and local government payrolls and 0.004 percent of state and local government revenues. Moreover, as discussed in this final rule,[497] the Department has determined, upon consideration of commenter feedback, that a delayed applicability date is appropriate for the new standard salary level and the HCE total annual compensation threshold. Specifically, the new $1,128 per week standard salary level and $151,164 per year HCE total annual compensation threshold will not be applicable until January 1, 2025.

D. Least Burdensome Option or Explanation Required

This final rule has described the Department's consideration of various options throughout the preamble (*see* section V.B.4.iv) and economic impact analysis (*see* section VII.C.8). The Department believes that it has chosen the least burdensome but still cost-effective methodology to update the salary level consistent with the Department's statutory obligation to define and delimit the scope of the EAP exemption. Although some alternative options considered would set the standard salary level at a rate lower than the finalized level, that outcome would not necessarily be the most cost-effective or least-burdensome. A salary level equal to or below the long test level would result in the exemption of lower-salaried employees who traditionally were entitled to overtime protection under the long test either because of their low salary or because they perform large amounts of nonexempt work. This approach would also effectively place the burden of the move from a two-test system to a one-test system on employees who historically were nonexempt because they earned between the long and short test salary levels but did not meet the long duties test.

Selecting a standard salary level in a one-test system inevitably affects the impact of providing overtime protection to employees paid between the long and short test salary levels. Too low of a salary level shifts the impact of the move to a one-test system to employees by exempting lower-salaried employees who perform large amounts of nonexempt work. However, too high a salary level shifts the impact of the move to a one-test system to employers by denying them the use of the exemption for lower-salaried employees who traditionally were exempt under the long duties test, thereby increasing their labor costs. The Department has determined that setting the standard salary level equivalent to the earnings of the 35th percentile of full-time salaried workers in the lowest-wage Census Region will more effectively identify in a one-test system who is employed in a bona fide EAP capacity in a manner that reasonably distributes among employees earning between the long and short test salary levels and their employers the impact of the Department's move from a two-test to a one-test system. The Department believes that the final rule reduces burden on employers of nonexempt workers who earn between the current and finalized standard salary level. Currently, employers must rely on the duties test to determine the exemption status of these workers. Under this final rule, the exemption status of these workers will be determined based on the simpler salary level test.

The Department is also adopting a mechanism to regularly update the standard salary level and HCE total compensation requirement for wage growth, which will ensure that the thresholds continue to work efficiently to help identify EAP employees. As

[496] *See* sections V.A.3, VII.C.

[497] *See* section IV.

noted above, the history of the part 541 regulations shows multiple, significant gaps during which the earnings thresholds were not updated and their effectiveness in helping to define the EAP exemption decreased as wages increased. Routine updates of the earnings thresholds to reflect wage growth will bring certainty and stability to employers and employees alike.

X. Executive Order 13132, Federalism

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism and determined that it does not have federalism implications. The proposed rule would 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.

XI. Executive Order 13175, Indian Tribal Governments

This rule will not have tribal implications under Executive Order 13175 that would require a tribal summary impact statement. The rule would 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.

List of Subjects in 29 CFR Part 541

Labor, Minimum wages, Overtime pay, Salaries, Teachers, Wages.

For the reasons set out in the preamble, the Wage and Hour Division, Department of Labor amends Title 29 CFR chapter V, as follows:

PART 541—DEFINING AND DELIMITING THE EXEMPTIONS FOR EXECUTIVE, ADMINISTRATIVE, PROFESSIONAL, COMPUTER AND OUTSIDE SALES EMPLOYEES

■ 1. The authority citation for part 541 continues to read as follows:

Authority: 29 U.S.C. 213; Pub. L. 101–583, 104 Stat. 2871; Reorganization Plan No. 6 of 1950 (3 CFR, 1945–53 Comp., p. 1004); Secretary's Order 01–2014 (Dec. 19, 2014), 79 FR 77527 (Dec. 24, 2014).

■ 2. Add § 541.5 to read as follows:

§ 541.5 Severability.

The provisions of this part are separate and severable and operate independently from one another. If any provision of this part is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision must be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding be one of utter invalidity or unenforceability, in which event the provision will be severable from part 541 and will not affect the remainder thereof.

■ 3. Amend § 541.100, by revising paragraph (a)(1) to read as follows:

§ 541.100 General rule for executive employees.

(a) * * *

(1) Compensated on a salary basis at not less than the level set forth in § 541.600;

* * * * *

■ 4. Amend § 541.200, by revising paragraph (a)(1) to read as follows:

§ 541.200 General rule for administrative employees.

(a) * * *

(1) Compensated on a salary or fee basis at not less than the level set forth in § 541.600;

* * * * *

■ 5. Amend § 541.204, by revising paragraph (a)(1) to read as follows:

§ 541.204 Educational establishments.

(a) * * *

(1) Compensated on a salary or fee basis at not less than the level set forth in § 541.600; or on a salary basis which is at least equal to the entrance salary for teachers in the educational establishment by which employed; and

* * * * *

■ 6. Amend § 541.300, by revising paragraph (a)(1) to read as follows:

§ 541.300 General rule for professional employees.

(a) * * *

(1) Compensated on a salary or fee basis at not less than the level set forth in § 541.600; and

* * * * *

■ 7. Amend § 541.400, by revising the first sentence of paragraph (b) to read as follows:

§ 541.400 General rule for computer employees.

* * * * *

(b) The section 13(a)(1) exemption applies to any computer employee who is compensated on a salary or fee basis at not less than the level set forth in § 541.600. * * *

* * * * *

■ 8. Revise § 541.600 to read as follows:

§ 541.600 Amount of salary required.

(a) *Standard salary level.* To qualify as an exempt executive, administrative, or professional employee under section 13(a)(1) of the Act, an employee must be compensated on a salary basis at a rate per week of not less than the amount set forth in paragraphs (a)(1) through (3) of this section, exclusive of board, lodging or other facilities, unless paragraph (b) or (c) of this section applies. Administrative and professional employees may also be paid on a fee basis, as defined in § 541.605.

(1) Beginning on July 1, 2024, $844 per week (the 20th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region and/or retail industry nationally).

(2) Beginning on January 1, 2025, $1,128 per week (the 35th percentile of weekly earnings of full-time nonhourly workers in the lowest-wage Census Region).

(3) As of July 1, 2027, the level calculated pursuant to § 541.607(b)(1).

(b) *Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, U.S. Virgin Islands.* To qualify as an exempt executive, administrative, or professional employee under section 13(a)(1) of the Act, an employee in the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, or the U.S. Virgin Islands employed by employers other than the Federal Government must be compensated on a salary basis at a rate of not less than $455 per week, exclusive of board, lodging or other facilities. Administrative and professional employees may also be paid on a fee basis, as defined in § 541.605.

(c) *American Samoa.* To qualify as an exempt executive, administrative, or professional employee under section 13(a)(1) of the Act, an employee in American Samoa employed by employers other than the Federal Government must be compensated on a salary basis at a rate of not less than $380 per week, exclusive of board, lodging or other facilities. Administrative and professional employees may also be paid on a fee basis, as defined in § 541.605.

(d) *Frequency of payment.* The salary level requirement may be translated into equivalent amounts for periods longer than one week. For example, the $1,128 per week requirement described in paragraph (a)(2) of this section would be met if the employee is compensated biweekly on a salary basis of not less than $2,256, semimonthly on a salary basis of not less than $2,444, or monthly on a salary basis of not less than $4,888. However, the shortest period of payment that will meet this compensation requirement is one week.

(e) *Alternative salary level for academic administrative employees.* In

the case of academic administrative employees, the salary level requirement also may be met by compensation on a salary basis at a rate at least equal to the entrance salary for teachers in the educational establishment by which the employee is employed, as provided in § 541.204(a)(1).

(f) *Hourly rate for computer employees.* In the case of computer employees, the compensation requirement also may be met by compensation on an hourly basis at a rate not less than $27.63 an hour, as provided in § 541.400(b).

(g) *Exceptions to the standard salary criteria.* In the case of professional employees, the compensation requirements in this section shall not apply to employees engaged as teachers (*see* § 541.303); employees who hold a valid license or certificate permitting the practice of law or medicine or any of their branches and are actually engaged in the practice thereof (*see* § 541.304); or to employees who hold the requisite academic degree for the general practice of medicine and are engaged in an internship or resident program pursuant to the practice of the profession (*see* § 541.304). In the case of medical occupations, the exception from the salary or fee requirement does not apply to pharmacists, nurses, therapists, technologists, sanitarians, dietitians, social workers, psychologists, psychometrists, or other professions which service the medical profession.

■ 9. Amend § 541.601 by revising paragraph (a), the first sentence of paragraph (b)(1), and paragraph (b)(2) to read as follows:

§ 541.601 Highly compensated employees.

(a) An employee shall be exempt under section 13(a)(1) of the Act if the employee receives total annual compensation of not less than the amount set forth in paragraph (a)(1) through (4) of this section, and the employee customarily and regularly performs any one or more of the exempt duties or responsibilities of an executive, administrative, or professional employee identified in subpart B, C, or D of this part:

(1) Beginning on July 1, 2024, $132,964 per year (the annualized earnings amount of the 80th percentile of full-time nonhourly workers nationally).

(2) Beginning on January 1, 2025, $151,164 per year (the annualized earnings amount of the 85th percentile of full-time nonhourly workers nationally).

(3) As of July 1, 2027, the total annual compensation level calculated pursuant to § 541.607(b)(2).

(4) Where the annual period covers periods during which multiple total annual compensation levels apply, the amount of total annual compensation due will be determined on a proportional basis.

(b)(1) Total annual compensation must include at least a weekly amount equal to that required by § 541.600(a)(1) through (3) paid on a salary or fee basis as set forth in §§ 541.602 and 541.605, except that § 541.602(a)(3) shall not apply to highly compensated employees. * * *

(2) If an employee's total annual compensation does not total at least the amount set forth in paragraph (a) of this section by the last pay period of the 52-week period, the employer may, during the last pay period or within one month after the end of the 52-week period, make one final payment sufficient to achieve the required level. For example, for a 52-week period beginning January 1, 2025, an employee may earn $135,000 in base salary, and the employer may anticipate based upon past sales that the employee also will earn $20,000 in commissions. However, due to poor sales in the final quarter of the year, the employee only earns $14,000 in commissions. In this situation, the employer may within one month after the end of the year make a payment of at least $2,164 to the employee. Any such final payment made after the end of the 52-week period may count only toward the prior year's total annual compensation and not toward the total annual compensation in the year it was paid. If the employer fails to make such a payment, the employee does not qualify as a highly compensated employee, but may still qualify as exempt under subpart B, C, or D of this part.

* * * * *

■ 10. Amend § 541.602 by revising the first sentence of paragraph (a)(3) and the first sentence of paragraph (a)(3)(i) to read as follows:

§ 541.602 Salary basis.

* * * * *

(a)(3) Up to ten percent of the salary amount required by § 541.600(a) through (c) may be satisfied by the payment of nondiscretionary bonuses, incentives, and commissions, that are paid annually or more frequently. * * *

(i) If by the last pay period of the 52-week period the sum of the employee's weekly salary plus nondiscretionary bonus, incentive, and commission payments received is less than 52 times the weekly salary amount required by § 541.600(a) through (c), the employer may make one final payment sufficient to achieve the required level no later than the next pay period after the end of the year. * * *

* * * * *

■ 11. Amend § 541.604 by

■ a. Revising the second, third, and fourth sentences of paragraph (a) and;

■ b. Revising the third sentence in paragraph (b).

The revisions and additions read as follows:

§ 541.604 Minimum guarantee plus extras.

(a) * * * Thus, for example under the salary requirement described in § 541.600(a)(2), an exempt employee guaranteed at least $1,128 each week paid on a salary basis may also receive additional compensation of a one percent commission on sales. An exempt employee also may receive a percentage of the sales or profits of the employer if the employment arrangement also includes a guarantee of at least $1,128 each week paid on a salary basis. Similarly, the exemption is not lost if an exempt employee who is guaranteed at least $1,128 each week paid on a salary basis also receives additional compensation based on hours worked for work beyond the normal workweek. * * *

(b) * * * Thus, for example under the salary requirement described in § 541.600(a)(2), an exempt employee guaranteed compensation of at least $1,210 for any week in which the employee performs any work, and who normally works four or five shifts each week, may be paid $350 per shift without violating the $1,128 per week salary basis requirement. * * *

■ 12. Amend § 541.605 by revising paragraph (b) to read as follows:

§ 541.605 Fee basis.

* * * * *

(b) To determine whether the fee payment meets the minimum amount of salary required for exemption under these regulations, the amount paid to the employee will be tested by determining the time worked on the job and whether the fee payment is at a rate that would amount to at least the minimum salary per week, as required by §§ 541.600(a) through (c) and 541.602(a), if the employee worked 40 hours. Thus, for example under the salary requirement described in § 541.600(a)(2), an artist paid $600 for a picture that took 20 hours to complete meets the $1,128 minimum salary requirement for exemption since earnings at this rate would yield the artist $1,200 if 40 hours were worked.

■ 13. Add § 541.607 to read as follows:

§ 541.607 Regular updates to amounts of salary and compensation required.

(a) *Initial update*—(1) *Standard salary level.* Beginning on July 1, 2024, the amount required to be paid per week to an exempt employee on a salary or fee basis, as applicable, pursuant to § 541.600(a)(1) will be not less than $844.

(2) *Highly compensated employees.* Beginning on July 1, 2024, the amount required to be paid in total annual compensation to an exempt highly compensated employee pursuant to § 541.601(a)(1) will be not less than $132,964.

(b) *Future updates*—(1) *Standard salary level.* (i) As of July 1, 2027, and every 3 years thereafter, the amount required to be paid to an exempt employee on a salary or fee basis, as applicable, pursuant to § 541.600(a) will be updated to reflect current earnings data.

(ii) The Secretary will determine the future update amounts by applying the methodology in effect under § 541.600(a) at the time the Secretary issues the notice required by paragraph (b)(3) of this section to current earnings data.

(2) *Highly compensated employees.* (i) As of July 1, 2027, and every 3 years thereafter, the amount required to be paid in total annual compensation to an exempt highly compensated employee pursuant to § 541.601(a) will be updated to reflect current earnings data.

(ii) The Secretary will determine the future update amounts by applying the methodology used to determine the total annual compensation amount in effect under § 541.601(a) at the time the Secretary issues the notice required by paragraph (b)(3) of this section to current earnings data.

(3) *Notice.* (i) Not fewer than 150 days before each future update of the earnings requirements under paragraphs (b)(1) and (2) of this section, the Secretary will publish a notice in the **Federal Register** stating the updated amounts based on the most recent available 4 quarters of CPS MORG data, or its successor publication, as published by the Bureau of Labor Statistics.

(ii) No later than the effective date of the updated earnings requirements, the Wage and Hour Division will publish on its website the updated amounts for employees paid pursuant to this part.

(4) *Delay of updates.* A future update to the earnings thresholds under this section is delayed from taking effect for a period of 120 days if the Secretary has separately published a notice of proposed rulemaking in the **Federal Register**, not fewer than 150 days before the date the update is set to take effect, proposing changes to the earnings threshold(s) and/or updating mechanism due to unforeseen economic or other conditions. The Secretary must state in the notice issued pursuant to paragraph (b)(3)(i) of this section that the scheduled update is delayed in accordance with this paragraph (b)(4). If the Secretary does not issue a final rule affecting the scheduled update to the earnings thresholds by the end of the 120-day extension period, the updated amounts published in accordance with paragraph (b)(3) of this section will take effect upon the expiration of the 120-day period. The 120-day delay of a scheduled update under this paragraph will not change the effective dates for future updates of the earnings requirements under this section.

Signed this 11th day of April, 2024.

Jessica Looman,

Administrator, Wage and Hour Division.

[FR Doc. 2024–08038 Filed 4–24–24; 8:45 am]

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Part V

Department of Health and Human Services

45 CFR Parts 160 and 164
HIPAA Privacy Rule To Support Reproductive Health Care Privacy; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

RIN 0945–AA20

HIPAA Privacy Rule To Support Reproductive Health Care Privacy

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or ''Department'') is issuing this final rule to modify the Standards for Privacy of Individually Identifiable Health Information (''Privacy Rule'') under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). The Department is issuing this final rule after careful consideration of all public comments received in response to the notice of proposed rulemaking (NPRM) for the HIPAA Privacy Rule to Support Reproductive Health Care Privacy (''2023 Privacy Rule NPRM'') and public comments received on proposals to revise provisions of the HIPAA Privacy Rule in the NPRM for the Confidentiality of Substance Use Disorder (SUD) Patient Records (''2022 Part 2 NPRM'').

DATES:

Effective date: This final rule is effective on June 25, 2024.

Compliance date: Persons subject to this regulation must comply with the applicable requirements of this final rule by December 23, 2024, except for the applicable requirements of 45 CFR 164.520 in this final rule. Persons subject to this regulation must comply with the applicable requirements of 45 CFR 164.520 in this final rule by February 16, 2026.

FOR FURTHER INFORMATION CONTACT: Marissa Gordon-Nguyen at (202) 240–3110 or (800) 537–7697 (TDD), or by email at *OCRPrivacy@hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

TABLE OF ACRONYMS

Term	Meaning
AMA	American Medical Association.
API	Application Programming Interface.
CARES Act	Coronavirus Aid, Relief, and Economic Security Act.
CDC	Centers for Disease Control and Prevention.
CLIA	Clinical Laboratory Improvement Amendments of 1988.
CMS	Centers for Medicare & Medicaid Services.
DOD	Department of Defense.

TABLE OF ACRONYMS—Continued

Term	Meaning
Department or HHS	Department of Health and Human Services.
EHR	Electronic Health Record.
E.O.	Executive Order.
FDA	Food and Drug Administration.
FHIR®	Fast Healthcare Interoperability Resources®.
FTC	Federal Trade Commission.
GINA	Genetic Information Nondiscrimination Act of 2008.
Health IT	Health Information Technology.
HIE	Health Information Exchange.
HIPAA	Health Insurance Portability and Accountability Act of 1996.
HITECH Act	Health Information Technology for Economic and Clinical Health Act of 2009.
ICR	Information Collection Request.
IIHI	Individually Identifiable Health Information.
NCVHS	National Committee on Vital and Health Statistics.
NICS	National Instant Criminal Background Check System.
NPP	Notice of Privacy Practices.
NPRM	Notice of Proposed Rulemaking.
OCR	Office for Civil Rights.
OHCA	Organized Health Care Arrangement.
OMB	Office of Management and Budget.
ONC	Office of the National Coordinator for Health Information Technology.
PHI	Protected Health Information.
PRA	Paperwork Reduction Act of 1995.
RFA	Regulatory Flexibility Act.
RIA	Regulatory Impact Analysis.
SBA	Small Business Administration.
SSA	Social Security Act of 1935.
TPO	Treatment, Payment, or Health Care Operations.
UMRA	Unfunded Mandates Reform Act of 1995.

I. Executive Summary

A. Overview

In this final rule, the Department of Health and Human Services (HHS or ''Department'') modifies certain provisions of the Standards for Privacy of Individually Identifiable Health Information (''Privacy Rule''), issued pursuant to section 264 of the Administrative Simplification provisions of title II, subtitle F, of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[1] The Privacy Rule [2] is one of several rules, collectively known as the HIPAA Rules,[3] that protect the privacy and security of individuals' protected health information [4] (PHI), which is individually identifiable health information [5] (IIHI) transmitted by or maintained in electronic media or any other form or medium, with certain exceptions.[6]

The Privacy Rule requires the disclosure of PHI only in the following circumstances: when required by the Secretary to investigate a regulated entity's compliance with the Privacy Rule and to the individual pursuant to the individual's right of access and the individual's right to an accounting of disclosures.[7] Any other uses or disclosures described in the Privacy Rule are either permitted or prohibited, as specified in the Privacy Rule. For example, the Privacy Rule permits, but does not require, a regulated entity to disclose PHI to conduct quality improvement activities when applicable conditions are met, and it prohibits a regulated entity from selling PHI except pursuant to and in compliance with 45 CFR 164.508(a)(4).[8]

In accordance with its statutory mandate, the Department promulgated the Privacy Rule and continues to administer and enforce it to ensure that individuals are not afraid to seek health care from, or share important information with, their health care providers because of a concern that their sensitive information will be disclosed outside of their relationship with their health care provider. Protecting privacy promotes trust between health care providers and individuals, advancing access to and improving the quality of health care. To achieve this goal, the Department generally has applied the same privacy standards to nearly all PHI, regardless of the type of health care at issue. Notably, special protections were given to psychotherapy notes, owing in part to the particularly

[1] Subtitle F of title II of HIPAA (Pub. L. 104–191, 110 Stat. 1936 (Aug. 21, 1996)) added a new part C to title XI of the Social Security Act of 1935 (SSA), Public Law 74–271, 49 Stat. 620 (Aug. 14, 1935), (*see* sections 1171–1179 of the SSA (codified at 42 U.S.C. 1320d–1320d–8)), as well as promulgating section 264 of HIPAA (codified at 42 U.S.C. 1320d–2 note), which authorizes the Secretary to promulgate regulations with respect to the privacy of individually identifiable health information. The Privacy Rule has subsequently been amended pursuant to the Genetic Information Nondiscrimination Act of 2008 (GINA), title I, section 105, Public Law 110–233, 122 Stat. 881 (May 21, 2008) (codified at 42 U.S.C. 2000ff), and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, Public Law 111–5, 123 Stat. 226 (Feb. 17, 2009) (codified at 42 U.S.C. 1390w–4(O)(2)).

[2] 45 CFR parts 160 and 164, subparts A and E. For a history of the Privacy Rule, *see infra* Section II.B., ''Regulatory History.''

[3] *See also* the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C; the HIPAA Breach Notification Rule, 45 CFR part 164, subpart D; and the HIPAA Enforcement Rule, 45 CFR part 160, subparts C, D, and E.

[4] 45 CFR 160.103 (definition of ''Protected health information'').

[5] 42 U.S.C. 1320d. *See also* 45 CFR 160.103 (definition of ''Individually identifiable health information'').

[6] At times throughout this final rule, the Department uses the terms ''health information'' or ''individuals' health information'' to refer generically to health information pertaining to an individual or individuals. In contrast, the Department's use of the term ''IIHI'' refers to a category of health information defined in HIPAA, and ''PHI'' is used to refer specifically to a category of IIHI that is defined by and subject to the privacy and security standards promulgated in the HIPAA Rules.

[7] *See* 45 CFR 164.502(2) and (4).

[8] *See* 45 CFR 164.512(i) and 164.502(a)(5)(ii).

sensitive information those notes contain.[9]

Under its statutory authority to administer and enforce the HIPAA Rules, the Department may modify the HIPAA Rules as needed.[10] The Supreme Court decision in *Dobbs* v. *Jackson Women's Health Organization* [11] (*Dobbs*) overturned precedent that protected a constitutional right to abortion and altered the legal and health care landscape. This decision has far-reaching implications for reproductive health care beyond its effects on access to abortion.[12] This changing legal landscape increases the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect, including the trust of individuals in health care providers and the health care system.[13] The threat that PHI will be disclosed and used to conduct such an investigation against, or to impose liability upon, an individual or another person is likely to chill an individual's willingness to seek lawful health care treatment or to provide full information to their health care providers when obtaining that treatment, and on the willingness of health care providers to provide such care.[14] These developments in the legal environment increase the potential that use and disclosure of PHI about an individual's reproductive health will undermine access to and the quality of health care generally.

In order to continue to protect privacy in a manner that promotes trust between individuals and health care providers and advances access to, and improves the quality of, health care, we have determined that the Privacy Rule must be modified to limit the circumstances in which provisions of the Privacy Rule permit the use or disclosure of an individual's PHI about reproductive health care for certain non-health care purposes, where such use or disclosure could be detrimental to privacy of the individual or another person or the individual's trust in their health care providers. This determination was informed by our expertise in administering the Privacy Rule, questions we have received from members of the public and Congress, comments we received on the 2023 HIPAA Privacy Rule to Support Reproductive Health Care Privacy notice of proposed rulemaking (NPRM) (''2023 Privacy Rule NPRM''),[15] and our analysis of the state of privacy for IIHI.

This final rule (''2024 Privacy Rule'') amends provisions of the Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals' ability to obtain lawful reproductive health care. This final rule balances the interests of society in obtaining PHI for non-health care purposes with the interests of the individual, the Federal Government, and society in protecting individual privacy, thereby improving the effectiveness of the health care system by ensuring that persons are not deterred from seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided.

The Department carefully analyzed state prohibitions and restrictions on an individual's ability to obtain high-quality health care and their effects on health information privacy and the relationships between individuals and their health care providers after *Dobbs;* assessed trends in state legislative activity with respect to the privacy of PHI; and conducted a thorough review of the text, history, and purposes of HIPAA and the Privacy Rule. The Department also engaged in extensive discussions with HHS agencies and other Federal departments, including the Department of Justice; consulted with the National Committee on Vital and Health Statistics (NCVHS) and the Attorney General as required by section 264(d) of HIPAA, and with Indian Tribes as required by Executive Order 13175; [16] held listening sessions with and reviewed correspondence from stakeholders, including covered entities, states, individuals, and patient advocates; and reviewed correspondence to HHS from Members of Congress.[17] The modifications made to the Privacy Rule by this final rule are the result of this work.

B. Effective and Compliance Dates

1. 2023 Privacy Rule NPRM

In the 2023 Privacy Rule NPRM, the Department proposed an effective date for a final rule that would occur 60 days after publication, and a compliance date that would occur 180 days after the effective date.[18] Taken together, the two dates would give entities 240 days after publication to implement compliance measures. In the preamble to the proposed rule, the Department stated that it did not believe that the proposed rule would pose unique implementation challenges that would justify an extended compliance period (*i.e.,* a period longer than the standard 180 days provided in 45 CFR 160.105).[19] The Department also asserted that adherence to the standard compliance period is necessary to timely address the circumstances described in the 2023 Privacy Rule NPRM.

2. Overview of Comments

A commenter urged the Department to move quickly to issue the final rule and to provide a 180-day compliance period

[9] *See* 45 CFR 164.501 and 164.508(a)(2).

[10] Section 1174(b)(1) of Public Law 104–191 (codified at 42 U.S.C. 1320d–3).

[11] 597 U.S. 215 (2022).

[12] *See* Melissa Suran, ''Treating Cancer in Pregnant Patients After *Roe* v *Wade* Overturned,'' JAMA (Sept. 29, 2022), *https://jamanetwork-com.hhsnih.idm.oclc.org/journals/jama/fullarticle/2797062?resultClick=1* and Rita Rubin, ''How Abortion Bans Could Affect Care for Miscarriage and Infertility,'' JAMA (June 28, 2022), *https://jamanetwork-com.hhsnih.idm.oclc.org/journals/jama/fullarticle/2793921?resultClick=1.*

[13] *See infra* National Committee on Vital and Health Statistics (NCVHS) discussion, Section II.A.1., expressing concern for harm caused by disclosing identifiable health information for non-health care purposes.

[14] *See* Whitney S. Rice et al. '' 'Post-*Roe*' Abortion Policy Context Heightens Imperative for Multilevel, Comprehensive, Integrated Health Education,'' (Sept. 29, 2022), *https://journals.sagepub.com/doi/full/10.1177/10901981221125399* (''New ethical and legal complexities around patient counseling are emerging, particularly in states limiting or eliminating abortion access, due to more extreme abortion restrictions. Clinicians in such contexts may be forced to adhere to legal requirements of states which run counter to well-being and desires of patients, violating the medical principles of beneficence and respect for patient autonomy'').

[15] 88 FR 23506 (Apr. 17, 2023).

[16] *See* 65 FR 67249 (Nov. 11, 2000). *See also* Presidential Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships (Jan. 26, 2021), *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-tribal-consultation-and-strengthening-nation-to-nation-relationships/* and Dep't of Health and Human Servs., Tribal Consultation Policy, *https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf. See also* 88 FR 23506 (Apr. 17, 2023) (notice of Tribal consultation). The Department consulted with representatives of Tribal Nations on May 17, 2023. During the consultation, the representatives raised issues of health inequities and privacy of health information, specifically among American Indians and Alaskan Natives after *Dobbs.*

[17] Letter from U.S. Senator Tammy Baldwin et al. to HHS Sec'y Xavier Becerra (Mar. 7, 2023) (addressing HIPAA privacy regulations and *Dobbs* v. *Jackson Women's Health Organization*). Letter from U.S. Senator Patty Murray et al. to HHS Sec'y Xavier Becerra (Sept. 13, 2022) (addressing HIPAA privacy regulations and *Dobbs* v. *Jackson Women's Health Organization*). Letter from U.S. Representative Earl Blumenauer et al. to HHS Sec'y Xavier Becerra (Aug. 30, 2022) (addressing HIPAA privacy regulations and *Dobbs* v. *Jackson Women's Health Organization*). Letter from U.S. Senator Michael F. Bennet et al. to HHS Sec'y Xavier Becerra (July 1, 2022) (addressing HIPAA privacy regulations and *Dobbs* v. *Jackson Women's Health Organization*).

[18] *See* 88 FR 23506, 23510 (Apr. 17, 2023).

[19] *See id.*

as proposed. Some commenters requested that the Department provide additional time for regulated entities to comply with the proposed modifications to the Privacy Rule. Several commenters requested that the Department coordinate compliance deadlines across its rulemakings, while a few commenters specifically encouraged the Department to provide additional time for compliance with the modifications to the Notice of Privacy Practices (NPP) requirements proposed in the 2023 Privacy Rule NPRM.

3. Final Rule

This final rule is effective on June 25, 2024. Covered entities and business associates of all sizes will have 180 days beyond the effective date of the final rule to comply with the final rule's provisions, with the exception of the NPP provisions, which we address separately below. We understand that some covered entities and business associates remain concerned that a 180-day period may not provide sufficient time to come into compliance with the modified requirements. However, we believe that providing a 180-day compliance period best comports with section 1175(b)(2) of the Social Security Act of 1935 (SSA), 42 U.S.C. 1320d–4, and our implementing provision at 45 CFR 160.104(c)(1), which require the Secretary to provide at least a 180-day period for covered entities to comply with modifications to standards and implementation specifications in the HIPAA Rules, and also that providing a 180-day compliance period best protects the privacy and security of individuals' PHI in a timely manner that reflects the urgency of addressing the changes in the legal landscape and their effects on individuals, regulated entities, and other persons, while balancing the burden imposed upon regulated entities of implementing this final rule.

Section 160.104(a) permits the Department to adopt a modification to a standard or implementation specification adopted under the Privacy Rule no more frequently than once every 12 months.[20] As discussed above, we are required to provide a minimum of a 180-day compliance period when adopting a modification, but we are permitted to provide a longer compliance period based on the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.[21] The Department makes every effort to consider the burden and cost of implementation for regulated entities when determining an appropriate compliance date.

While we recognize that regulated entities will need to revise and implement changes to their policies and procedures in response to the modifications in this final rule, we do not believe that these changes are so significant as to require more than a 180-day compliance period. This final rule narrowly tailors the application of its changes to certain limited circumstances involving lawful reproductive health care and clarifies that regulated entities are not expected to know or be aware of laws other than those with which they are required to comply. While it adds a condition to certain requests for uses and disclosures, the affected requests already require careful review by regulated entities for compliance with previously imposed conditions. Thus, we do not believe it will be difficult for regulated entities to adjust their policies and procedures to accommodate this new requirement. The other modifications finalized in this rule are in service of implementing the two changes above and impose minimal burden on regulated entities. Additionally, the Department believes, based on its evaluation of the evolving privacy landscape, that the changes made by this final rule are of particular urgency. Accordingly, we believe that a 180-day compliance period, combined with a 60-day effective date, is sufficient for regulated entities to make the changes required by most of the modifications in this final rule, with the exception of the NPP provisions.

We separately consider the question of the compliance date for the modifications to the NPP provisions. In the 2022 Confidentiality of Substance Use Disorder (SUD) Patient Records NPRM (''2022 Part 2 NPRM''),[22] the Department proposed, among other things, to revise 45 CFR 164.520 as required by section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[23] The Department proposed to provide the same compliance date for both the proposed modifications to 45 CFR 164.520 and the more extensive modifications to 42 CFR part 2 (''Part 2'').[24] The 2024 Confidentiality of Substance Use Disorder (SUD) Patient Records Final Rule (''2024 Part 2 Rule'') explicitly noted that the Department was not finalizing the proposed modifications to the NPP provisions at that time, but that we planned to do so in a future HIPAA final rule.[25] The Department also acknowledged that some covered entities might have NPPs that would not reflect updated changes to policies and procedures addressing how Part 2 records are used and disclosed. Rather than requiring covered entities to revise their NPPs twice in a short period of time, the Department announced in the 2024 Part 2 Rule that it would exercise enforcement discretion related to the requirement that covered entities update their NPPs whenever material changes are made to privacy practices until the compliance date established by a future HIPAA final rule.[26] The Department is finalizing the modifications to the NPP required by section 3221 of the CARES Act in this rule and aligning the effective and compliance dates for all of the modified NPP requirements with those of the 2024 Part 2 Rule.

The compliance date of the 2024 Part 2 Rule is February 16, 2026, substantially later than the compliance date for most of this final rule, because of the significant changes required for compliance with the 2024 Part 2 Rule. Accordingly, in compliance with 45 CFR 160.104 and consistent with the NPP proposals included in the 2022 Part 2 NPRM and public comment, we are aligning the compliance date for the NPP changes required by this final rule with the compliance date for the 2024 Part 2 Rule so that covered entities regulated under both rules can implement all changes to their NPPs at the same time. Covered entities are expected to be in compliance with the modifications to 45 CFR 164.520 on February 16, 2026.

4. Response to Public Comments

Comment: One commenter expressed support for the proposal in the 2023 Privacy Rule NPRM to establish a 180-day compliance date and urged the Department to issue a final rule quickly. Some commenters sought an extension of the compliance date for twelve to eighteen months, explaining that extensive policy and legal work, process and software changes, documentation and training would be required to implement the 2023 Privacy Rule NPRM.

One commenter suggested phasing in the attestation requirement so that ''downstream'' regulated entities, such as business associates and managed care organizations, would have a later compliance date than health care providers.

[20] 45 CFR 160.104(a).

[21] 45 CFR 160.104(c)(2).

[22] 87 FR 74216 (Dec. 2, 2022).

[23] Public Law 116–136, 134 Stat. 281 (Mar. 27, 2020).

[24] 89 FR 12472 (Feb. 16, 2024).

[25] *Id.* at 12482, 12528, and 12530.

[26] *Id.* at 12482, 12528, and 12530.

Response: We appreciate the commenters' suggestions, but as discussed above, based on our assessment, we do not believe the modifications required by this final rule will require longer to implement.

Comment: Some commenters requested that the Department coordinate compliance deadlines of final rules that revise the Privacy Rule or publish one final rule addressing the proposals in the NPRMs to enable regulated entities to leverage the resources required to implement the changes to achieve compliance with all of the new requirements at one time.

One commenter explained that each NPRM would involve operational changes requiring significant resources and effort and expressed their belief that a single comprehensive final rule would allow regulated entities to make all of the required changes, including revisions to policies and procedures, development of new or revised workflows, electronic health record (EHR) updates, and technology enhancements.

Response: We appreciate the commenters' suggestion, but we do not believe that it is necessary to fully align the compliance dates for the 2024 Part 2 Rule and the 2024 Privacy Rule. By imposing separate compliance deadlines, we are able to act more quickly to protect the privacy of PHI.

However, consistent with 45 CFR 160.104 and as requested by public comment, we are applying the same compliance date for covered entities to revise their NPPs to address modifications made to 45 CFR 164.520 in response to and consistent with the CARES Act and to support reproductive health care privacy. The compliance date for the NPP provisions is February 16, 2026.[27] Part 2 programs, including those that are covered entities, can choose to implement the changes to their NPPs that are required by the 2024 Part 2 Rule prior to the compliance date, but there is no requirement that they do so.

II. Statutory and Regulatory Background

A. Statutory Authority and History

1. Health Insurance Portability and Accountability Act of 1996 (HIPAA)

In 1996, Congress enacted HIPAA[28] to reform the health care delivery system to ''improve portability and continuity of health insurance coverage in the group and individual markets.''[29] To enable health care delivery system reform, Congress included in HIPAA requirements for standards to support the electronic exchange of health information. According to section 261, ''[i]t is the purpose of this subtitle to improve [. . .] the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information [. . .].''[30] Congress applied the Administrative Simplification provisions directly to three types of entities known as ''covered entities''—health plans, health care clearinghouses, and health care providers who transmit information electronically in connection with a transaction for which HHS has adopted a standard.[31]

Section 262(a) of HIPAA required the Secretary to adopt uniform standards ''to enable health information to be exchanged electronically.''[32] Congress directed the Secretary to adopt standards for unique identifiers to identify individuals, employers, health plans, and health care providers across the nation[33] and standards for, among other things, transactions and data elements relating to health information,[34] the security of that information,[35] and verification of electronic signatures.[36]

Congress recognized that the standardization of certain electronic health care transactions required by HIPAA posed risks to the privacy of confidential health information and viewed individual privacy, confidentiality, and data security as critical for orderly administrative simplification.[37] Thus, as explained in the preamble to the 2023 Privacy Rule NPRM,[38] Congress provided the Department with the authority to regulate the privacy of IIHI. According to one Member of Congress, privacy standards would create an additional layer of protection beyond the oath pledged by health care providers to keep information secure and, as described by another Member, would further protect information from being used in a ''malicious or discriminatory manner.''[39] Congress intended for the law to enhance individuals' trust in health care providers, which required that the law provide additional protection for the confidentiality of IIHI. As described by a Member of Congress: ''The bill would also establish strict security standards for health information because Americans clearly want to make sure that their health care records can only be used by the medical professionals that treat them. Often, we assume that because doctors take an oath of confidentiality that in fact all who touch their records operate by the same standards. Clearly, they do not.''[40] Moreover, Congress considered that health care reform required an approach that would not compromise privacy as health information became more accessible.[41]

Accordingly, section 264(a) directed the Secretary to submit to Congress detailed recommendations for Federal ''standards with respect to the privacy of [IIHI]'' nationwide within one year of HIPAA's enactment.[42] The statute made clear that the Secretary had the authority to promulgate regulations if Congress did not enact legislation covering these matters within three years.[43] Congress directed the Secretary to ensure that the regulations promulgated ''address at least'' the following three subjects: (1) the rights that an individual who is a subject of IIHI should have; (2) the procedures that should be established for the exercise of such rights; and (3) the uses and disclosures of such information that should be authorized or required.[44]

Additionally, Congress provided a clear statement that HIPAA's provisions would ''supersede any contrary

[27] 89 FR 12472 (Feb. 16, 2024).

[28] Public Law 104–191, 110 Stat. 1936 (Aug. 21, 1996).

[29] *See* H.R. Rep. No. 104–496, at 66–67 (1996).

[30] 42 U.S.C. 1320d note (Statutory Notes and Related Subsidiaries: Purpose). Subtitle F also amended related provisions of the SSA.

[31] *See* section 262 of Public Law 104–191, adding section 1172 to the SSA (codified at 42 U.S.C. 1320d–1). *See also* section 13404 of the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115 (Feb. 17, 2009) (codified at 42 U.S.C. 17934) (applying privacy provisions and penalties to business associates of covered entities).

[32] 42 U.S.C. 1320d2(a)(1).

[33] 42 U.S.C. 1320d–2(b)(1).

[34] 42 U.S.C. 1320d–2(a), (c), and (f).

[35] 42 U.S.C. 1320d–2(d).

[36] 42 U.S.C. 1320d–2(e).

[37] On a resolution waiving points of order against the Conference Report to H.R. 3103, members debated an ''erosion of privacy'' balanced against the administrative simplification provisions. Thus, from HIPAA's inception, privacy has been a central concern to be addressed as legislative changes eased disclosures of PHI. *See* 142 Cong. Rec. H9777 and H9780; *see also* H.R. Rep. No. 104–736, at 177 and 264 (1996); 142 Cong. Rec. H9780 (daily ed. Aug. 1, 1996) (statement of Rep. Sawyer); 142 Cong. Rec. H9792 (daily ed. Aug. 1, 1996) (statement of Rep. McDermott); and 142 Cong. Rec. S9515–16 (daily ed. Aug. 2, 1996) (statement of Sen. Simon).

[38] 88 FR 23506, 23511 (Apr. 17, 2023).

[39] *See* statement of Rep. Sawyer, *supra* note 37. *See also* statement of Sen. Simon, *supra* note 37.

[40] Statement of Rep. Sawyer, *supra* note 37.

[41] *See* H.R. Rep. No. 104–496 Part 1, at 99–100 (Mar. 25, 1996).

[42] 42 U.S.C. 1320d–2 note.

[43] *Id.*

[44] *Id.*

provision of State law,'' with certain limited exceptions.[45] One exception to this general preemption authority is for ''state privacy laws that are contrary to and more stringent than the corresponding federal standard, requirement, or implementation specification.'' [46] Thus, Congress intended for the Department to create privacy standards to safeguard health information while respecting the ability of states to provide individuals with additional health information privacy.

Congress required the Secretary to consult with the NCVHS,[47] thereby ensuring that the Secretary's decisions reflected public and expert involvement and advice in carrying out the requirements of section 264.[48] NCVHS sent its initial recommendations to the Secretary in a letter to the Secretary on June 27, 1997. Importantly, NCVHS advised that ''strong substantive and procedural protections'' should be imposed if health information were to be disclosed to law enforcement, and, where identifiable health information would be made available for non-health purposes, individuals should be afforded assurances that their data would not be used against them.[49] Additionally, NCVHS ''unanimously'' recommended that ''[. . .] the Secretary and the Administration assign the highest priority to the development of a strong position on health privacy that provides the highest possible level of protection for the privacy rights of patients.'' [50] NCVHS further noted that failure to do so would ''undermine public confidence in the health care system, expose patients to continuing invasions of privacy, subject record keepers to potentially significant legal liability, and interfere with the ability of health care providers and others to operate the health care delivery and payment system in an effective and efficient manner,'' which would undermine what Congress intended.[51]

NCVHS further recommended that ''any rules regulating disclosures of identifiable health information be as clear and as narrow as possible. Each group of users must be required to justify their need for health information and must accept reasonable substantive and procedural limitations on access.'' [52] According to NCVHS, this would allow for the disclosures that society deemed necessary and appropriate while providing individuals with clear expectations regarding their health information privacy.

As we noted in the 2023 Privacy Rule NPRM,[53] Congress contemplated that the Department's rulemaking authorities under HIPAA would not be static. Congress specifically built in a mechanism to adapt such regulations as technology and health care evolve, directing that the Secretary review and modify the Administrative Simplification standards as determined appropriate, but not more frequently than once every 12 months.[54] That statutory directive complements the Secretary's general rulemaking authority to ''make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which each is charged under this chapter.'' [55]

2. Health Information Technology for Economic and Clinical Health (HITECH) Act

On February 17, 2009, Congress enacted the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) [56] to promote the widespread adoption and standardization of health information technology (health IT). The HITECH Act included additional HIPAA privacy and security requirements for covered entities and business associates and expanded certain rights of individuals with respect to their PHI.

Congress understood the importance of a relationship between a connected health IT landscape, ''a necessary and vital component of health care reform,'' [57] and privacy and security standards when it enacted the HITECH Act. The Purpose statement of an accompanying House of Representatives report [58] on the Energy and Commerce Recovery and Reinvestment Act [59] recognizes that ''[i]n addition to costs, concerns about the security and privacy of health information have also been regarded as an obstacle to the adoption of [health IT].'' The Senate Report for S. 336 [60] similarly acknowledges that ''[i]nformation technology systems linked securely and with strong privacy protections can improve the quality and efficiency of health care while producing significant cost savings.'' [61] As the Department explained in the 2013 regulation referred to as the ''Omnibus Rule'' [62] and discussed in greater detail below, the HITECH Act's additional HIPAA privacy and security requirements [63] supported Congress' goal of promoting widespread adoption and interoperability of health IT by ''strengthen[ing] the privacy and security protections for health information established by HIPAA.'' [64]

In passing the HITECH Act, Congress instructed the Department that any new health IT standards adopted under section 3004 of the Public Health Service Act (PHSA) must take into account the privacy and security requirements of the HIPAA Rules.[65] Congress also affirmed that the existing HIPAA Rules were to remain in effect to the extent that they are consistent with the HITECH Act and directed the Secretary to revise the HIPAA Rules as necessary for consistency with the

[45] 42 U.S.C. 1320d–7.

[46] 65 FR 82580 (the exception applies under section 1178(a)(2)(B) of the SSA and section 264(c)(2) of HIPAA).

[47] NCVHS serves as the Secretary's statutory public advisory body for health data, statistics, privacy, and national health information policy and HIPAA. NCVHS also advises the Secretary, ''reports regularly to Congress on HIPAA implementation, and serves as a forum for interaction between HHS and interested private sector groups on a range of health data issues.'' Nat'l Comm. On Vital and Health Statistics, ''About NCVHS,'' *https://ncvhs.hhs.gov/; see also* ''NCVHS 60th Anniversary Symposium and History,'' U.S. Dep't of Health and Human Servs., at 28–29 (Feb. 2011), *https://ncvhs.hhs.gov/wp-content/uploads/2014/05/60_years_of_difference.pdf.*

[48] *See* section 264(a) and (d) of Public Law 104–191 (codified at 42 U.S.C. 1320d–2 note).

[49] Letter from NCVHS Chair Don E. Detmer to HHS Sec'y Donna E. Shalala (June 27, 1997) (forwarding NCVHS recommendations), *https://ncvhs.hhs.gov/rrp/june-27-1997-letter-to-the-secretary-with-recommendations-on-health-privacy-and-confidentiality/.*

[50] *Id.* at Principal Findings and Recommendations.

[51] *Id.*

[52] *Id.* at Third-Party Disclosures.

[53] 88 FR 23506, 23513 (Apr. 17, 2023).

[54] *See* section 1174(b)(1) of Public Law 104–191 (codified at 42 U.S.C. 1320d–3).

[55] Section 1102 of the SSA (codified at 42 U.S.C. 1302).

[56] Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115 (Feb. 17, 2009) (codified at 42 U.S.C. 201 note).

[57] C. Stephen Redhead, Cong. Rsch. Serv., R40161, ''The Health Information Technology for Economic and Clinical Health (HITECH) Act,'' (2009), *https://crsreports.congress.gov/product/pdf/R/R40161/9* (''[Health IT], which generally refers to the use of computer applications in medical practice, is widely viewed as a necessary and vital component of health care reform.'').

[58] H.R. Rep. No. 111–7, at 74 (2009), accompanying H.R. 629, 111th Cong.

[59] H.R. 629, Energy and Commerce Recovery and Reinvestment Act of 2009, introduced in the House on January 22, 2009, contained nearly identical provisions to subtitle D of the HITECH Act.

[60] Congress enacted the American Recovery and Reinvestment Act of 2009, which included the HITECH Act, on February 17, 2009. While it was the House version of the bill, H.R. 1, that was enacted, the Senate version, S. 336, contained nearly identical provisions to subtitle D of the HITECH Act.

[61] S. Rep. No. 111–3 accompanying S. 336, 111th Cong., at 59 (2009).

[62] 78 FR 5566 (Jan. 25, 2013).

[63] Subtitle D of title XIII of the HITECH Act (codified at 42 U.S.C. 17921, 42 U.S.C. 17931–17941, and 42 U.S.C. 17951–17953).

[64] 78 FR 5566, 5568 (Jan. 25, 2013).

[65] Section 3009(a)(1)(B) of the PHSA, as added by section 13101 of the HITECH Act (codified at 42 U.S.C. 300jj–19(a)(1)).

HITECH Act.[66] Congress confirmed that the new law was not intended to have any effect on authorities already granted under HIPAA to the Department, including section 264 of that statute and the regulations issued under that provision.[67] Congress thus affirmed the Secretary's ongoing rulemaking authority to modify the Privacy Rule's standards and implementation specifications as often as every 12 months when appropriate, including to strengthen privacy and security protections for IIHI.

B. Regulatory History

The Secretary has delegated the authority to administer the HIPAA Rules and to make decisions regarding their implementation, interpretation, and enforcement to the HHS Office for Civil Rights (OCR).[68] Since the enactment of the HITECH Act, the Department has exercised its authority to modify the Privacy Rule several times—in 2013, 2014, and 2016.[69]

1. 2000 Privacy Rule

As directed by HIPAA, the Department provided a series of recommendations to Congress for a potential new law that would address the confidentiality of IIHI.[70] Congress did not act within its three-year self-imposed deadline. Accordingly, the Department published a proposed rule on November 3, 1999,[71] and issued the first final rule establishing ''Standards for Privacy of Individually Identifiable Health Information'' (''2000 Privacy Rule'') on December 28, 2000.[72]

The primary goal of the Privacy Rule was to provide greater protection to individuals' privacy to engender a trusting relationship between individuals and health care providers. As announced, the final rule set standards to protect the privacy of IIHI to ''begin to address growing public concerns that advances in electronic technology and evolution in the health care industry are resulting, or may result, in a substantial erosion of the privacy surrounding'' health information.[73] On the eve of that rule's issuance, the President issued an Executive Order recognizing the importance of protecting individual privacy, explaining that ''[p]rotecting the privacy of patients' protected health information promotes trust in the health care system. It improves the quality of health care by fostering an environment in which patients can feel more comfortable in providing health care professionals with accurate and detailed information about their personal health.'' [74]

Since its promulgation, the Privacy Rule has protected PHI by limiting the circumstances under which covered entities and their business associates (collectively, ''regulated entities'') are permitted or required to use or disclose PHI and by requiring covered entities to have safeguards in place to protect the privacy of PHI. In adopting these regulations, the Department acknowledged the need to balance several competing factors, including existing legal expectations, individuals' privacy expectations, and societal expectations.[75] The Department noted in the preamble that the large number of comments from individuals and groups representing individuals demonstrated the deep public concern about the need to protect the privacy of IIHI and constituted evidence of the importance of protecting privacy and the potential adverse consequences to individuals and their health if such protections are not extended.[76] Through its policy choices in the 2000 Privacy Rule, the Department struck a balance between competing interests—the necessity of protecting privacy and the public interest in using identifiable health information for vital public and private purposes—in a way that was also workable for the varied stakeholders.[77]

In the 2000 Privacy Rule, the Department established ''general rules'' for uses and disclosures of PHI, codified at 45 CFR 164.502.[78] The 2000 Privacy Rule also specified the circumstances in which a covered entity was required to obtain an individual's consent,[79] authorization,[80] or the opportunity for the individual to agree or object.[81] Additionally, it established rules for when a covered entity is permitted to use or disclose PHI without an individual's consent, authorization, or opportunity to agree or object.[82] In particular, the Privacy Rule permits certain uses and disclosures of PHI, without the individual's authorization, for identified activities that benefit the community, such as public health activities, judicial and administrative proceedings, law enforcement purposes, and research.[83]

The Privacy Rule also established the rights of individuals with respect to their PHI, including the right to receive adequate notice of a covered entity's privacy practices, the right to request restrictions of uses and disclosures, the right to access (*i.e.,* to inspect and obtain a copy of) their PHI, the right to request an amendment of their PHI, and the right to receive an accounting of disclosures.[84]

In the 2000 Privacy Rule, the Secretary exercised her statutory authority to adopt 45 CFR 160.104(a), which reserves the Secretary's ability to modify any standard or implementation specification adopted under the Administrative Simplification provisions.[85] The Secretary first invoked this modification authority to amend the Privacy Rule in 2002 [86] and made additional modifications in 2013,[87] and 2016,[88] as described below.

2. 2002 Privacy Rule

After publication of the 2000 Privacy Rule, the Department received many inquiries and unsolicited comments about the Privacy Rule's effects and operation. As a result, the Department opened the 2000 Privacy Rule for further comment in February 2001, less than one month before the effective date and 25 months before the compliance date for most covered entities, and issued clarifying guidance on its implementation.[89] NCVHS' Subcommittee on Privacy, Confidentiality and Security held public

[66] Section 13421(b) of the HITECH Act (codified at 42 U.S.C. 17951).

[67] Section 3009(a)(1)(A) of the PHSA, as added by section 13101 of the HITECH Act (codified at 42 U.S.C. 300jj–19(a)(1)).

[68] *See* U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, Off. for Civil Rights; Statement of Delegation of Authority, 65 FR 82381 (Dec. 28, 2000); U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, Off. for Civil Rights; Delegation of Authority, 74 FR 38630 (Aug. 4, 2009); U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, Statement of Organization, Functions and Delegations of Authority, 81 FR 95622 (Dec. 28, 2016).

[69] *See* 78 FR 5566 (Jan. 25, 2013); 79 FR 7290 (Feb. 6, 2014); 81 FR 382 (Jan. 6, 2016).

[70] *See* U.S. Dep't of Health and Hum. Servs., Off. of the Assistant Sec'y for Plan. and Evaluation, ''Recommendations of the Secretary of Health and Human Services, pursuant to section 264 of the Health Insurance Portability and Accountability Act of 1996,'' Section I.A. (Sept. 1997), *https://aspe.hhs.gov/reports/confidentiality-individually-identifiable-health-information.*

[71] 64 FR 59918 (Nov. 3, 1999).

[72] 65 FR 82462 (Dec. 28, 2000).

[73] *Id.*

[74] *See* Executive Order 13181 (Dec. 20, 2000), 65 FR 81321.

[75] *See* 65 FR 82462, 82471 (Dec. 28, 2000).

[76] *See id.* at 82472.

[77] *See id.*

[78] 65 FR 82462 (Dec. 28, 2000).

[79] 45 CFR 164.506 was originally titled ''Consent for uses or disclosures to carry out treatment, payment, or health care operations.''

[80] 45 CFR 164.508.

[81] 45 CFR 164.510.

[82] 45 CFR 164.512.

[83] *See* 64 FR 59918, 59955 (Nov. 3, 1999).

[84] *See* 45 CFR 164.520, 164.522, 164.524, 164.526, and 164.528.

[85] *See* 65 FR 82462, 82800 (Dec. 28, 2000).

[86] *See* 67 FR 53182 (Aug. 14, 2002).

[87] 78 FR 5566 (Jan. 25, 2013).

[88] 81 FR 382 (Jan. 6, 2016).

[89] 66 FR 12738 (Feb. 28, 2001).

hearings about the 2000 Privacy Rule. From those hearings, the Department obtained additional information about concerns related to key provisions and their potential unintended consequences for health care quality and access.[90] On March 27, 2002, the Department proposed modifications to the 2000 Privacy Rule to clarify the requirements and correct potential problems that could threaten access to, or quality of, health care.[91]

In response to comments on the proposed rule, the Department finalized modifications to the Privacy Rule on August 14, 2002 (''2002 Privacy Rule'').[92] This final rule clarified HIPAA's requirements while maintaining strong protections for the privacy of IIHI.[93] These modifications addressed certain workability issues, including but not limited to clarifying distinctions between health care operations and marketing; modifying the minimum necessary standard to exclude disclosures authorized by individuals and clarify its operation; eliminating the consent requirement for uses and disclosures of PHI for treatment, payment, or health care operations (TPO), and to otherwise clarify the role of consent in the Privacy Rule; and making other modifications and conforming amendments consistent with the proposed rule. The Department also included modifications to the provisions permitting the use or disclosure of PHI for public health activities and for research activities without consent, authorization, or an opportunity to agree or object.

3. 2013 Omnibus Rule

Following the enactment of the HITECH Act, the Department issued an NPRM, entitled ''Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health [HITECH] Act'' (''2010 NPRM''),[94] which proposed to implement certain HITECH Act requirements. In 2013, the Department issued the final rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health [HITECH] Act and the Genetic Information Nondiscrimination Act, and Other Modifications to the HIPAA Rules (''2013 Omnibus Rule''),[95] which implemented many of the new HITECH Act requirements, including strengthening individuals' privacy rights related to their PHI.

The Department also finalized regulatory provisions that were not required by the HITECH Act, but were necessary to address the workability and effectiveness of the Privacy Rule and to increase flexibility for and decrease burden on regulated entities.[96] In the 2010 NPRM, the Department noted that it had not amended the Privacy Rule since 2002.[97] It further explained that information gleaned from contact with the public since that time, enforcement experience, and technical corrections needed to eliminate ambiguity provided the impetus for the Department's actions to make certain regulatory changes.[98]

For example, the Department modified its prior interpretation of the Privacy Rule requirement at 45 CFR 164.508(c)(1)(iv) that a description of a research purpose must be study specific.[99] The Department explained that, under its new interpretation, the research purposes need only be described adequately such that it would be reasonable for an individual to expect that their PHI could be used or disclosed for such future research.[100] In the 2013 Omnibus Rule, the Department explained that this change was based on the concerns expressed by covered entities, researchers, and other commenters on the 2010 NPRM that the former requirement did not represent current research practices. The Department provided a similar explanation for its modifications to the Privacy Rule that permit certain disclosures of student immunization records to schools without an authorization.[101] Additionally, based on a recommendation made at an NCVHS meeting, the Department requested comment on and finalized proposed revisions to the definition of PHI to exclude information regarding an individual who has been deceased for more than 50 years.[102] For the latter, the Department noted that it was balancing the privacy interests of decedents' living relatives and other affected individuals against the legitimate needs of public archivists to obtain records.[103]

None of the changes described in the paragraph above were required by the HITECH Act. Rather, the Department determined that it was necessary to promulgate these changes pursuant to its existing general rulemaking authority under HIPAA. NCVHS and the public also recommended other changes between the publication of the 2002 Privacy Rule and the 2013 Omnibus Rule, including the creation of specific categories of PHI, such as ''Sexuality and Reproductive Health Information'' that would allow for special protections of such PHI.[104] The Department declined to propose specific protections for certain categories of PHI at that time because of concerns about the ability of regulated entities to segment PHI and the effects on care coordination. Many of those concerns are still present and so, the Department did not propose and determined not to establish a specific category of particularly sensitive PHI in this rulemaking. Instead, as discussed more fully below, the Department is finalizing a purpose-based prohibition against certain uses and disclosures.

[90] 67 FR 53182, 53183 (Aug. 14, 2002).

[91] 67 FR 14775 (Mar. 27, 2002).

[92] 67 FR 53182 (Aug. 14, 2002). See the final rule for changes in the entirety. The 2002 Privacy Rule was issued before the compliance date for the 2000 Privacy Rule. Thus, covered entities never implemented the 2000 Privacy Rule. Instead, they implemented the 2000 Privacy Rule as modified by the 2002 Privacy Rule.

[93] *See* 67 FR 53182 (Aug. 14, 2002).

[94] 75 FR 40868 (July 14, 2010).

[95] 78 FR 5566 (Jan. 25, 2013). In addition to finalizing requirements of the HITECH Act that were proposed in the 2010 NPRM, the Department adopted modifications to the Enforcement Rule not previously adopted in an earlier interim final rule, 74 FR 56123 (Oct. 30, 2009), and to the Breach Notification Rule not previously adopted in an interim final rule, 74 FR 42739 (Aug. 24, 2009). The Department also finalized previously proposed Privacy Rule modifications as required by GINA, 74 FR 51698 (Oct. 7, 2009).

[96] *See* 78 FR 5566 (Jan. 25, 2013) (explaining that the Department was using its general authority under HIPAA to make a number of changes to the Privacy Rule that were intended to increase workability and flexibility, decrease burden, and better harmonize the requirements with those under other Departmental regulations). The Department's general authority to modify the Privacy Rule is codified in HIPAA section 264(c), and OCR conducts rulemaking under HIPAA based on authority granted by the Secretary.

[97] *See* 75 FR 40868, 40871 (July 14, 2010).

[98] 75 FR 40868, 40871 (July 14, 2010).

[99] *See* 78 FR 5566, 5611 (Jan. 25, 2013).

[100] *See id.* at 5612.

[101] *Id.* at 5616–17. *See also* 45 CFR 164.512(b)(1).

[102] 78 FR 5566, 5614 (Jan. 25, 2013). *See also* 45 CFR 164.502(f) and the definition of ''Protected health information'' at 45 CFR 160.103, excluding IIHI regarding a person who has been deceased for more than 50 years.

[103] In addition to the rulemakings discussed here, the Department has modified the Privacy Rule for workability purposes and in response to changes in circumstances on two other occasions, and it issued another notice of proposed rulemaking in 2021 for the same reasons. *See* 79 FR 7289 (Feb. 6, 2014), 81 FR 382 (Jan. 6, 2016), and 86 FR 6446 (Jan. 21, 2021).

[104] *See* Letter from NCVHS Chair Simon P. Cohn to HHS Sec'y Michael O. Leavitt (June 22, 2006), *https://ncvhs.hhs.gov/rrp/june-22-2006-letter-to-the-secretary-recommendations-regarding-privacy-and-confidentiality-in-the-nationwide-health-information-network/;* Letter from NCVHS Chair Simon P. Cohn to HHS Sec'y Michael O. Leavitt (Feb. 20, 2008) (listing categories of health information that are commonly considered to contain sensitive information), *https://ncvhs.hhs.gov/wp-content/uploads/2014/05/080220lt.pdf;* Letter from NCVHS Chair Justine M. Carr to HHS Sec'y Kathleen Sebelius (Nov. 10, 2010) (forwarding NCVHS recommendations), *https://ncvhs.hhs.gov/wp-content/uploads/2014/05/101110lt.pdf.*

4. 2024 Privacy Rule

On April 17, 2023, the Department issued an NPRM [105] to modify the Privacy Rule for the purpose of prohibiting uses and disclosures of PHI for criminal, civil, or administrative investigations or proceedings against persons for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided. To properly execute the HIPAA statutory mandate, and in accordance with the regulatory authority granted to it by Congress, the Department continually monitors and evaluates the evolving environment for health information privacy nationally, including the interaction of the Privacy Rule and state statutes and regulations governing the privacy of health information. In keeping with the Department's practice, this final rule accommodates state autonomy to the extent consistent with the need to maintain rules for health information privacy that serve HIPAA's objectives. The regulation thus preempts state law only to the extent necessary to achieve Congress' directive to establish a standard for the privacy of IIHI for the purpose of improving the effectiveness of the health care system. As discussed below, achieving that objective requires individuals to trust that their health care providers will maintain privacy of PHI about lawful reproductive health care. In addition, NCVHS held a virtual public meeting that included a discussion about the proposed rule on June 14, 2023,[106] and provided recommendations to the Department based on this discussion, briefings at their July 2022 [107] and December 2022 [108] meetings, and the expertise of its members.[109] The resultant public record and subsequent recommendations submitted to the Department by NCVHS, along with other public comments on the 2023 Privacy Rule NPRM, informed the development of these modifications.

[105] 88 FR 23506.

[106] *See* Meeting of NCVHS (June 14, 2023), *https://ncvhs.hhs.gov/meetings/full-committee-meeting-13/.*

[107] *See* Meeting of NCVHS, Briefing on Legislative Developments in Data Privacy (July 21, 2022), *https://ncvhs.hhs.gov/meetings/full-committee-meeting-11/.*

[108] *See* Meeting of NCVHS, Briefing by Cason Schmit (Dec. 7, 2022), *https://ncvhs.hhs.gov/meetings/full-committee-meeting-12/.*

[109] Letter from NCVHS Chair Jacki Monson to HHS Sec'y Xavier Becerra (June 14, 2023) (forwarding NCVHS recommendations), *https://ncvhs.hhs.gov/wp-content/uploads/2023/06/NCVHS-Comments-on-HIPAA-Reproduction-Health-NPRM-Final-508.pdf.*

III. Justification for This Rulemaking

A. HIPAA Encourages Trust and Confidence by Carefully Balancing Individuals' Privacy Interests With Others' Interests in Using or Disclosing PHI

1. Privacy Protections Ensure That Individuals Have Access to, and Are Comfortable Accessing, High-Quality Health Care

The goal of a functioning health care system is to provide high-quality health care that results in the best possible outcomes for individuals. To achieve that goal, a functioning health care system depends in part on individuals trusting health care providers. Thus, trust between individuals and health care providers is essential to an individual's health and well-being.[110] Protecting the privacy of an individual's health information is ''a crucial element for honest health discussions.'' [111] The original Hippocratic Oath required physicians to pledge to maintain the confidentiality of health information they learn about individuals.[112] Without confidence that private information will remain private, individuals—to their own detriment—are reluctant to share information with health care providers.

When proposing the 2000 Privacy Rule, the Department recognized that individuals may be deterred from seeking needed health care if they do not trust that their sensitive information will be kept private.[113] The Department described its policy choices as stemming from a motivation to develop and maintain a relationship of trust between individuals and health care providers. The Department explained that a fundamental assumption of the 2000 Privacy Rule was that the greatest benefits of improved privacy protection would be realized in the future as individuals gain increasing trust in their health care provider's ability to maintain the confidentiality of their health information.[114] As a result, the Privacy Rule strengthened protections for health information privacy, including the right of individuals to determine who has access to their health information.

Despite the Privacy Rule's rights and protections, individuals do not have confidence that their IIHI is being protected adequately. In a 2022 survey on patient privacy, the American Medical Association (AMA) found that, of 1,000 patients surveyed: (1) nearly 75% were concerned about protecting the privacy of their own health information; and (2) 59% of patients worried about health data being used by companies to discriminate against them or their loved ones.[115] According to the AMA, a lack of health information privacy raises many questions about circumstances that could put individuals and health care providers in legal peril, and that the ''primary purpose of increasing [health information] privacy is to build public trust, not inhibit data exchange.'' [116]

The Federal Government also has a strong interest in ensuring that individuals have access to high-quality health care.[117] This is true at both an

[110] *See* Jennifer Richmond et al., ''Development and Validation of the Trust in My Doctor, Trust in Doctors in General, and Trust in the Health Care Team Scales,'' 298 Social Science & Medicine 114827 (2022), *https://www.sciencedirect.com/science/article/abs/pii/S0277953622001332?via%3Dihub; see also* Fallon E. Chipidza et al., ''Impact of the Doctor-Patient Relationship,'' The Primary Care Companion for CNS Disorders (Oct. 2015), *https://www.psychiatrist.com/pcc/delivery/patient-physician-communication/impact-doctor-patient-relationship/. See* Testimony (transcribed) of William G. Plested, III, M.D., Member, Board of Trustees, American Medical Association, Hearing on Confidentiality of Patient Medical Records before House of Representatives Committee on Ways and Means, Subcommittee on Health (Feb. 17, 2000), *https://www.govinfo.gov/content/pkg/CHRG-106hhrg66897/html/CHRG-106hhrg66897.htm.* (''Trust is the foundation of the patient/physician relationship.'')

[111] *See* Am. Med. Ass'n, ''Patient Perspectives Around Data Privacy,'' (2022), *https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.*

[112] *See* John C. Moskop et al., ''From Hippocrates to HIPAA: Privacy and Confidentiality in Emergency Medicine—Part I: Conceptual, Moral, and Legal Foundations,'' 45 Ann Emerg. Med.1 (Jan. 2005) (quoting the Oath of Hippocrates, ''What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself [. . .].''), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7132445/#bib1.*

[113] *See* 64 FR 59918, 60006 (Nov. 3, 1999) (In the 1999 Privacy Rule NPRM, the Department discussed confidentiality as an important component of trust between individuals and health care providers and cited a 1994 consumer privacy survey that indicated that a lack of privacy may deter patients from obtaining preventive care and treatment.). *See id.* at 60019.

[114] *See* 64 FR 59918, 60006 (Nov. 3, 1999).

[115] *See* ''Patient Perspectives Around Data Privacy,'' *supra* note 111.

[116] *Id.* at 2.

[117] *See* Testimony (transcribed) of Peter R. Orszag, Director, Congressional Budget Office, Hearing on Comparative Clinical Effectiveness before House of Representatives Committee on Ways and Means, Subcommittee on Health, 2007 WL 1686358 (June 12, 2007) (''because federal health insurance programs play a large role in financing medical care and represent a significant expenditure, the federal government itself has an interest in evaluations of the effectiveness of different health care approaches''); Statement of Sen. Durenberger introducing S.1836, American Health Quality Act of 1991 and reading bill text, 137 Cong. Rec. S26720 (Oct. 17, 1991) (''[T]he Federal Government has a demonstrated interest in assessing the quality of care, access to care, and the costs of care through

individual and population level. In the 2000 Privacy Rule, the Department noted that high-quality health care depends on an individual being able to share sensitive information with their health care provider based on the trust that the information shared will be protected and kept confidential.[118] An effective health care system requires an individual to share sensitive health information with their health care providers. They do so with the reasonable expectation that this information is going to be used to treat them. The prospect of the disclosure of highly sensitive PHI by regulated entities can result in medical mistrust and the deterioration of the confidential, safe environment that is necessary to provide high-quality health care, operate a functional health care system, and improve the public's health generally.[119] High-quality health care cannot be attained without patient candor. Health care providers rely on an individual's health information to diagnose them and provide them with appropriate treatment options and may not be able to reach an accurate diagnosis or recommend the best course of action for the individual if the individual's medical records lack complete information about their health history. However, an individual may be unwilling to seek treatment or share highly sensitive PHI when they are concerned about the confidentiality and security of PHI provided to treating health care providers.[120] The Department has long recognized that health care professionals who lose the trust of their patients cannot deliver high-quality care.[121] Similarly, if a health care provider does not trust that the PHI they include in an individual's medical records will be kept private, the health care provider may leave gaps or include inaccuracies when preparing medical records, creating a risk that ongoing or future health care would be compromised. In contrast, heightened confidentiality and privacy protections enable a health care provider to feel confident maintaining full and complete medical records.

Incomplete medical records and health care avoidance not only inhibit the quality of health care an individual receives; they are also detrimental to efforts to improve public health. The objective of public health is to prevent disease in and improve the health of populations. Barriers that undermine the willingness of individuals to seek health care in a timely manner or to provide complete and accurate health information to their health care providers undermine the overall objective of public health. For example, individuals who are not candid with their health care providers because of concerns about potential negative consequences of a loss of privacy may withhold information about a variety of health matters that have public health implications, such as communicable diseases or vaccinations.[122] Experience also shows that medical mistrust—especially in communities of color and other communities that have been marginalized or negatively affected by historical and current health care disparities—can create damaging and chilling effects on individuals' willingness to seek appropriate and lawful health care for medical conditions that can worsen without treatment.[123]

2. The Department's Approach to the Privacy Rule Has Long Sought To Balance the Interests of Individuals and Society

While recognizing the importance of preserving individuals' trust, the Department has consistently taken the approach of balancing the interests of the individual in the privacy of their PHI with society's interests, including in the free flow of information that enables the provision of effective and efficient health care services. Such an approach derives from Congress's direction, in 1996, to improve the efficiency and effectiveness of the health care system by encouraging the development of a health information system while taking into account the privacy of IIHI and the uses and disclosures of such information that should be authorized or required.[124] In past rulemakings, the Department has made revisions to the Privacy Rule to balance an individual's privacy expectations with a covered entity's need for information for reimbursement and quality purposes.[125] As the Department previously explained, ''Patient privacy must be balanced against other public goods, such as research and the risk of compromising such research projects if researchers could not continue to use such data.'' [126] The 2000 Privacy Rule included permissions for regulated entities to disclose PHI under certain conditions, including for judicial and administrative proceedings and law enforcement purposes, because an individual's right to privacy in information about themselves is not absolute. For example, it does not prevent reporting of public health information on communicable diseases, nor does it prevent law enforcement

the evaluative activities of several Federal agencies.'').

[118] *See* 65 FR 82462, 82463 (Dec. 28, 2000).

[119] *See, e.g.,* Brooke Rockwern et al., Medical Informatics Committee and Ethics, Professionalism and Human Rights Committee of the American College of Physicians, ''Health Information Privacy, Protection, and Use in the Expanding Digital Health Ecosystem: A Position Paper of the American College of Physicians,'' 174 Ann Intern Med. 994 (Jul. 2021) (discussing the need for trust in the health care system as necessary to mitigate a global pandemic); Johanna Birkhäuer et. al, ''Trust in the Health Care Professional and Health Outcome: A Meta-Analysis,'' 12 PLoS One e0170988 (Feb. 7, 2017). *See also* Eric Boodman, ''In a doctor's suspicion after a miscarriage, a glimpse of expanding medical mistrust,'' STAT News (June 29, 2022), *https://www.statnews.com/2022/06/29/doctor-suspicion-after-miscarriage-glimpse-of-expanding-medical-mistrust/* (Sarah Prager, professor of obstetrics and gynecology at the University of Washington, stating that it is a bad precedent if clinical spaces become unsafe for patients because, ''[a health care provider's] ability to take care of patients relies on trust, and that will be impossible moving forward.'').

[120] *See* ''Development and Validation of the Trust in My Doctor, Trust in Doctors in General, and Trust in the Health Care Team Scales,'' *supra* note 110; Bradley E. Iott et al., ''Trust and Privacy: How Patient Trust in Providers is Related to Privacy Behaviors and Attitudes,'' 2019 AMIA Annu Symp Proc 487 (Mar. 2020), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7153104/;* Pamela Sankar et al., ''Patient Perspectives of Medical Confidentiality: a Review of the Literature,'' 18 J. of Gen. Internal Med. 659 (Aug. 2003), *https://pubmed.ncbi.nlm.nih.gov/12911650/.*

[121] *See* 65 FR 82462, 82468 (Dec. 28, 2000).

[122] *See* Letter from NCVHS Chair Simon P. Cohn, *supra* note 104, at 2 (2006) (with forwarded NCVHS recommendations, ''Individual trust in the privacy and confidentiality of their personal health information also promotes public health, because individuals with potentially contagious or communicable diseases are not inhibited from seeking treatment.'').

[123] *See* Texas Dep't of State Health Servs., ''Texas Maternal Mortality and Morbidity Review Committee and Department of State Health Services Joint Biennial Report 2022,'' at 41 (Dec. 2022) *https://www.dshs.texas.gov/sites/default/files/legislative/2022-Reports/2022-MMMRC-DSHS-Joint-Biennial-Report.pdf;* Lynn M. Paltrow et al., ''Arrests of and forced interventions on pregnant women in the United States, 1973–2005: implications for women's legal status and public health,'' 38 J. Health Pol. Pol'y Law 299 (2013) (finding that hospital staff are most likely to report pregnant low-income and patients of color, especially Black women, to the authorities.); Terri-ann Monique Thompson et al., ''Racism Runs Through It: Examining the Sexual and Reproductive Health Experience of Black Women in the South,'' 41 Health Affairs 195 (Feb. 2022) (discussing how individual racism affects reproductive health care use by undermining the patient-doctor relationship), *https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01422*); Joli Hunt, ''Maternal Mortality among Black Women in the United States,'' Ballard Brief (July 2021), *https://ballardbrief.byu.edu/issue-briefs/maternal-mortality-among-black-women-in-the-united-states/* (discussing the disproportionately high rate of Black maternal mortality and morbidity); Austin Frakt, ''Bad Medicine: The Harm that Comes from Racism,'' The New York Times (July 8, 2020), *https://www.nytimes.com/2020/01/13/upshot/bad-medicine-the-harm-that-comes-from-racism.html.*

[124] 42 U.S.C. 1320d note and 1320d–2 note.

[125] *See* 67 FR 53182, 53216 (Aug. 14, 2002).

[126] *Id.* at 53226.

from obtaining information when due process has been observed.[127]

In more recent rulemakings revising the Privacy Rule, the Department has continued its efforts to build and maintain individuals' trust in the health care system while balancing the interests of individuals with those of others. For example, in explaining revisions made as part of the 2013 Omnibus Rule, the Department recognized that covered entities must balance protecting the privacy of health information with sharing health information with those responsible for ensuring public health and safety.[128] The Privacy Rule was also revised in 2016 (''2016 Privacy Rule'') in accordance with an administration-wide effort to curb gun violence across the nation.[129] The 2016 Privacy Rule was tailored to authorize the disclosure of a limited set of PHI [130] for a narrow, specific purpose, that is, to permit only regulated entities that are state agencies or other entities designated by a state to collect and report information to the National Instant Criminal Background Check System (NICS) or a lawful authority making an adjudication or commitment as described by 18 U.S.C. 922(g)(4) to disclose to NICS the identities of individuals who are subject to a Federal ''mental health prohibitor,'' that disqualifies them from shipping, transporting, possessing, or receiving a firearm. As explained in the 2016 Privacy Rule, the Federal mental health prohibitor applies only to the extent that the individual is involuntarily committed or determined by a court or other lawful authority to be a danger to self or others, or is unable to manage their own affairs because of a mental illness or condition.[131] Similar to this final rule, the 2016 Privacy Rule balanced public safety goals with individuals' privacy interests by clearly limiting permissible disclosures to those that are necessary to ensure that individuals are not discouraged from seeking lawful health care, in this case, voluntary treatment for mental health needs.[132] In the 2013 Omnibus Rule and 2016 Privacy Rule, the Department ensured that the disclosures were necessary for the public good and were not for the purpose of harming the individual. This approach is consistent with the NCVHS recommendations to the Secretary relating to health information privacy: ''The Committee strongly supports limiting use and disclosure of identifiable information to the minimum amount necessary to accomplish the purpose. The Committee also strongly believes that when identifiable health information is made available for non-health uses, patients deserve a strong assurance that the data will not be used to harm them.'' [133]

Consistent with Congress's directive to promulgate ''standards with respect to the privacy of [IIHI]'' that, among other things, address the ''uses and disclosures of such information that should be authorized or required,'' [134] the Department recognizes a variety of interests with respect to health information. These include individuals' interests in the privacy of their health information, society's interests in ensuring the effectiveness of the health care system, and other interests of society in using IIHI for certain non-health care purposes. As part of balancing these interests, the Department has also recognized that it may be necessary to afford additional protection to certain types of health information because those types of information are particularly sensitive and often involve highly personal health care decisions. For example, the Department affords special privacy protections to psychotherapy notes. These protections are afforded in part because of the particularly sensitive information those notes contain and in part because of the unique function of these records, which are by definition maintained separately from an individual's medical record.[135] As we previously explained, the primary value of psychotherapy notes is to the specific provider, and the promise of strict confidentiality helps to ensure that the patient will feel comfortable freely and completely disclosing very personal information essential to successful treatment.[136] The Department elaborated that even the possibility of disclosure may impede development of the confidential relationship necessary for successful treatment because of the sensitive nature of the problems for which individuals consult psychotherapists and the potential embarrassment that may be engendered by the disclosure of confidential communications made during counseling sessions.[137] Therefore, to support the development and maintenance of an individual's trust and protect the relationship between an individual and their therapist, the Privacy Rule permits the disclosure of psychotherapy notes without an individual's authorization only in limited circumstances, such as to avert a serious and imminent threat to health or safety. Those limited circumstances do not include judicial and administrative proceedings or law enforcement purposes unless the disclosure is ''necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.'' [138]

Information about an individual's reproductive health and associated health care is also especially sensitive and has long been recognized as such. As stated in the AMA's Principles of Medical Ethics, the ''decision to terminate a pregnancy should be made privately within the relationship of trust between patient and physician in keeping with the patient's unique values and needs and the physician's best professional judgment.'' [139] NCVHS first noted reproductive health information as an example of a category of health information commonly considered to contain sensitive information in

[127] 65 FR 82462, 82464 (Dec. 28, 2000).

[128] *See* 78 FR 5566, 5616 (Jan. 25, 2013).

[129] 81 FR 382 (Jan. 6, 2016); *see, e.g.,* 78 FR 4297 (Jan. 22, 2013) and 78 FR 4295 (Jan. 22, 2013); *see also* Colleen Curtis, ''President Obama Announces New Measures to Prevent Gun Violence,'' The White House President Barack Obama (Jan. 16, 2013), *https://obamawhitehouse.archives.gov/blog/2013/01/16/president-obama-announces-new-measures-prevent-gun-violence.*

[130] This PHI includes limited demographic and certain other information needed for the purposes of reporting to NICS. 45 CFR 164.512(k)(7)(iii)(A). In preamble, the Department explained that generally the information described at 45 CFR 164.512(k)(7)(iii)(A) would be limited to the data elements required to create a NICS record and certain other elements to the extent that they are necessary to exclude false matches: Social Security number, State of residence, height, weight, place of birth, eye color, hair color, and race. 81 FR 382, 390 (Jan. 6, 2016).

[131] 81 FR 382, 386–388 (Jan. 6, 2016).

[132] *Id.* The Department addressed concerns about the possible chilling effect on individuals seeking health care by explaining that (1) the permission is limited to only those covered entities that order the involuntary commitments or make the other adjudications that cause individuals to be subject to the Federal mental health prohibitor, or that serve as repositories of such information for NICS reporting purposes; (2) the specified regulated entities are permitted to disclose NICS data only to designated repositories or the NICS; (3) the information that may be disclosed is limited to certain demographic or other information that is necessary for NICS reporting; and (4) the rulemaking did not expand the permission to encompass State law prohibitor information.

[133] Letter from NCVHS Chair Don E. Detmer to HHS Sec'y Donna E. Shalala (June 27, 1997) (forwarding NCVHS recommendations), *https://ncvhs.hhs.gov/rrp/june-27-1997-letter-to-the-secretary-with-recommendations-on-health-privacy-and-confidentiality/.*

[134] 42 U.S.C. 1320d–2 note.

[135] *See* 45 CFR 164.501 (definition of ''Psychotherapy notes'').

[136] *See* 64 FR 59918, 59941 (Nov. 3, 1999).

[137] *See id.*

[138] 45 CFR 164.508(a)(2).

[139] Council on Ethical and Judicial Affairs, ''Ethics, Amendment to Opinion 4.2.7, Abortion H–140.823,'' Am. Med. Ass'n (2022), *https://policysearch.ama-assn.org/policyfinder/detail/%224.2.7%20Abortion%22?uri=%2FAMADoc%2FHOD.xml-H-140.823.xml.*

2006.[140] Between 2005 and 2010, NCVHS held nine hearings that addressed questions about sensitive information in medical records and identified additional categories of sensitive information beyond those addressed in Federal and state law, including ''sexuality and reproductive health information.'' In several letters to the Secretary during that period, NCVHS recommended that the Department identify and define categories of sensitive information, including ''reproductive health.'' [141] In a 2010 letter to the Secretary, NCVHS elaborated that, after extensive testimony on sensitive categories of health information, ''reproductive health'' should be expanded to ''sexuality and reproductive health information,'' because:

> Information about sexuality and reproductive history is often very sensitive. Some reproductive issues may expose people to political controversy (such as protests from abortion proponents), and public knowledge of an individual's reproductive history may place [them] at risk of stigmatization.'' Additionally, individuals may wish to have their reproductive history segmented so that it is not viewed by family members who otherwise have access to their records. Parents may wish to delay telling their offspring about adoption, gamete donation, or the use of other forms of assisted reproduction technology in their conception, and, thus, it may be important to have the capacity to segment these records.[142]

The Department did not provide specific protections for certain categories of PHI upon receipt of the recommendation or as part of the 2013 Omnibus Rule because of concerns about the ability of regulated entities to segment PHI and the effects on care coordination. While we recognized the sensitive nature of reproductive health information before this rulemaking, the Department believed that the Supreme Court's recognition of a constitutional right to abortion coupled with the privacy protections afforded by the HIPAA Rules provided the necessary trust to promote access to and quality of health care. As a result of the changed legal landscape for reproductive health care broadly, including abortion, the range of circumstances in which PHI about legal reproductive health care could be sought and used in investigations or to impose liability expanded significantly. Now that states have much broader power to criminalize and regulate reproductive choices—and that some states have already exercised that power in a variety of ways [143]—individuals legitimately have a far greater fear that especially sensitive information about lawful health care will not be kept private. This changed environment requires additional privacy protections to help restore the Privacy Rule's carefully-struck balance between individual and societal interests. Because the concerns regarding segmentation and the negative impact on care coordination remain, the Department did not propose and is not establishing a new category of particularly sensitive PHI in this final rule. Instead, as discussed more fully below, the Department is finalizing its proposed purpose-based prohibition against certain uses and disclosures.

B. Developments in the Legal Environment Are Eroding Individuals' Trust in the Health Care System

The Supreme Court's decision in *Dobbs* overturned *Roe* v. *Wade* [144] and *Planned Parenthood of Southeastern Pennsylvania* v. *Casey,*[145] thereby enabling states to significantly restrict access to abortion.[146] Following the Supreme Court's decision, the legal landscape has shifted as laws significantly restricting access to abortion have in fact become effective in some jurisdictions. This change has also led to questions about both the current and future lawfulness of other types of reproductive health care, and therefore, the ability of individuals to access such health care.[147] Thus, this shift may interfere with the longstanding expectations of individuals, established by HIPAA and the Privacy Rule, with respect to the privacy of their PHI.[148] For example, while the Privacy Rule currently permits, but does not require, uses and disclosures of PHI for certain purposes,[149] including when another law requires a regulated entity to make the use or disclosure,[150] regulated entities after *Dobbs* may feel compelled by other applicable law to use or disclose PHI to law enforcement or other persons who may use that health information against an individual, a regulated entity, or another person who has sought, obtained, provided, or facilitated reproductive health care, even when such health care is lawful in the circumstances in which the health care is obtained.[151]

As a consequence of these developments in Federal and state law, an individual's expectation of privacy of their health information (irrespective of whether an individual is or was pregnant) is threatened by the potential use or disclosure of PHI to identify persons who seek, obtain, provide, or facilitate lawful reproductive health care. Thus, these developments have created an environment in which individuals are more likely to fear that their PHI will be requested from regulated entities for use against individuals, health care providers, and others, merely because such persons sought, obtained, provided, or facilitated lawful reproductive health care.[152] The potential increased demand for PHI for these purposes is not limited to states in which providing or obtaining certain reproductive health care is no longer legal. Rather, the changes in the legal landscape have nationwide implications, not only because of their effects on the relationship between health care providers and individuals, but also because of the potential effects on the flow of health information across state lines. For example, an individual who travels out-of-state to obtain reproductive health care that is lawful under the circumstances in which it is provided may now be reluctant to have that information disclosed to a health care provider in their home state if they

[140] *See* Letter from NCVHS Chair Simon P. Cohn (2006), *supra* note 104.

[141] *See* Letter from NCVHS Chair Simon P. Cohn (2006), *supra* note 104; Letter from NCVHS Chair Simon P. Cohn (2008), *supra* note 104; Letter from NCVHS Chair Justine M. Carr (2010), *supra* note 104.

[142] *See* Letter from NCVHS Chair Justine M. Carr (2010), *supra* note 104.

[143] *See LePage* v. *Center for Reproductive Medicine,* SC–2022–0515 (Feb. 16, 2024).

[144] 410 U.S. 113 (1973).

[145] 505 U.S. 833 (1992).

[146] *Dobbs,* 597 U.S. 299–302.

[147] *See, e.g.,* Carmel Shachar et al., ''Informational Privacy After Dobbs,'' 75 Ala. L. Rev. 1 (2023), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4570500* and Andrzej Kulczycki, ''Dobbs: Navigating the New Quagmire and Its Impacts on Abortion and Reproductive Health Care,'' Health Education & Behavior (2022), *https://doi.org/10.1177/10901981221125430.*

[148] *See, e.g.,* Kayte Spector-Bagdady & Michelle M. Mello, ''Protecting the Privacy of Reproductive Health Information After the Fall of *Roe* v. *Wade,*'' 3 JAMA Network e222656 (June 30, 2022), *https://jamanetwork.com/journals/jama-health-forum/fullarticle/2794032*; Lisa G. Gill, ''What does the overturn of Roe v. Wade mean for you?,'' Consumer Reports (June 24, 2022), *https://www.consumerreports.org/health-privacy/what-does-the-overturn-of-roe-v-wade-mean-for-you-a1957506408/.*

[149] 45 CFR 164.502(a)(1).

[150] 45 CFR 164.512(a).

[151] *See* Laura J. Faherty et al. ''Consensus Guidelines and State Policies: The Gap Between Principle and Practice at the Intersection of Substance Use and Pregnancy,'' American Journal of Obstetrics & Gynecology Maternal-Fetal Medicine (Aug. 2020) (discussing a concern raised by multiple organizations that pregnant women will hesitate to seek prenatal care and addiction treatment during pregnancy because their concerns that disclosing substance use to health care providers will increase the likelihood that they will face legal penalties); *see also* ''Informational Privacy After Dobbs,'' *supra* note 147.

[152] *See, e.g.,* Yvonne Lindgren et al., ''Reclaiming Tort Law to Protect Reproductive Rights,'' 75 Alabama L. Rev. 355 (2023), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4435834.*

fear that it may then be used against them or a loved one in their home state. A health care provider may be unable to provide appropriate health care if they are unaware of the individual's recent health history, which could have significant negative health consequences. Individuals and health care providers may also be reluctant to disclose PHI to health plans with a multi-state presence because of concerns that one of those states will seek to obtain that PHI to investigate or impose liability on the individual or the health care provider, even if there is no nexus with that state other than the presence of the health plan in that state. Such reluctance may have significant ramifications for access to reproductive health care, given the cost associated with obtaining such health care, and health care generally.

Additionally, PHI is more likely to be transmitted across state lines as the electronic exchange of PHI increases because it is easier and more efficient to send information electronically. For instance, the Trusted Exchange Framework and Common Agreement (TEFCA) initiative established under the 21st Century Cures Act and the Centers for Medicare & Medicaid Services (CMS) Interoperability and Prior Authorization Final Rule will spur greater use and disclosure of PHI by regulated entities and to health apps and others.[153] Different components of a health information exchange/health information network (HIE/HIN) may be located in different states, meaning that the PHI may be transmitted across state lines, and thus affected by laws severely restricting access to reproductive health care, even where both the health care and the recipient of the PHI are located in states where access to such health care is not substantially restricted.

According to commenters, individuals are increasingly concerned about the confidentiality of discussions with their health care providers. As a result, some individuals are not confiding fully in their health care providers, increasing the risk that their medical records will not be complete and accurate, leading to decreases in health care quality and safety. This lack of openness is also likely to affect the information and treatment recommendations health care providers provide to individuals because health care providers will not be sufficiently informed to provide thorough and accurate information and guidance.[154]

Individuals are not alone in their fears. Indeed, according to commenters, some health care providers are afraid to provide lawful health care because they are concerned that in doing so, they risk being subjected to investigation and possible liability.[155] The Department is aware that some health care providers, such as clinicians and pharmacies, are hesitant to provide lawful health care or lawfully prescribe or fill prescriptions for medications that can result in pregnancy loss, even when the health care or those prescriptions are intended to treat individuals for other health matters, because of fear of law enforcement action.[156] Some health care providers are also not providing individuals with information to address concerns about their reproductive health, even where their communications would be lawful, out of fear of criminal prosecution, civil suit, or loss of their clinical license.[157] This may result in individuals making decisions about their health care with incomplete information, which could have serious implications for health outcomes. These fears also increase the risk that individual medical records will not be maintained with completeness and accuracy, which will in turn affect the quality of health care provided to individuals and their safety. Fears about potential prosecution, even when Federal law protects the actions of health care providers, are likely to negatively affect the accuracy of medical records maintained by health care providers and thereby harm individuals.

As explained by commenters and supported by research, these impingements on the privacy of health information about reproductive health care are likely to have a disproportionately greater effect on women, individuals of reproductive age, and individuals from communities that have been historically underserved, marginalized, or subject to discrimination or systemic disadvantage by virtue of their race, disability, social or economic status, geographic location, or environment.[158] Historically

[153] *See* section 3001(c) of the PHSA, as amended by section 4003(b) of the 21st Century Cures Act, Public Law 114–255, 130 Stat. 1165 (codified at 42 U.S.C. 300jj–11(c)). For more information, *see* Office of the Nat'l Coordinator for Health Info. Tech., ''Trusted Exchange Framework and Common Agreement (TEFCA),'' *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca; See also* 89 FR 8758 (Feb. 8, 2024); ''CMS Interoperability and Prior Authorization Final Rule CMS–0057–F,'' Centers for Medicare & Medicaid (Jan. 17, 2024), *https://www.cms.gov/newsroom/fact-sheets/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f.*

[154] *See* Eric Boodman, ''In a doctor's suspicion after a miscarriage, a glimpse of expanding medical mistrust,'' STAT News (June 29, 2022), *https://www.statnews.com/2022/06/29/doctor-suspicion-after-miscarriage-glimpse-of-expanding-medical-mistrust/#:~:text=In%20a%20doctor's%20suspicion%20after,glimpse%20of%20expanding%20medical%20mistrust&text=The%20idea%20that%20she,used%20contraceptives%20and%20trusted%20them.*

[155] *See also* Melissa Suran, ''As Laws Restricting Health Care Surge, Some US Physicians Choose Between Fight or Flight,'' JAMA, 329(22):1899–1903 (May 17, 2023) (discussing a maternal-fetal medicine specialist who stated that she moved to another state because of legislation that restricts evidence-based health care and prevents her from fulfilling her ethical obligation to protect her patients' health.), *https://pubmed.ncbi.nlm.nih.gov/37195699/.*

[156] *See* Off. for Civil Rights, ''HHS Office for Civil Rights Resolves Complaints with CVS and Walgreens to Ensure Timely Access to Medications for Women and Support Persons with Disabilities,'' U.S. Dep't of Health and Human Servs. (June 16, 2023), *https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/cvs-walgreens/index.html. See also* Kathryn Starzyk et al., ''More than half of patients with a rheumatic disease or immunologic condition undergoing methotrexate treatment reside in states in which the overturning of *Roe* v. *Wade* can jeopardize access to medications with abortifacient potential,'' 75 Arthritis Rheumatol 328 (Feb. 2023); *see also* Celine Castronuovo, ''Many Female Arthritis Drug Users Face Restrictions After *Dobbs,*'' Bloomberg Law (Nov. 14, 2022) (noting that 16 out of 524 patients responding to a survey indicated that they've had trouble getting methotrexate, their arthritis medication, since the *Dobbs* decision.) *https://news.bloomberglaw.com/health-law-and-business/many-female-arthritis-drug-users-face-restrictions-after-dobbs;* Interview with Donald Miller, PharmD, ''Methotrexate access becomes challenging for some patients following Supreme Court decision on abortion,'' Pharmacy Times (July 20, 2022), *https://www.pharmacytimes.com/view/methotrexate-access-becomes-challenging-for-patients-following-supreme-court-decision-on-abortion;* Jamie Ducharme, ''Abortion restrictions may be making it harder for patients to get a cancer and arthritis drug,'' Time (July 6, 2022), *https://time.com/6194179/abortion-restrictions-methotrexate-cancer-arthritis/;* Katie Shepherd & Frances Stead Sellers, ''Abortion bans complicate access to drugs for cancer, arthritis, even ulcers,'' The Washington Post (Aug. 8, 2022), *https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/.*

[157] *See* Michelle Oberman & Lisa Soleymani Lehmann, ''Doctors' duty to provide abortion information,'' J. of Law and Biosciences. (Sept. 1, 2023) *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10474560/;* Whitney Arey et al., ''Abortion Access and Medically Complex Pregnancies Before and After Texas Senate Bill 8,'' 141 Obstet Gynecol. 995 (May 1, 2023) (concluding that ''Abortion restrictions limit shared decision making, compromise patient care, and put pregnant people's health at risk.''); ''1 Year Without *Roe,*'' Center for American Progress (Jun. 23, 2023) (where a physician detailed her fear about speaking freely with her patients after *Dobbs* ''worried a vigilante posing as a new patient would attempt to bait her into talking about abortion and attempt to sue her, and she sometimes skirts the topic of abortion when speaking with patients about their health care options.'')

[158] *See* Christine Dehlendorf et al., ''Disparities in Abortion Rates: A Public Health Approach,'' Am. J. of Pub. Health (Oct. 2013), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3780732/. See also* Kiara Alfonseca, ''Why Abortion Restrictions Disproportionately Impact People of Color,'' ABC News (June 24, 2022), *https://abcnews.go.com/Health/abortion-restrictions-disproportionately-impact-people-color/story?id=84467809;* Dulce Gonzalez et al., Robert Wood Johnson Foundation, ''Perceptions of Discrimination and Unfair Judgment While Seeking Health Care'' (Mar. 31,

underserved and marginalized individuals are also more likely to be the subjects of investigations and other activities to impose liability for seeking or obtaining reproductive health care, even where such health care is lawful under the circumstances in which it is provided.[159] They are also less likely to have adequate access to legal counsel to defend themselves from such actions.[160] These inequities may be exacerbated where individuals face multiple, intersecting disparities, such as having limited English proficiency [161] and disability.[162] Such individuals are thus especially likely to be concerned that information they share with their health care providers about their reproductive health care will not remain private. This is particularly true considering the historic lack of trust, negative experiences, and fear of discrimination that many members of historically underrepresented and marginalized communities and communities of color have in the health care system; [163] such individuals are more likely to be deterred from seeking or obtaining health care—or from giving their health care providers full information.

Congress contemplated that the Department would need to modify standards adopted under HIPAA's Administrative Simplification provisions and directed the Secretary to review standards adopted under 42 U.S.C. 1320d-2 periodically.[164] In accordance with this directive and based on the Department's expertise and analysis and the recent developments in the legal landscape, there is a compelling need to provide additional protections to PHI about lawful reproductive health care. Accordingly, consistent with Congress's directions to the Department, in HIPAA, as amended by Genetic Information Nondiscrimination Act (GINA) and the HITECH Act, to establish standards and requirements for the electronic transmission of certain health information, including the privacy thereof, for the development of a health information system, the Department is restricting certain uses and disclosures of PHI for particular non-health care purposes to provide such protections.

C. To Protect the Trust Between Individuals and Health Care Providers, the Department Is Restricting Certain Uses and Disclosures of PHI for Particular Non-Health Care Purposes

As discussed above, Congress enacted HIPAA to improve the efficiency and effectiveness of the health care system, which includes ensuring that individuals have trust in the health care system. Congress also directed the Department to develop standards with respect to the privacy of IIHI as part of its decision to encourage the development of a health information system. To preserve such trust, and to encourage the development and use of a nationwide health information system, it is appropriate and necessary for Federal law and policy to protect the confidentiality of medical records, especially those that are highly sensitive. Accordingly, to protect the trust between individuals and health care providers, this rule restricts certain uses and disclosures of PHI for particular non-health care purposes, *i.e.,* for using or disclosing PHI to conduct a criminal, civil, or administrative investigation into or to impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating

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2021), *https://www.rwjf.org/en/insights/our-research/2021/03/perceptions-of-discrimination-and-unfair-judgment-while-seeking-health-care.html;* Susan A. Cohen, ''Abortion and Women of Color: The Bigger Picture,'' 11 Guttmacher Pol'y Rev. (Aug. 6, 2008), *https://www.guttmacher.org/gpr/2008/08/abortion-and-women-color-bigger-picture;* ''The Disproportionate Harm of Abortion Bans: Spotlight on Dobbs v. Jackson Women's Health,'' Center for Reproductive Rights (Nov. 29, 2021), *https://reproductiverights.org/supreme-court-case-mississippi-abortion-ban-disproportionate-harm/* (''Abuses such as forced sterilization of Black, Indigenous, and other people of color and individuals with disabilities specifically exacerbate medical mistrust within reproductive healthcare.'').

[159] *See* Brief of Amici Curiae for Organizations Dedicated to the Fight for Reproductive Justice—Mississippi in Action, et al. at *35–36, *Dobbs,* 597 U.S. 215 (discussing the likelihood that individuals, particularly those from marginalized communities who terminate their pregnancies and anyone who assists them may be disproportionally likely to face criminal investigation or arrest, given the rates of incarceration of persons from such communities.); *see also* Elizabeth Yuko, ''Women of Color Will Face More Criminalized Pregnancies in Post-'*Roe*' America,'' Rolling Stone (Jul. 7, 2020) (''Historically, we've seen the criminalization of people of color, young people, and people with lower incomes who've had miscarriages and other types of pregnancy losses that the state deemed were their fault [. . .] These groups are the most likely to be reported to law enforcement and investigated''); *see also* Sentencing Project, State-by-State Data, *https://www.sentencingproject.org/research/us-criminal-justice-data/* (last visited Feb. 16, 2024) (U.S. Total: Imprisonment rate per 100,000 residents—355; Black/White disparity—4.8:1; Latinx/White disparity—1.3:1); Racial Disparities in Incarceration, Vera Institute of Justice (Aug. 21, 2023), *https://trends.vera.org/* (Prison population rate per 100,000 residents ages 15 to 64. U.S. total incarceration rate 2021 Q2—298, Asian American/Pacific Islander incarceration rate 2021 Q2—100, Black/African American incarceration rate 2021 Q2—1,310, Latinx incarceration rate 2021 Q2—671, Native American incarceration rate 2021 Q2—1,021, White incarceration rate 2021 Q2—281).

[160] *See* Columbia Law Sch. Hum. Rts. Inst. & and Ne. Univ. Sch. of Law Program on Hum. Rts. and the Glob. Econ.,'' Equal Access to Justice: Ensuring Meaningful Access to Counsel in Civil Cases, Including Immigration Proceedings'' (July 2014), *https://hri.law.columbia.edu/sites/default/files/publications/equal_access_to_justice_-_cerd_shadow_report.pdf. See also* Lauren Hoffman et al., Ctr. For Am. Progress, ''Report: State Abortion Bans Will Harm Women and Families' Economic Security Across the US'' (Aug. 25, 2022), *https://www.americanprogress.org/article/state-abortion-bans-will-harm-women-and-families-economic-security-across-the-us/.*

[161] *See* Myasar Ihmud, ''Lost in Translation: Language Barriers to Accessing Justice in the American Court System,'' UIC Law Review (2023) (discussing ''access to justice for [limited English proficient (LEP)] individuals is hindered because they are unable to communicate with the court or understand the proceedings. Case law shows that, when unable to communicate with the court, LEP litigants are unable to defend themselves appropriately in criminal or immigration hearings, protect their homes, or keep custody of their children.''), *https://repository.law.uic.edu/cgi/viewcontent.cgi?article=2908&context=lawreview; see also* ''Language Access & Cultural Sensitivity,'' Legal Services Corporation (last visited Feb. 21, 2024) (describing how legal aid organizations should plan for providing meaningful access to language services. As of 2013, ''close to 25 million people, about 8 percent of the population, has limited English proficiency.''), *https://www.lsc.gov/i-am-grantee/model-practices-innovations/language-access-cultural-sensitivity.*

[162] *See, e.g.,* Gautam Gulati et al., ''The experience of law enforcement officers interfacing with suspects who have an intellectual disability—A systematic review,'' International Journal of Law and Psychiatry (Sept.-Oct. 2020) (''It is not uncommon for people with [intellectual disability] to be suspects or accused persons when interfacing with Law Enforcement Officers (LEOs) and therefore face arrest, interview and/or custody.''), *https://www.sciencedirect.com/science/article/pii/S016025272030073X.*

[163] *See* Leslie Read et al., The Deloitte Ctr. for Health Solutions, ''Rebuilding Trust in Health Care: What Do Consumers Want—and Need—Organizations to Do?,'' at 3 (Aug. 5, 2021) (With focus groups of 525 individuals in the United States who identify as Black, Hispanic, Asian, or Native American, ''[f]ifty-five percent reported a negative experience where they lost trust in a health care provider.''), *https://www2.deloitte.com/us/en/insights/industry/health-care/trust-in-health-care-system.html;* Liz Hamel et al., Kaiser Family Foundation, ''The Undefeated Survey on Race and Health,'' at 23 (Oct. 2020) (Percent who say they can trust the health care system to do what is right for them or their community almost all of the time or most of the time: Black adults: 44%; Hispanic adults: 50%; White adults: 55%), *https://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf;* U.S. Dep't of Health and Hum. Servs., Assistant Sec'y for Pol. & Eval., Off. of Health Pol., ''Issue Brief: Health Insurance Coverage and Access to Care for LGBTQ+ Individuals: Current Trends and Key Challenges,'' at 9 (June 2021) (A 2021 survey found that 18 percent of LGBTQ+ individuals reported avoiding going to a doctor or seeking health care out of concern that they would face discrimination or poor treatment because of their sexual orientation or gender identity.), *https://aspe.hhs.gov/sites/default/files/2021-07/lgbt-health-ib.pdf;* Abigail A. Sewell, ''Disaggregating Ethnoracial Disparities in Physician Trust,'' Soc. Science Rsch. (Nov. 2015), *https://pubmed.ncbi.nlm.nih.gov/26463531/;* Irena Stepanikova et al., ''Patients' Race, Ethnicity, Language, and Trust in a Physician,'' J. of Health and Soc. Behavior (Dec. 2006), *https://pubmed.ncbi.nlm.nih.gov/17240927/.*

[164] Congress' directions regarding the issuance of standards for the privacy of IIHI are codified at 42 U.S.C. 1320d–2 note. *See also* 45 CFR 160.104(a).

lawful reproductive health care, or to identify any person to initiate such activities.

Information about reproductive health care is particularly sensitive and requires heightened privacy protection. The Department's approach is consistent with efforts across the Federal Government. For example, the Department of Defense (DOD) has recognized such privacy concerns. In a memorandum to DOD leaders, the Secretary of Defense directed the DOD to ''[e]stablish additional privacy protections for reproductive health care information'' for service members and ''[d]isseminate guidance that directs Department of Defense health care providers that they may not notify or disclose reproductive health information to commanders unless this presumption is overcome by specific exceptions set forth in policy.'' [165] The Federal Trade Commission (FTC) has also recognized that information about personal reproductive matters is ''particularly sensitive'' and has committed to using the full scope of its authorities to protect consumers' privacy, including the privacy of their health information and other sensitive data.[166] In business guidance, the FTC explained that ''[t]he exposure of health information and medical conditions, especially data related to sexual activity or reproductive health, may subject people to discrimination, stigma, mental anguish, or other serious harms.'' [167]

As discussed above, the Department has long provided special protections for psychotherapy notes because of the sensitivity around this information. However, unlike psychotherapy notes, which by their very nature are easily segregated, reproductive health information is not easily segregated. Additionally, regulated entities generally do not have the ability to segment certain PHI such that regulated entities could afford special protections for specific categories of PHI.[168] Where such technology is available, it is generally cost prohibitive and burdensome to implement.[169] Therefore, the Department did not propose, and is not finalizing, a newly defined subset of PHI. Creating such a subset would create barriers to disclosing PHI for care coordination because the PHI would need to be segregated from the remaining medical record. Instead, consistent with the Privacy Rule's longstanding overall approach,[170] the Department is finalizing a purpose-based prohibition against certain uses and disclosures. This rule seeks to protect individuals' privacy interests in their PHI about reproductive health care and the interests of society in an effective health care system by enabling individuals and licensed health care professionals to make decisions about reproductive health care based on a complete medical record, while balancing those interests with other interests of society in obtaining PHI for certain non-health care purposes.

To assist in effectuating this prohibition, the Department is also requiring regulated entities to obtain an attestation in certain circumstances from the person requesting the use or disclosure stating that the use or disclosure is not for a prohibited purpose. A person (including a regulated entity or someone who requests PHI) who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual would be subject to potential criminal liability.[171] Thus, a person who knowingly and in violation of HIPAA falsifies an attestation (*e.g.,* makes a material misrepresentation about the intended uses of the PHI requested) to obtain (or cause to be disclosed) an individual's IIHI could be subject to the criminal penalties provided by the statute.[172] Additionally, a regulated entity is subject to potential civil penalties for violations of the HIPAA Rules, including a failure to obtain a valid attestation before disclosing PHI, where an attestation is required.[173] The purpose-based prohibition, in concert with the attestation, will restrict the use and disclosure of PHI about lawful reproductive health care where the use or disclosure could harm HIPAA's overall goals of increasing trust in the health care system, improving health care quality, and protecting individual privacy. At the same time, it will allow uses and disclosures that either support those goals or do not substantially interfere with their achievement.

Consistent with the Privacy Rule's approach, the Department is clarifying that the purpose-based prohibition applies only in certain circumstances, recognizing the interests of both the Federal Government and states while also protecting the information privacy interests of persons who seek, obtain, provide, or facilitate lawful reproductive health care. Thus, the Department is finalizing a Rule of

[165] Dep't of Defense, Memorandum Re: Ensuring Access to Reproductive Health Care, at 1 (Oct. 20, 2022) (removed emphasis on ''not'' in original), *https://media.defense.gov/2022/Oct/20/2003099747/-1/-1/1/MEMORANDUM-ENSURING-ACCESS-TO-REPRODUCTIVE-HEALTH-CARE.PDF.*

[166] Kristin Cohen, ''Location, health, and other sensitive information: FTC committed to fully enforcing the law against illegal use and sharing of highly sensitive data'', Federal Trade Commission Business Blog (July 11, 2022), *https://www.ftc.gov/business-guidance/blog/2022/07/location-health-and-other-sensitive-information-ftc-committed-fully-enforcing-law-against-illegal* (last accessed Nov. 15, 2022).

[167] *Id.*

[168] *See* Daniel M. Walker et al., ''Interoperability in a Post-*Roe* Era Sustaining Progress While Protecting Reproductive Health Information,'' JAMA (Nov. 1, 2022) (discussing that segregation of records for reproductive health care is more difficult than for SUD treatment records because ''reproductive health services are often provided in the same settings as other primary and acute care and thus could be inferred or directly reflected in many parts of the record.''), *https://jamanetwork-com.ezproxyhhs.nihlibrary.nih.gov/journals/jama/fullarticle/2797865; See, e.g.,* 87 FR 74216, 74221 (Dec. 2, 2022) (noting that 42 CFR part 2 previously resulted in the separation of SUD treatment records previous from other health records, which led to the creation of data ''silos'' that hampered the integration of SUD treatment records into covered entities' electronic record systems and billing processes. When considering amendments to the relevant statute, some lawmakers argued that the silos perpetuated negative stereotypes about persons with SUD and inhibited coordination of care during the opioid epidemic.). *See also* Health Info. Tech. Advisory Comm., ''Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2019,'' 2019 ONC Ann. Rep., at 37 (Feb. 19, 2020), *https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf* (''The new certification criteria that support the sharing of data via third-party apps will help advance the use of data segmentation, but adoption of this capability by the industry is not yet widespread.'').

[169] *See* 88 FR 23746, 23898 (Apr. 18, 2023) (explaining that while there are standards for security labels for document-based exchange that the Office of the National Coordinator for Health Information Technology (ONC) adopted in full in 2020 for the criteria in 45 CFR 170.315(b)(7) and (b)(8) to support the application of security labels at a granular level for sending in and receiving, standards to define the technical requirements for the actions described by the security label vocabularies do not yet exist. In the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule, published in 2020, ONC estimated a cost of the certification criteria and standards adopted for security labels in 45 CFR 170.315(b)(7) and (b)(8). The Department estimated the total cost to developers could range from $2,910,400 to $6,933,600 and that it would be a onetime cost. (85 FR 25926) The criteria do not include the ability for health IT to take the actions described by the security labels. Additionally, ONC did not require that health IT be certified to the criteria described above, making it essentially voluntary. Accordingly, the estimates for health IT developer and health care provider costs were likely significantly lower than they would have been if health IT were required to be certified to the criteria for participation. Thus, the total cost of implementing full segmentation capabilities is likely substantially higher than the per-product cost estimates provided by the Department in that rule). *See also* 88 FR 23746, 23875 (Apr. 18, 2023) (discussing examples of challenges or technical limitations to electronic health information segmentation that have been described to ONC).

[170] *See* 64 FR 59918, at 59924, 59939, and 59955 (Nov. 3, 1999).

[171] *See* 42 U.S.C. 1320d–6(a).

[172] *See* 42 U.S.C. 1320d–6(b).

[173] *See* 42 U.S.C. 1320d–5. *See also* 45 CFR part 160, subparts A, D, and E.

Applicability that balances the privacy interests of individuals and the interests of society in an effective health care system with those of society in the use of PHI for other non-health care purposes by limiting the new prohibition to certain circumstances.

The Department's experience administering the Privacy Rule, research cited below, our assessment of the needs of individuals and health care providers in light of recent developments to the legal landscape, public comments, and the Regulatory Impact Analysis, in Section VI below, all provide support for the changes finalized in this rulemaking. These changes will improve individuals' confidence in the confidentiality of their PHI and their trust in the health care system, creating myriad benefits for the health care system. Balancing the privacy interests of individuals and the use of PHI for other societal priorities will continue to support an effective health care system, as Congress intended. This final rule will deter the creation of inaccurate and incomplete medical records, which will help to support the provision of appropriate lawful health care. Health care providers base their treatment recommendations on PHI contained within existing medical records, as well as information shared with them directly by the individual. Thus, where individuals withhold information from their health care providers about lawful health care, health care providers may not be in possession of all of the necessary information to make an informed recommendation for an appropriate treatment plan, which may result in negative health outcomes at both the individual and population level. It will also improve the confidence of individuals, including among the Nation's most vulnerable communities, that they can securely seek or obtain or share that they sought or obtained lawful reproductive health care without that information being used or disclosed for the purpose of investigating or imposing liability on them for seeking or obtaining that lawful health care. By improving individuals' confidence and trust in their relationships with their health care providers, it will make individuals more likely to, for example, comply with preventative health screening recommendations, which will protect against a decline in individual and population health outcomes related to missed preventative health screenings. Additional intangible benefits from increased privacy protections in this area include enhanced support for survivors of rape, incest, and sex trafficking. The new attestation requirement discussed in greater detail below will help to assure regulated entities of their ability to operationalize these changes and avoid exposure to HIPAA liability for impermissible disclosures.

IV. General Discussion of Public Comments

The Department received more than 25,900 comments in response to its proposed rule. Overall, these comments represent the views of approximately 51,500 individuals and 350 organizations. Slightly more than half of the individuals and organizations who shared their views expressed general support for the 2023 Privacy Rule NPRM and its objectives. Less than one percent expressed mixed views. Organizational commenters included professional and trade associations, including those representing medical professionals, health plans, health care providers, health information management professionals, health information management system vendors, release-of-information vendors, employers, epidemiologists, and attorneys. The Department also received comments from advocacy organizations, including those representing patients, privacy advocates, faith-based organizations, and civil rights organizations. The NCVHS also provided comments, as did members of Congress, state, local, and Tribal government officials and public health authorities. Other commenters included health care systems, hospitals, and health care professionals.

A. General Comments in Support of the Proposed Rule

Comment: Many commenters expressed general support for the proposed rule and urged the Department to protect the privacy of individuals by limiting uses and disclosures of PHI for certain purposes where the use or disclosure of information is about reproductive health care that is lawful under the circumstances in which such health care is provided.

Many health care providers and individuals emphasized the importance of trusting relationships between individuals and their health care providers. According to individual commenters, a trusting relationship permits individuals to participate in sensitive and difficult conversations with their health care providers and enables health care providers to furnish high-quality and appropriate health care and to maintain accurate and complete medical records, including records that contain information about reproductive health care.

Many organizations also submitted comments that expressed agreement with the Department's position on the importance of the relationship between HIPAA and the HIPAA Rules and trust between individuals and health care providers. For example, an organization commented that privacy has long been a ''hallmark'' of medical care and agreed with the Department that Congress recognized this principle when it enacted HIPAA. Some organizations commented that the HIPAA framework of law and rules provides individuals with the necessary trust and confidence to seek reproductive health care without fear of being prosecuted or targeted by law enforcement, including in medical emergencies.

Other commenters stated that a trusting confidential relationship between an individual and a health care provider is an essential prerequisite to the delivery of high-quality health care. They also asserted that protective privacy laws, including HIPAA, help to ensure that individuals do not forgo health care.

Many individuals asserted that the proposed safeguards are urgently needed to provide individuals with the confidence to seek health care. According to the commenters, the proposal would increase the likelihood that pregnant individuals would receive essential health care, thus improving their overall well-being. One commenter expressed support for the proposal because they believe people should not be held liable or face punishment for seeking, obtaining, providing, or facilitating lawful health care. Another commenter expressed concerns that the increase in state legislation targeting reproductive health care has placed significant burdens on physicians and increased the risk of maternal morbidity and mortality for individuals.

A few commenters also expressed agreement with the Department's assertion that the proposed restrictions would clarify legal obligations of regulated entities with respect to the disclosure of PHI for certain non-health related purposes and would enable persons requesting PHI, including health plans, to better understand when such disclosures are permitted.

Response: The Department appreciates these comments and is finalizing the proposed rule with modification, as described in greater detail below. Consistent with HIPAA's goals, this final rule will support the development and maintenance of trust between individuals and their health care providers, encouraging individuals

to be forthright with health care providers regarding their health history and providing valuable clarity to the regulated community and individuals concerning their privacy rights with respect to lawfully provided health care. In so doing, the Department helps to support access to health care by increasing individuals' confidence in the privacy of their PHI about lawfully provided reproductive health care. We are taking these actions as a result of our ongoing evaluation of the environment, including the legal landscape, and consistent with the Privacy Rule's longstanding balance of individual privacy and societal interests in PHI for non-health care purposes.

Comment: A wide cross-section of commenters, including individuals, health care providers, patient advocacy organizations, reproductive rights organizations, state law enforcement agencies, and others all agreed that individuals who frequently experience discrimination generally also experience it when seeking health care.

Many of these commenters urged the Department to recognize that there is a trust deficit in relationships between individuals and health care providers in communities that frequently experience discrimination. Many commenters cited scholarly journals and research articles showing that women of color especially suffer poorer medical outcomes, including higher maternal mortality and denial of medical interventions or treatments.

Commenters who answered the Department's request for comment about whether members of ''historically underserved and minority communities'' are more likely to be the subject of investigations into or proceedings against persons in connection with seeking, obtaining, providing, or facilitating lawful reproductive health care unanimously responded in the affirmative. Some commenters expressed concern about the current legal environment's disproportionately negative effect on the privacy of women and members of marginalized and historically underserved communities and communities of color, such as immigrants who might avoid obtaining health care because of fears that their PHI could be shared with government officials. In general, commenters encouraged the Department to consider the likely negative implications of reduced health information privacy when combined with these disparities on health outcomes for members of marginalized and historically underserved communities and communities of color when crafting the final rule.

Some commenters expressed concern about the current legal environment's disproportionately negative effect on the privacy of members of marginalized and historically underserved communities and communities of color, such as women of color, immigrants and American Indians and Alaska Natives, who might withhold information from health care providers or avoid obtaining health care because of fears that their PHI could be shared with government officials or used to investigate or impose liability on them.

Among commenters that addressed this topic, many supported the Department's proposed purpose-based prohibition. Commenters stated that the proposed rule would help to mitigate medical mistrust of individuals in marginalized and historically underserved communities and communities of color and reduce the racial disparities that result from the increased criminalization of reproductive health care.

Several commenters also addressed the issue of the availability of legal counsel among these communities. A few commenters asserted that individuals who are members of marginalized and historically underserved communities and communities of color are less likely to have access to legal counsel, despite being more likely to be subjects of investigations into or proceedings against persons in connection with obtaining providing or facilitating lawful sexual and reproductive health care and cited to related studies.

Response: We appreciate these comments and thank commenters for sharing these important considerations. As we discussed in the 2023 Privacy Rule NPRM and again here, the experiences of individuals from communities that have been historically underserved, marginalized, or subject to discrimination or systemic disadvantage by virtue of their race, disability, social or economic status, geographic location, or environment have significant negative effects on their relationships with health care providers and their willingness to seek necessary health care. We agree that the current legal landscape has exacerbated the health inequities that these individuals encounter when seeking reproductive health care services. The Department expects that the steps we have taken in this rule will meaningfully strengthen the privacy of PHI about lawful reproductive health care, and as a result, will help to mitigate the exacerbation of health disparities for members of marginalized and historically underserved communities and communities of color.

The Department is actively working to reduce health disparities. In recent months, we released a new plan to address language barriers and strengthen language access in health care,[174] and issued three proposed rules to address health disparities: one to revise existing regulations to strengthen prohibitions against discrimination on the basis of a disability in health care and human services programs; [175] another to issue new regulations to advance non-discrimination in health and human service programs for the LGBTQI+ community; [176] and a third to revise existing regulations to prohibit discrimination on the basis of race, color, national origin, sex, age, and disability in a range of health programs.[177] The Department will continue to work to address these concerns, ensure that individuals have access to and do not forgo necessary health care, and build individuals' trust that health care providers can and will protect the privacy of individuals' sensitive health information.

Comment: A few commenters agreed with the Department's position that the proposed rule would appropriately protect individuals against growing threats to their privacy with respect to PHI about reproductive health care while permitting states to conduct law enforcement activities.

Response: The Privacy Rule always has and continues to balance privacy interests and other societal interests by permitting disclosures of PHI to support

[174] Press Release, ''Breaking Language Barriers: Biden-Harris Administration Announces New Plan to Address Language Barriers and Strengthen Language Access,'' U.S. Dep't of Health and Human Servs. (Nov. 15, 2023), *https://www.hhs.gov/about/news/2023/11/15/breaking-language-barriers-biden-harris-administration-announces-new-plan-address-language-barriers-strengthen-language-access.html.*

[175] Press Release, ''HHS Issues New Proposed Rule to Strengthen Prohibitions Against Discrimination on the Basis of a Disability in Health Care and Human Services Programs,'' U.S. Dep't of Health and Human Servs. (Sept. 7, 2023), *https://www.hhs.gov/about/news/2023/09/07/hhs-issues-new-proposed-rule-to-strengthen-prohibitions-against-discrimination-on-basis-of-disability-in-health-care-and-human-services-programs.html.*

[176] Press Release, ''HHS Issues Proposed Rule to Advance Non-discrimination in Health and Human Service Programs for LGBTQI+ Community,'' U.S. Dep't of Health and Human Servs. (July 11, 2023), *https://www.hhs.gov/about/news/2023/07/11/hhs-issues-proposed-rule-advance-non-discrimination-health-human-service-programs-lgbtqi-community.html.*

[177] Press Release, ''HHS Announces Proposed Rule to Strengthen Nondiscrimination in Health Care,'' U.S. Dep't of Health and Human Servs. (July 25, 2022), *https://www.hhs.gov/about/news/2022/07/25/hhs-announces-proposed-rule-to-strengthen-nondiscrimination-in-health-care.html.*

public policy goals, including disclosures to support certain criminal, civil, and administrative law enforcement activities; the operation of courts and tribunals; health oversight activities; the duties of coroners and medical examiners; and the reporting of child abuse, domestic violence, and neglect to appropriate authorities. We appreciate these comments that recognized the growing threat to the privacy of PHI and the need to strike an appropriate balance between ensuring health care privacy and conducting law enforcement activities. We are finalizing the proposed rule with modification as described in greater detail below.

B. General Comments in Opposition to the Proposed Rule

Comment: Several commenters generally opposed the proposed rule because of their opposition to certain types of reproductive health care. Many commenters opposed the proposed rule generally because they believed that it would harm women and children. Other commenters expressed concern that the proposals would increase administrative burdens and costs for health care providers; impede parental rights; prevent mandatory reporting of child abuse or abuse, domestic violence, and neglect; infringe upon states' rights; thwart law enforcement investigations; inhibit disclosures for public health activities; and protect those who engage in unlawful activities.

Response: The modifications to the Privacy Rule in this final rule directly advance Congress' directive in HIPAA to improve the efficiency and effectiveness of the health care system by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information,[178] including a standard for the privacy of IIHI that, among other things, addresses the ''uses and disclosures of such information that should be authorized or required.'' [179] As discussed in greater detail elsewhere in this final rule, a trusting relationship between individuals and health care providers is the foundation of effective health care. A primary goal of the Privacy Rule is to ensure the privacy of an individual's PHI while permitting necessary uses and disclosures of PHI that enable high-quality health care and protect the health and well-being of all individuals, including women and children, and the public.

From the outset, the Department structured the Privacy Rule to ensure that individuals do not forgo lawful health care when needed—or withhold important information from their health care providers that may affect the quality of health care they receive out of a fear that their sensitive information would be revealed outside of their relationship with their health care provider. The Department has long been committed to protecting the privacy of PHI and providing the opportunity for an authentic, trusting relationship between individuals and health care providers. As we discussed in the 2023 Privacy Rule NPRM and again here, this final rule will help engender trust between individuals and health care providers and confidence in the health care system. We believe that this confidence will eliminate some of the burdens health care providers face in providing high-quality health care, encourage health care providers to accurately document PHI in an individual's medical record, and encourage individuals to provide health care providers with their complete and accurate health history, all of which will ultimately support better health outcomes. Nothing in this final rule sets forth a particular standard of care or affects the ability of health care providers to exercise their professional judgment.

This final rule protects the relationship between individuals and health care providers by protecting the privacy of PHI in circumstances where recent legal developments have increased concerns about that information being used and disclosed to harm persons who seek, obtain, provide, or facilitate reproductive health care under circumstances in which such health care is lawful, while continuing to permit uses and disclosures that confer other social benefits. It is narrowly tailored and respects the interests of both states and the Department. The final rule continues to permit regulated entities to use or disclose PHI to comply with certain mandatory reporting laws, for public health activities, and for law enforcement purposes when the uses and disclosures are compliant with the applicable provisions of the Privacy Rule.

Further, consistent with the longstanding operation of the Privacy Rule, this final rule requires that, in certain circumstances, regulated entities obtain information from persons requesting PHI, such as law enforcement, before the regulated entities may use or disclose the requested PHI. The Department recognizes that this final rule may increase the burden on those persons making requests for PHI, such as federal and state law enforcement officials, by requiring, in certain circumstances, that regulated entities obtain more information from such persons than previously required, and may, at times, prevent regulated entities from using or disclosing PHI that they previously would have been permitted to use or disclose. For example, the Department recognizes that situations may arise where a regulated entity reasonably determines that reproductive health care was lawfully provided, while at the same time, the person requesting the PHI (*e.g.,* law enforcement) reasonably believes otherwise. In such circumstances, where the regulated entity provided the reproductive health care, and upon receiving a request for the PHI for a purpose that implicates the prohibition, reasonably determines that the provision of reproductive health care was lawful, the final rule would prohibit the regulated entity from disclosing PHI for certain types of investigations into the provision of such health care. This constitutes a change from the current Privacy Rule, under which a regulated entity is permitted, but not required, to make a use or disclosure under 45 CFR 164.512(f) of information that is ''relevant and material to a legitimate'' law enforcement inquiry, provided that certain conditions are met; these conditions include, for example, that the request is specific and limited in scope to the extent reasonably practicable given the purpose for which the information is sought.[180] Similarly, the Department acknowledges that, where the regulated entity did not provide the reproductive health care that is the subject of the investigation or imposition of liability, the Rule of Applicability and Presumption, discussed below, may require regulated entities to obtain additional information, that is, factual information that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided, from persons requesting PHI before using or disclosing the requested PHI.

Consistent with HIPAA and the Department's longstanding approach in the Privacy Rule, the Department is finalizing an approach that strikes an appropriate balance between the privacy interests of individuals and the interests of law enforcement, and private parties afforded legal rights of action, in

[178] *See* 42 U.S.C. 1320d note.

[179] *See* 42 U.S.C. 1320d-2 note.

[180] *See* 45 CFR 164.512(f)(1)(ii)(C).

obtaining PHI for certain non-health care purposes. While this approach may adversely affect particular interests of law enforcement, and private parties afforded legal rights of action, in some cases, the Department believes that the final rule best balances these competing interests by enhancing privacy protections without unduly interfering with legitimate law enforcement activities and does so in a manner that is consistent with the approach taken elsewhere in the Privacy Rule. As explained above, individual privacy interests are especially strong where individuals seek lawful reproductive health care. In particular, individuals may forgo lawful health care or avoid disclosing previous lawful health care to providers because they fear that their PHI will be disclosed. The Department believes these concerns are exacerbated by the prospect of state investigations into, and resulting intimidation and criminalization of, health care providers for providing lawful reproductive health care, as well as state laws encouraging state residents to sue persons who facilitate individuals' access to legal health care. The final rule addresses these interests by protecting privacy in situations where the reproductive health care at issue is especially likely to be lawful under the circumstances in which such health care was provided. Where a regulated entity receives a request for PHI about reproductive health care that the regulated entity provided, such health care is likely to be lawful where the regulated entity reasonably determines, based on all information in its possession, that such health care was lawful under the circumstances in which it was provided. Similarly, where a regulated entity receives a request for PHI about reproductive health care that the regulated entity did not provide, such health care is likely to be lawful where law enforcement is unable to provide factual information that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

The Department recognizes that, in some cases, the approach adopted in this final rule may inadvertently prohibit the disclosure of PHI about reproductive health care that was unlawfully provided, such as where a health care provider reasonably but incorrectly determines that the reproductive health care it provided was lawful under the circumstances in which such health care was provided. This is similar to how the Privacy Rule has always potentially prevented the use or disclosure of PHI that could be useful to law enforcement in certain circumstances because the request for PHI does not meet the conditions of the applicable permission. Nevertheless, given the importance of protecting individual privacy in this area, the Department has determined that the final rule adopts the appropriate balance between individual privacy and the interests of other persons, such as law enforcement. Specifically, the Department believes that the benefits to individual privacy of a broadly protective rule outweigh the benefits to societal interests in the use or disclosure of PHI from a narrower rule. While a narrower rule would more broadly permit disclosures related to PHI that might concern reproductive health care that is not lawful under the circumstances in which it is provided, such a rule would inadvertently permit more disclosures of PHI about lawful reproductive health care. Accordingly, the Department concludes that the final rule must be sufficiently broad to protect against such disclosures, given the paramount importance of individual privacy in this area.

Moreover, as explained above, individual privacy interests are paramount to promote free and open communication between individuals and their health care providers, thereby ensuring that individuals receive high-quality care based on their accurate medical history. Society has long recognized that information exchanged as part of a specific relationship for which trust is paramount should be entitled to heightened protection (*e.g.,* marital privilege, attorney-client privilege, doctor-patient privilege). Similarly, this final rule seeks to address situations where privacy interests are especially important, based both on the content of the information that is protected from disclosure (concerning lawful reproductive health care) and the context in which that information is shared (concerning a trust-based relationship between individuals and their health care providers).

In contrast, the potential adverse effects of this final rule on other interests, such as those of law enforcement, are limited by the narrow scope of this final rule. This final rule does not seek to prohibit disclosures of PHI where the request is for reasons other than investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. For example, as explained in the NPRM and below, the final rule does not prohibit the use or disclosure of PHI for investigating alleged violations of the Federal False Claims Act or a state equivalent; conducting an audit by an Inspector General aimed at protecting the integrity of the Medicare or Medicaid program where the audit is not inconsistent with this final rule; investigating alleged violations of Federal nondiscrimination laws or abusive conduct, such as sexual assault, that occur in connection with reproductive health care; or determining whether a person or entity violated 18 U.S.C. 248 regarding freedom of access to clinic entrances. In each of these cases, the request is not made for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

Even when the request is for the purpose of investigating or imposing liability on the mere act of seeking, obtaining, providing, or facilitating reproductive health care, this final rule does not seek to prohibit disclosures of PHI about reproductive health care that is not lawful under the circumstances in which it was provided. Thus, in most situations involving reproductive health care that is not lawful under the circumstances in which it is provided, this final rule will not prevent the use or disclosure of PHI to investigate or impose liability on persons for such legal violations, provided such disclosures are otherwise permitted by the Privacy Rule. Moreover, where a regulated entity did not provide the reproductive health care at issue, this final rule prohibits the use or disclosure of PHI where the person making the request does not provide sufficient information to overcome the presumption of legality. In such cases, law enforcement agencies and other persons have a reduced interest in obtaining such PHI where the information does not demonstrate to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided.

This final rule does not prohibit the use or disclosure of PHI to investigate or impose liability on persons where reproductive health care is unlawful under the circumstances in which it is provided. Instead, the final rule prohibits the use or disclosure of PHI in narrowly tailored circumstances (*i.e.,* where the use or disclosure is to conduct an investigation or impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that

is lawful under the circumstances in which such health care is provided, or to identify a person for such activities). For example, once this final rule is in effect, a covered health care provider may still disclose PHI to a medical licensing board investigating a health care provider's actions related to their obligation to report suspected elder abuse, assuming the disclosure meets the conditions of an applicable Privacy Rule permission. This is because the final rule does not bar the use or disclosure of PHI for health oversight purposes, which is unrelated to the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

Additionally, even where the final rule prohibits the use or disclosure of PHI to investigate potentially unlawful reproductive health care (*i.e.,* where a regulated entity reasonably determines that the reproductive health care they provided was lawful, or where the presumption of legality is not overcome), law enforcement retains other ways of investigating reproductive health care that they suspect may have been unlawfully provided. For example, law enforcement retains the use of other traditional and otherwise lawful investigatory means for obtaining information, such as conducting witness interviews and accessing other sources of information not covered by HIPAA. The final rule is therefore tailored to protect the relationship between individuals and their health care providers specifically, while leaving unaffected law enforcement's ability to conduct investigations using information from other sources.

With respect to commenters' concerns about parental rights, this final rule also does not interfere with the ability of states to define the nature of the relationship between a minor and a parent or guardian.

Comment: A few commenters that expressed negative views asserted that the proposed rule exceeded the Department's statutory authority under HIPAA or was beyond the Department's rulemaking authority. Some commenters stated that the rulemaking was arbitrary and capricious and would make it difficult for law enforcement to investigate reproductive health care and engage in health oversight activities and would require health care providers to provide certain types of health care against which they have objections. Some commenters expressed concern about the balance of powers between the states and the federal government. Other commenters suggested that the proposals preempt state laws serving public health, safety, and welfare.

Response: As discussed above, Congress explicitly stated that the purpose of HIPAA's Administrative Simplification provisions was to improve the efficiency and effectiveness of the health care system. For the health care system to be effective, individuals must trust that information that they share with health care providers about lawful health care will remain private. Accordingly, since their inception, the HIPAA Rules have required that regulated entities narrowly tailor disclosures to law enforcement to protect an individual's privacy.[181] While the Department is adopting an approach in this final rule that is more protective of privacy interests than the current Privacy Rule in certain circumstances, these changes are necessary to appropriately balance privacy interests and the interests of law enforcement, and private parties afforded legal rights of action, in light of the changing legal environment. This is discussed in detail above. In both the 2023 Privacy Rule NPRM and this final rule, the Department cited to multiple studies documenting the real-world harm to health and health care in the changing legal environment. As explained above, the Department acknowledges that this final rule may affect certain state interests in obtaining PHI to investigate potentially unlawful reproductive health care, but the Department has tailored the final rule to strike the appropriate balance between privacy interests and state interests. This final rule limits the potential harm to individuals, health care providers, and others resulting from the disclosure of PHI to investigate or punish individuals for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. We emphasize that nothing in this rule or any of the HIPAA Rules requires a health care provider to provide any type of health care, including any type of reproductive health care.

Comment: Several commenters asserted that the proposed rule would impede states' enforcement of their own laws, including those concerning sexual assault and sex trafficking. Many commenters opposed the proposed rule because they believed it would inhibit the ability of states to investigate or enforce laws prohibiting minors from obtaining certain types of health care and prevent the commenters from reporting minors who they believe are coerced into obtaining such health care to authorities.

Response: This rule does not prohibit the disclosure of PHI for investigating allegations of or imposing liability for sexual assault, sex trafficking, or coercing minors into obtaining reproductive health care. Rather, this final rule modifies the existing HIPAA Privacy Rule standards by prohibiting uses and disclosures of PHI to investigate or impose liability on individuals, regulated entities, or other persons for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such reproductive health care is provided, or to identify any person to investigate or impose liability on them for such purposes. Accordingly, requests for the disclosure of PHI to investigate such allegations of or impose liability for such crimes do not fall within the final rule's prohibition, and the presumption of lawfulness likewise would not be triggered because the prohibition would not apply. A regulated entity therefore would not be prohibited from disclosing an individual's PHI when subpoenaed by law enforcement for the purpose of investigating such allegations, assuming that law enforcement provided a valid attestation and met the other conditions of the applicable permission.

Moreover, as explained above, the final rule is tailored to prohibit disclosures related to lawful reproductive health care, thereby reducing the interference with law enforcement interests to create an appropriate balance with privacy interests.

Comment: Some states expressed concern that the proposed rule would intrude into areas where the HIPAA Rules have previously acknowledged state control, such as enforcement of state and local laws, regulation of the practice of health care, and reporting of abuse.

Response: This final rule balances the interests of individuals in the privacy of their PHI and of society in an effective health care system with those of society in obtaining PHI for certain non-health care purposes. The Privacy Rule always has and continues to permit disclosures of PHI to support public policy goals, including disclosures to support criminal, civil, and administrative law enforcement activities; the operation of courts and tribunals; health oversight activities; the duties of coroners and medical examiners; and the reporting of child abuse, domestic violence, and neglect to appropriate authorities. As explained above, while the final rule adopts an approach that is more

[181] *See, e.g.,* 45 CFR 164.512(f) and 164.514(d)(3)(iii).

protective of privacy interests in certain circumstances than the previous Privacy Rule, the final rule continues to balance the interests that HIPAA Rules have long sought to protect with those of society in PHI.

C. Other General Comments on the Proposed Rule

Comment: Commenters urged the Department to provide enhanced privacy protections for health information that is not covered by existing frameworks or specifically addressed in the proposed rule. A few professional associations expressed support for revising the Privacy Rule to provide stronger protection for the privacy of reproductive health care information and urged the Department to modify the Privacy Rule to provide even stronger protections than those proposed in the 2023 Privacy Rule NPRM.

Response: The Department's authority under HIPAA is limited to protecting the privacy of IIHI that is maintained or transmitted by covered entities and, in some cases, their business associates. Specific modifications to the Privacy Rule to protect the privacy of PHI are described in greater detail below. Consistent with the Department's longstanding approach with respect to the Privacy Rule, the modifications we are finalizing in this rule strike a balance between protecting an individual's right to health information privacy with the interests of society in permitting the disclosure of PHI to support the investigation or imposition of liability for unlawful conduct. In particular, the final rule does not prohibit the disclosure of PHI about reproductive health care that was unlawfully provided, because an individual's privacy interests in reproductive health care that is not lawful (*e.g.,* a particular type of reproductive health care that is provided by a nurse practitioner in a state that requires that type of reproductive health care to be provided by a physician) are comparatively lower than a state's interests in investigating and imposing liability on persons for unlawful reproductive health care. We will continue to monitor legal developments and their effects on individual privacy as we consider the need for future modifications to the Privacy Rule.

Comment: Several commenters questioned how the proposed rule would affect their current business associate and data exchange agreements.

Response: The modifications in this final rule may require regulated entities to revise existing business associate agreements where such agreements permit regulated entities to engage in activities that are no longer permitted under the revised Privacy Rule. Regulated entities must be in compliance with the provisions of this rule by December 23, 2024.

Comment: A few commenters requested clarification of whether minors and legal adults have the same protections under the Privacy Rule and whether this rule would alter existing protections.

Response: The final rule does not change how the Privacy Rule applies to adults and minors. Thus, all of the protections provided to PHI by this final rule apply equally to adults and minors. For example, under this final rule, a regulated entity is prohibited from using or disclosing a minor's PHI for the purposes prohibited under 45 CFR 164.502(a)(5)(iii). The Privacy Rule generally permits a parent to have access to the medical records about their child as their minor child's personal representative when such access is consistent with state or other law, with limited exceptions.[182] Additional information about how the Privacy Rule applies to minors can be found at 45 CFR 164.502(g) and on the OCR website.[183]

Comment: Many commenters urged the Department to take an educational approach, rather than a punitive one, with respect to enforcement against regulated entities. In addition, many commenters addressed the need for resources and education for successful implementation of the proposed changes to the Privacy Rule. They called for the Department to collaborate with and educate regulated entities, individuals, and others affected by the proposed revisions, such as law enforcement, as well as for the Department to partner with other Federal agencies and state governments to conduct the education. Some suggested that educational resources should include multiple media formats and a centralized platform.

Response: The Department frequently issues non-binding guidance and conducts outreach to help regulated entities achieve compliance. We appreciate these recommendations and will consider these topics for future guidance. Regulated entities are expected to comply with the Privacy Rule as revised once the compliance date has passed.

V. Summary of Final Rule Provisions and Public Comments and Responses

The Department is modifying the Privacy Rule to strengthen privacy protections for individuals' PHI by adding a new category of prohibited uses and disclosures of PHI. This final rule prohibits a regulated entity from using or disclosing an individual's PHI for the purpose of conducting a criminal, civil, or administrative investigation into or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided, meaning that it is either: (1) lawful under the circumstances in which such health care is provided and in the state in which it is provided; or (2) protected, required, or authorized by Federal law, including the United States Constitution, regardless of the state in which such health care is provided. In both of these circumstances, as explained above, the interests of the individual in the privacy of their PHI and of society in ensuring an effective health care system outweighs those of society in the use of PHI for non-health care purposes. To operationalize this modification, the Department is revising or clarifying certain definitions and terms that apply to the Privacy Rule, as well as other HIPAA Rules. This final rule also prohibits a regulated entity from using or disclosing an individual's PHI for the purpose of identifying an individual, health care provider, or other person for the purpose of initiating such an investigation or proceeding against the individual, a health care provider, or other person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided.

To effectuate these proposals, the Department is finalizing conforming and clarifying changes to the HIPAA Rules. These changes include, but are not limited to, clarifying the definition of ''person'' to reflect longstanding statutory language defining the term; adopting new definitions of ''public health'' surveillance, investigation, or intervention, and ''reproductive health care''; adding a new category of prohibited uses and disclosures; clarifying that a regulated entity may not decline to recognize a person as a personal representative for the purposes of the Privacy Rule because they provide or facilitate reproductive health care for an individual; imposing a new

[182] *See* 45 CFR 164.502(g) (describing personal representatives) and 164.524(a)(3) (describing reviewable grounds for denial of access to PHI by a personal representative).

[183] Off. for Civil Rights, ''Health Information Privacy,'' U.S. Dep't of Health and Human Servs., *https://www.hhs.gov/hipaa/index.html.*

requirement that, in certain circumstances, regulated entities must first obtain an attestation that a requested use or disclosure is not for a prohibited purpose; and requiring modifications to covered entities' NPPs to inform individuals that their PHI may not be used or disclosed for a purpose prohibited under this final rule.

The Department's section-by-section description of the final rule is below.

A. Section 160.103 Definitions

1. Clarifying the Definition of ''Person''

HIPAA does not define the term ''person.'' [184] The HIPAA Rules have long defined ''person'' to mean ''a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.'' [185] This meaning was based on the definition of ''person'' adopted by Congress in the original SSA, as an ''individual, a trust or estate, a partnership, or a corporation.'' [186]

In 2002, Congress enacted 1 U.S.C. 8, which defines ''person,'' ''human being,'' ''child,'' and ''individual.'' [187] The statute specifies that these definitions shall apply when ''determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States.'' [188] The Department understands 1 U.S.C. 8 to provide definitions of ''person,'' ''individual,'' and ''child'' that do not include a fertilized egg, embryo, or fetus, and are consistent with the Department's understanding of those terms, as used in the SSA, HIPAA, and the HIPAA Rules.

The Department proposed to clarify the term ''natural person'' in a manner consistent with 1 U.S.C. 8.[189] Thus, the Department proposed to clarify that all terms subsumed within the definition of ''natural person,'' such as ''individual,'' [190] are limited to the confines of the term ''person.'' [191] As discussed in the 2023 Privacy Rule NPRM, the purpose of this proposal was to better explain to regulated entities and other stakeholders the parameters of an ''individual'' whose PHI is protected by the HIPAA Rules.

Many individuals and organizations commented on the proposal to clarify the definition ''person.'' Organizational commenters, including professional associations representing health care providers, advocacy groups, and academic departments, generally supported the proposal. Several commenters applauded the proposed clarification because they believed it would limit disclosures of PHI in cases where no individual has been harmed.

Most opponents of the proposed clarification were individuals participating in form letter campaigns who expressed concern that the proposal might diminish access to prenatal care. Others asserted that the proposed clarification would contradict or conflict with existing laws, such as mandatory reporting laws and Federal statutes that rely upon a different definition of ''person.''

The final rule adopts the proposed clarification of the definition of person, to mean a ''natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.'' Therefore, an ''individual,'' ''child,'' or ''victim'' (*e.g.,* a victim of crime) under the HIPAA Rules must be a natural person. As we explained in the 2023 Privacy Rule NPRM, this clarification is consistent with the SSA, HIPAA, and 1 U.S.C. 8. This clarification applies only to regulations issued pursuant to the Administrative Simplification provisions of HIPAA.[192]

This clarification is consistent with the Privacy Rule's longstanding definitions of ''person'' [193] and ''individual,'' [194] as applied to Privacy Rule provisions permitting certain types of reports or other disclosures of PHI. For example, a regulated entity is permitted to disclose PHI about an individual who the regulated entity reasonably believes to be a victim of abuse, neglect, or domestic violence only where the individual is a ''natural person.'' [195] In addition, because a ''victim'' necessarily is a natural person, the permission to disclose PHI to avert a serious threat to health or safety at 45 CFR 164.512(j)(i) does not permit disclosures when the perceived threat does not involve the health or safety of a natural person or the public, or when an individual has not caused serious physical harm to a natural person.

Comment: Many organizational commenters expressed support for the proposal to clarify the definition of ''person.''

One commenter stated that this clarification should prevent law enforcement from attempting to avoid the proposed prohibition. According to another commenter, this proposed clarification is crucial as stakeholders adapt to the current reproductive health landscape.

Several commenters expressed support for the Department's proposal but requested additional clarifications. For example, one commenter recommended that the Department clarify whether the definition would preempt state laws.

Response: We take the opportunity to emphasize here that the clarification only applies to the HIPAA Rules and explains certain terms that apply to the permissions for uses and disclosures of PHI by regulated entities. We do not believe it is necessary to further clarify the final regulatory text because the current definition remains unchanged other than to incorporate the plain wording of 1 U.S.C. 8.

Comment: A few commenters expressed opposition to the Department's proposed clarification of ''person'' as tantamount to eliminating legal protections for and recognition of categories of human beings based on developmental stage. Some commenters maintained that the proposed clarification of ''person'' was inaccurate.

Several commenters opposed the proposed clarification of ''person'' because it would affect the provision of prenatal care.

A few commenters asserted that the proposed clarification would prevent the collection of medical information about reproductive health care for

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[184] *See* 42 U.S.C. 1320d–1320d–8.

[185] 45 CFR 160.103.

[186] *See* section 1101(3) of Public Law 74–271, 49 Stat. 620 (Aug. 14, 1935) (codified at 42 U.S.C. 1301(3)).

[187] 1 U.S.C. 8(a). The Department is not opining on whether any state law confers a particular legal status upon a fertilized egg, embryo, or fetus. Rather, the Department cites to this statute to help define the scope of privacy protections that attach pursuant to HIPAA and its implementing regulations.

[188] *Id.*

[189] 88 FR 23506, 23523 (Apr. 17, 2023).

[190] 45 CFR 160.103 (definition of ''Individual'').

[191] *See* Sharon T. Phelan, ''The Prenatal Record and the Initial Prenatal Visit,'' The Glob. Libr. of Women's Med. (last updated Jan. 2008) (PHI about the fetus is included in the mother's PHI), *https://www.glowm.com/section-view/heading/The%20Prenatal%20Record%20and%20the%20Initial%20Prenatal%20Visit/item/107#.Y7WRKofMKUl.*

[192] *See* 42 U.S.C. 1320d.

[193] 45 CFR 160.103 (definition of ''Person''). The Department first defined the term ''person'' in the HIPAA Rules as part of the 2003 Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings Interim Final Rule (2003 Interim Final Rule) to distinguish a ''natural person'' who could testify in the context of administrative proceedings from an ''entity'' (defined therein as a ''legal person'') on whose behalf a person would testify. *See* 45 CFR 160.502 of the 2003 Interim Final Rule, 68 FR 18895, 18898 (Apr. 17, 2003) (*Person* is defined to mean a natural person or a legal person).

[194] 45 CFR 160.103 (definition of ''Individual''). The definition of ''individual'' in the HIPAA Rules was first adopted in the 2000 Privacy Rule.

[195] *See* 45 CFR 164.512(c)(1). This provision explicitly excludes reports of child abuse, which are addressed by 45 CFR 164.512(b)(1).

important purposes, such as public health and research.

Response: We are clarifying the definition of person consistent with applicable Federal law only for the purpose of applying HIPAA's Administrative Simplification provisions. This clarification will not affect how the term ''person'' is applied for purposes of other laws, affect any rights or protections provided by any other law, or affect standards of health care, including prenatal care.

This final rule does not affect the reporting of vital statistics, nor does it affect the ability of regulated entities to use and disclose PHI for research. The Privacy Rule's standards for uses and disclosures for public health surveillance, investigations, and interventions, or for health oversight activities, are discussed elsewhere.

Comment: Several commenters requested additional clarifications to the Department's proposed clarification of ''person.'' A few commenters asserted that the proposed clarification would be overly expansive. Most of these same commenters disagreed with the Department's interpretation of 1 U.S.C. 8.[196] Commenters asserted that the clarification was inconsistent or conflicted with other laws.

Response: The clarified definition of person that we are finalizing in this rule does not change the Department's interpretation of the term or change definitions under other law, such as state law. It also is consistent with Federal law, including 1 U.S.C. 8, which specifically applies to Federal regulations, and other examples cited by commenters. For example, both GINA and the Privacy Rule protect the genetic information of a fetus carried by a pregnant individual as the PHI of the pregnant individual.[197]

The other laws cited by commenters address policy concerns that are different from those health information privacy issues addressed under HIPAA and do not address personhood. Even if those statutes did adopt different understandings of who is a ''person,'' the Department has the authority to clarify or define terms that apply to the Administrative Simplification regulations issued pursuant to HIPAA. Additionally, the definition in the final rule of 1 U.S.C. 8 is appropriate because it is consistent with the Department's longstanding interpretation of the term in the context of HIPAA's Administrative Simplification provisions and associated regulations. Many Federal and state laws operate with differing definitions of common terms, to which existing legal standards that govern how such differences are to be interpreted would apply.[198]

Comment: A few commenters asserted that the proposal would expand minors' access to hormone therapy or surgeries without requiring parental consent.

Response: The final rule's clarification to define the term ''person'' does not affect the ability of a parent to make decisions related to health care for an individual who is an unemancipated minor,[199] and nothing in this rule dictates a standard of care. The application of this definition is limited to the HIPAA Rules.

Comment: A few commenters asserted that the proposed clarification would help to prevent the misapplication of child abuse laws to individuals who engage in certain behaviors while pregnant (*e.g.,* use of an illicit substance or alcohol). Several other commenters expressed concern that this definition would limit the ability of a regulated entity to apply the Privacy Rule permission to use or disclose PHI to prevent a serious and imminent threat to a fertilized egg, embryo, or fetus.

Response: Under this final rule, a regulated entity would continue to be permitted to disclose PHI about an individual who the covered entity reasonably believes is a victim of child abuse or neglect, consistent with 45 CFR 164.512(b)(1)(ii), or a victim of abuse, neglect, or domestic violence, consistent with 45 CFR 164.512(c), to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence under the circumstances set forth under 45 CFR 164.512(c) where the individual meets the clarified definition of person. The Privacy Rule permission concerning serious and imminent threats [200] applies to threats to a person, consistent with the definition as clarified by this final rule, or the public.

2. Interpreting Terms Used in Section 1178(b) of the Social Security Act Reporting of Disease or Injury, Birth, or Death

Section 1178(a) of the SSA provides that HIPAA generally preempts contrary state laws with certain limited exceptions, such as those described in section 1178(b).[201] Specifically, section 1178(b) excepts from HIPAA's general preemption authority laws that provide for certain public health reporting, such as the reporting of disease or injury, birth, or death.[202] HIPAA does not define the terms in section 1178(b) that govern the scope of this exception to HIPAA's general preemption authority, nor has the Department previously defined such terms through rulemaking.

The Department recognizes that such public health reporting activities are an important means of identifying threats to the health and safety of the public. Accordingly, when a public health authority [203] has furnished documentation of its authority [204] to collect or receive such information, the Privacy Rule permits a regulated entity, without an individual's authorization, to use or disclose PHI to specified persons for public health activities.[205] These activities include all of the vital statistics reporting activities described in section 1178(b), including reporting of diseases and injuries, birth, or death.[206]

The Department proposed to interpret in preamble key terms used in section 1178(b) to clarify when HIPAA's general preemption authority applies. Specifically, the Department proposed an interpretation of section 1178(b) that would clarify that HIPAA's general preemption authority applies to laws that require regulated entities to use or disclose PHI for a purpose that would be prohibited under the proposed rule. Under this interpretation, the Privacy Rule permission to use or disclose PHI without an individual's authorization for the reporting of disease or injury, birth, or death [207] would not permit the use or disclosure of PHI for a criminal, civil, or administrative investigation into or proceeding against a person in connection with seeking, obtaining,

[196] 1 U.S.C. 8(a).

[197] Public Law 110–233, 122 Stat. 881. *See generally* Off. for Civil Rights, ''Health Information Privacy, Genetic Information,'' U.S. Dep't of Health and Human Servs. (Content last reviewed June 16, 2017), *https://www.hhs.gov/hipaa/for-professionals/special-topics/genetic-information/index.html#:~:text=The%20Genetic%20Information%20Nondiscrimination%20Act,into%20two%20sections%2C%20or%20Titles.*

[198] *See* 45 CFR 164.524. *See also* William Baude & Stephen E. Sachs, ''The Law of Interpretation,'' 130 Harv. L. Rev. 1079 (2017).

[199] 45 CFR 164.502(g).

[200] *See* 45 CFR 164.512(j)(1)(i).

[201] 42 U.S.C. 1320d–7(a)

[202] 42 U.S.C. 1320d–7(b).

[203] 45 CFR 164.501 (definition of ''Public health authority'').

[204] 45 CFR 164.514(h).

[205] This is unchanged by this final rule.

[206] *See* 45 CFR 164.512(b). The Privacy Rule addresses its interactions with laws governing excepted public health activities in two sections: 45 CFR 164.512(a), Standard: Uses and disclosures required by law, and 45 CFR 164.512(b), Standard: Uses and disclosures for public health activities.

[207] 45 CFR 164.512(b).

providing, or facilitating reproductive health care. The Department did not intend this clarification to prevent disclosures of PHI from regulated entities to public health authorities for public health purposes that have been and continue to be permitted under the Privacy Rule. Nor did the Department intend for this proposed clarification to prevent disclosures of PHI by regulated entities under other permissions in the Privacy Rule, such as for law enforcement purposes,[208] when made consistent with the conditions of the relevant permission and where the purpose of the disclosure is not one for which a use or disclosure would have been prohibited under 45 CFR 164.502(a)(5)(iii) as proposed.

The Department did not propose to define ''disease or injury,'' ''birth,'' or ''death,'' because we believed that these terms, when read with the definition of ''person'' and in the broader context of HIPAA, would exclude information about reproductive health care without the need for further clarification.[209] However, the Department invited public comment on whether it would be beneficial to make such clarification.

Few commenters addressed interpretation of these terms. Some commenters expressed concern that the Department's interpretation would prevent beneficial public health reporting about certain types of reproductive health care, while others requested that the Department prohibit public health reporting about certain types of reproductive health care. Some commenters on this issue agreed with the Department's interpretation and clarification of the terms used in 1178(b). Several of these commenters requested that the Department define or clarify these terms because reporting standards are inconsistent across states.

The Department declines to add definitions for ''disease or injury,'' ''birth,'' or ''death'' to the Privacy Rule in this final rule. However, we offer the discussion below to provide additional context on our interpretation of these terms.

At the time of HIPAA's enactment, state laws provided for the reporting of disease or injury, birth, or death by covered health care providers and other persons.[210] State public health reporting systems were well established and involved close collaboration between the state, local, or territorial jurisdiction and the Federal Government.[211] Reports generally were made to public health authorities or, in some specific cases, law enforcement (*e.g.,* reporting of gunshot wounds).[212] Similar public health reporting systems continue to exist today.

Reporting of ''disease or injury'' commonly refers to diagnosable health conditions reported for limited purposes such as workers' compensation, tort claims, or communicable or other disease or injury tracking efforts. States, territories, and Tribal governments require health care providers (*e.g.,* physicians, laboratories) and some others (*e.g.,* medical examiners, coroners, veterinarians,[213] local boards of health) to report cases of certain diseases or conditions that affect public health, such as coronavirus disease 2019 (COVID–19), malaria, and foodborne illnesses.[214] Such reporting enables public health practitioners to study and explain diseases and their spread, along with determining appropriate actions to prevent and respond to outbreaks.[215] States also require health care providers to report incidents of certain types of injuries, such as those caused by gunshots, knives, or burns.[216] Various Federal statutes use the phrase ''disease or injury'' similarly to refer to events such as workplace injuries for purposes of compensation.[217]

The limited meaning given to the terms ''disease'' and ''injury'' for purposes of public health reporting is clear from HIPAA's broader context. For instance, interpreting ''injury'' reporting to include disclosures about all instances of suspected criminal abuse would render the specific permission to report ''child abuse'' superfluous.[218] And interpreting ''disease'' reporting to include disclosures about any sort of disease for any purpose would both eviscerate HIPAA's general provisions protecting PHI and make superfluous the statutory requirement to not invalidate laws providing for public health surveillance, or public health investigation or intervention. For example, ''disease management activities'' constitute ''health care'' under the Privacy Rule. As such, a broad interpretation of ''disease or injury'' reporting could make potentially all the health records detailing a particular individual's treatment for any disease or injury disclosable to a public health authority or others unrelated to the health care.[219] Consequently, the Department has long understood ''disease or injury'' to narrowly refer to diagnosable health conditions reported for limited purposes such as workers' compensation, tort claims or in compliance with Federal laws that require states to conduct surveillance of specific diseases and injuries related to public health or Federal funding.[220]

With respect to reporting of ''births'' and ''deaths,'' such vital statistics are reported by health care providers to the vital registration systems operated in

[208] 45 CFR 164.512(f).

[209] 88 FR 23506, 23523 (Apr. 17, 2023).

[210] The 1996–98 Report of the NCVHS to the Secretary describes various types of activities considered to be public health during the era in which HIPAA was enacted, such as the collection of public health surveillance data on health status and health outcomes and vital statistics information. *See* Nat'l Comm. On Vital and Health Stats., Report of The National Committee on Vital and Health Statistics, 1996–98, (Dec. 1999), *https://ncvhs.hhs.gov/wp-content/uploads/2018/03/90727nv-508.pdf.*

[211] *Id.*

[212] *Id.*

[213] Richard N. Danila et al., ''Legal Authority for Infectious Disease Reporting in the United States: Case Study of the 2009 H1N1 Influenza Pandemic,'' 105 a.m. J. Public Health 13 (Jan. 2015).

[214] *See* ''Reportable Diseases,'' MedlinePlus, *https://medlineplus.gov/ency/article/001929.htm* (accessed Oct. 19, 2022). *See also* Nat'l Notifiable Diseases Surveillance Sys., ''What is Case Surveillance?,'' Ctrs. for Disease Control and Prevention (July 20, 2022), *https://www.cdc.gov/nndss/about/index.html.*

[215] *See* ''Reportable Diseases,'' *supra* note 215. Such reporting is a type of public health surveillance activity.

[216] *See* Victims Rts. Law Ctr., ''Mandatory Reporting of Non-Accidental Injuries: A State-by-State Guide'' (May 2014), *http://4e5ae7d17e.nxcli.net/wp-content/uploads/2021/01/Mandatory-Reporting-of-Non-Accidental-Injury-Statutes-by-State.pdf.*

[217] *See, e.g.,* 38 U.S.C. 1110 (referring to an ''injury suffered or disease contracted''); 10 U.S.C. 972 (discussing time lost as a result of ''disease or injury''); 38 U.S.C. 3500 (providing education for certain children whose parent suffered ''a disease or injury'' incurred or aggravated in the Armed Forces); *see also* 5 U.S.C. 8707 (insurance provision discussing compensation as a result of ''disease or injury''); 33 U.S.C. 765 (discussing retirement for disability as a result of ''disease or injury''); 15 U.S.C. 2607(c) (requiring chemical manufacturers to maintain records of ''occupational disease or injury'').

[218] 45 CFR 164.512(b)(ii).

[219] *See* 65 FR 82462, 82571 (Dec. 28, 2000) (recognizing that ''disease management activities'' often constitute ''health care'' under HIPAA); *Id.* at 82777 (discussing the importance of privacy for information about cancer, a ''disease'' that causes an ''indisputable'' ''societal burden''); *Id.* at 82778 (discussing the importance of privacy for information about sexually transmitted diseases, including Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS)); *Id.* at 82463–64 (noting that numerous states adopted laws protecting health information relating to certain health conditions such as communicable diseases, cancer, HIV/AIDS, and other stigmatized conditions.); *Id.* at 82731 (finding that there are no persuasive reasons to provide information contained within disease registries with special treatment as compared with other information that may be used to make decisions about an individual).

[220] *See, e.g.,* 65 FR 82462, 82517 (Dec. 28, 2000) (discussing tort litigation as information that could implicate IIHI); *Id.* at 82542 (discussing workers' compensation); *Id.* at 82527 (separately addressing disclosures about ''abuse, neglect or domestic violence'' and limiting such disclosures to only two circumstances, even if expressly authorized by state statute or regulation).

various jurisdictions [221] legally responsible for the registration of vital events.[222] State laws require birth certificates to be completed for all births, and Federal law mandates the national collection and publication of births and other vital statistics data.[223] Tracking and reporting death is a complex and decentralized process with a variety of systems used by more than 6,000 local vital registrars.[224] When HIPAA was enacted, the Model State Vital Statistics Act and Regulations, which is followed by most states,[225] included distinct categories for ''live births,'' ''fetal deaths,'' and ''induced terminations of pregnancy,'' with instructions that abortions ''shall not be reported as fetal deaths.'' [226] In light of that common understanding at the time of HIPAA's enactment, it is clear that the reporting of abortions is not included in the category of reporting of deaths for the purposes of HIPAA and does not fall within the scope of state death reporting activities that Congress specifically designated as excepted from preemption by HIPAA.

More generally, while Congress exempted certain ''[p]ublic health'' laws from preemption,[227] Congress chose not to create a general exception for criminal laws or other laws that address the disclosure of information about similar types of activities outside of the public health context.

For all these reasons, state laws requiring the use or disclosure of PHI for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying a person for such activities, are subject to HIPAA's general preemption provision. Similarly, the Privacy Rule's public health provisions that permit the disclosure of PHI for the reporting of disease or injury, birth, or death do not include permission to use or disclose PHI for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying a person for such activities. This general distinction between public health activities and investigation and enforcement activities is not limited to reproductive health care. Nevertheless, as discussed elsewhere in this final rule, the Department has chosen to strike a balance between privacy interests and other public policy interests. Consistent with the Department's longstanding approach that has allowed disclosures for law enforcement purposes in certain circumstances, the new prohibitions set forth in this rule apply only to lawful reproductive health care. State authorities cannot rely on the Privacy Rule's permissions for disclosures related to disease or injury, birth, or death to obtain PHI for the purpose of investigating or imposing liability for the provision of reproductive health care. However, as discussed above, state authorities may be able to invoke other permissions, such as the permission for disclosures for law enforcement purposes, to obtain such PHI where such disclosure is to investigate or impose liability on a person when the reproductive health care at issue is unlawful under the circumstances in which it is provided.

Comment: A few commenters expressed support for the Department's interpretation and clarification of the terms used in section 1178(b) of the SSA. A few commenters recommended that the Department define, rather than clarify, these terms. Some commenters requested that the Department further clarify the terms ''disease or injury,'' ''birth,'' and ''death,'' to explicitly exclude information about reproductive health care. Other commenters expressed opposition to the Department's clarifications.

Response: We decline to define ''disease or injury,'' ''birth,'' or ''death'' in this final rule. The Department's understanding of these terms is consistent with the Model State Vital Statistics Act and Regulations and its application in the context of the passage of HIPAA. We believe that the 2023 Privacy Rule NPRM preamble discussion is sufficient to clarify that such reporting does not include the use or disclosure of PHI for investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, including reproductive health care, or to identify a person for such activities.

Defining ''Public health,'' as used in the terms ''public health surveillance,'' ''public health investigation,'' and ''public health intervention.''

Section 1178(b) also excepts state laws providing for ''public health surveillance, or public health investigation or intervention'' from HIPAA's general preemption authority.[228] Neither HIPAA nor the Privacy Rule currently defines ''public health surveillance'' or ''public health investigation or intervention.'' Consistent with the statute, the Privacy Rule expressly permits a regulated entity to use or disclose PHI for ''public health'' surveillance, investigation, or intervention.[229] The Department proposed to define public health, as used in the terms ''public health surveillance,'' ''public health investigations,'' and ''public health interventions,'' to mean population-level activities to prevent disease and promote health of populations. In preamble to the 2023 Privacy Rule NPRM, the Department described public health surveillance as the ongoing, systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice.[230] The Department explained that public health investigations or interventions include monitoring real-time health status and identifying patterns to develop strategies to address chronic diseases and injuries, as well as using real-time data to identify and respond to acute outbreaks, emergencies, and other health hazards.[231] Public health surveillance, investigations, or interventions safeguard the health of the community by addressing ongoing or prospective population-level issues such as the spread of communicable diseases, even where these activities involve

[221] *See* ''Public Health Professionals Gateway, Public Health Systems & Best Practices, Health Department Governance,'' Ctrs. for Disease Control and Prevention (Nov. 25, 2022), *https://www.cdc.gov/publichealthgateway/sites governance/index.html.*

[222] *See* the list of events included in vital events, Nat'l Ctr. for Health Stats., ''About the National Vital Statistics System,'' Ctrs. for Disease Control and Prevention (Jan. 4, 2016), *https://www.cdc.gov/nchs/nvss/about_nvss.htm.*

[223] *See* Nat'l Ctr. for Health Stats., ''Birth Data,'' Ctrs. for Disease Control and Prevention (Dec. 6, 2022), *https://www.cdc.gov/nchs/nvss/births.htm.*

[224] *See* Ctrs. For Disease Control and Surveillance, ''How Tracking Deaths Protects Health,'' (July 2018), *https://www.cdc.gov/surveillance/pdfs/Tracking-Deaths-protects-healthh.pdf.*

[225] *See* Nat'l Ctr. for Health Stats., Ctrs. for Disease Control and Prevention, ''State Definitions and Reporting Requirements: For Live Births, Fetal Deaths, and Induced Terminations of Pregnancy,'' at 5 (1997), *https://www.cdc.gov/nchs/data/misc/itop97.pdf.*

[226] Nat'l Ctr. for Health Stats., Ctrs. for Disease Control and Prevention, ''Model State Vital Statistics Act and Regulations,'' at 8 (1992), *https://www.cdc.gov/nchs/data/misc/mvsact92b.pdf.*

[227] 42 U.S.C. 1178(b) (codified in HIPAA at 42 U.S.C. 1320d-7).

[228] Section 1178(a) of HIPAA.

[229] *See* 45 CFR 164.512(b)(1)(i); Off. for Civil Rights, ''Disclosures for Public Health Activities,'' U.S. Dep't of Health and Human Servs., *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-public-health-activities/index.html* (accessed Oct. 19, 2022).

[230] *See* ''Introduction to Public Health Surveillance,'' Ctrs. for Disease Control and Prevention (Nov. 15, 2018), *https://www.cdc.gov/training/publichealth101/surveillance.html.*

[231] *See* ''Public Health Professionals Gateway, Ten Essential Public Health Services,'' Ctrs. for Disease Control and Prevention (Dec. 1, 2022), *https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html.*

individual-level investigations or interventions.

The Department also proposed to expressly exclude certain activities from the definition of public health to distinguish between public health activities and certain criminal investigations. Specifically, the Department proposed to provide in regulatory text that the Privacy Rule's permissions to use and disclose PHI for the ''public health'' activities of surveillance, investigations, or interventions do not include criminal, civil, or administrative investigations into, or proceedings against, any person in connection with seeking, obtaining, providing, or facilitating reproductive health care, nor do they include identifying any person for the purpose of initiating such investigations or proceedings. The Department stated that any such actions are not public health activities that would be subject to the exception to HIPAA's general preemption authority for state laws providing for ''public health surveillance, or public health investigation or intervention.'' [232]

Commenters expressed mixed views on the proposal to define ''public health'' in the context of ''public health surveillance,'' ''public health investigations'' or ''public health interventions.'' Commenters expressing opposition to the proposal either disagreed with the Department's assertion that public health activities do not involve uses and disclosures that would be prohibited by the rule or asserted that the proposal would prevent public health reporting of reproductive health care. Some commenters generally supported the goal of the proposal but expressed concern that inclusion of the proposed language about ''population-level'' activities could prevent essential public health activities that involve specific persons, such as reporting data about specific health care services provided to specific persons that have a ''population-level'' effect and investigating the spread of communicable diseases.

Some commenters asserted that the proposal would frustrate states' ability to enforce their laws not related to public health, such as laws banning health care such as abortion. Supporters asserted that the proposal would help to prevent PHI from being disclosed for a purpose that would be prohibited under the proposed rule. Supportive commenters also expressed concern about states obtaining PHI based on an interpretation of ''public health investigations'' that includes the mandatory reporting of pregnant individuals who engage in certain activities, such as substance use. Other commenters asserted that disclosures of PHI to public health authorities should be limited because of the potential for PHI to be redisclosed for purposes that otherwise would be prohibited under the Privacy Rule.

The final rule adopts the proposed definition with some modifications. The final rule maintains the proposed rule's focus on activities aimed at preventing disease and improving the health of populations. This definition does not prevent disclosures of PHI by covered entities to public health authorities for public health activities that have long been permitted under the Privacy Rule. As discussed in the 2023 Privacy Rule NPRM, since the time of HIPAA's enactment, public health activities related to surveillance, investigation, or intervention have been widely understood to refer to activities aimed at improving the health of a population. For example, legal dictionaries define ''public health'' as ''[t]he health of the community at large,'' or ''[t]he healthful or sanitary condition of the general body of people or the community en masse; esp., the methods of maintaining the health of the community, as by preventive medicine or organized care for the sick.'' [233] Stedman's Medical Dictionary defines ''public health'' as ''the art and science of community health, concerned with statistics, epidemiology, hygiene, and the prevention and eradication of epidemic diseases; an effort organized by society to promote, protect, and restore the people's health; public health is a social institution, a service, and a practice.'' [234] The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry have described ''public health surveillance'' as ''the ongoing systematic collection, analysis and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice.'' [235] And many states similarly define ''public health'' to mean activities to support population health.[236] The Department likewise has used the term public health in this way since it first adopted the Privacy Rule.[237]

Public health surveillance, public health investigations, and public health interventions are activities that address population health concerns and have generalized public benefit [238] to the health of a population, including activities that involve specific persons. Examples of activities that prevent disease in and promote the health of populations include vaccination campaigns to eradicate communicable disease, surveillance of a community's use of emergency services after a natural disaster to improve allocation of resources to meet health needs, and investigation of the source of an outbreak of food poisoning. As explained in the preamble to the 2023 Privacy Rule NPRM,[239] there is a widely recognized distinction between public health activities, which primarily focus on improving the health of populations, and criminal investigations, which primarily focus on identifying and imposing liability on persons who have

[232] Section 1178(a) of SSA.

[233] ''Health, Public Health,'' Black's Law Dictionary (11th ed. 2019).

[234] ''Public Health,'' Stedman's Medical Dictionary 394520.

[235] Jonathan Weinstein, *In Re Miguel M.,* 55 N.Y.L. Sch. L. Rev. 389, 390 (2010) (citing Stephen B. Thacker, ''Historical Development,'' *in* Principles and Practice of Public Health Surveillance 1 (Steven M. Teutsch & R. Elliott Churchill eds., 2d ed., 2000)), *https://digitalcommons.nyls.edu/cgi/viewcontent.cgi?article=1599&context=nyls_law_review.*

[236] *See, e.g.,* Richard A. Goodman et al., ''Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations,'' 31 J. of Law, Med. & Ethics 684, 689–90 (2003); La. Rev. Stat. Ann. Sec. 40:3.1 (2011) (defining threats to public health as nuisances ''including but not limited to communicable, contagious, and infectious diseases, as well as illnesses, diseases, and genetic disorders or abnormalities''); N.C. Gen. Stat. sec. 130A–141.1(a) (2010) (defining public health investigations as the ''surveillance of an illness, condition, or symptoms that may indicate the existence of a communicable disease or condition'').

[237] *See, e.g.,* 65 FR 82462, 82464 (Dec. 28, 2000) (noting that reporting of public health information on communicable diseases is not prevented by individuals' right to information privacy); *Id.* at 82467 (discussing the importance of accurate medical records in recognizing troubling public health trends and in assessing the effectiveness of public health efforts); *Id.* at 82473 (discussing disclosure to ''a department of public health''); *Id.* at 82525 (recognizing that it may be necessary to disclose PHI about communicable diseases when conducting a public health intervention or investigation); *Id.* at 82526 (recognizing that an entity acts as a ''public health authority'' when, in its role as a component of the public health department, it conducts infectious disease surveillance); Stephen B. Thacker, Epidemiology Program Office, Ctrs. for Disease Control and Prevention, ''HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services,'' 52 MMWR 1 (Apr. 11, 2003), *https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm* (describing what traditionally are considered to be ''public health activities'' that require PHI).

[238] *See Miguel M.* v. *Barron,* 950 NE2d 107, at 111 (2011) (explaining ''[t]he apparent purpose of the public health exception is to facilitate government activities that protect large numbers of people from epidemics, environmental hazards, and the like, or that advance public health by accumulating valuable statistical information.'').

[239] 88 FR 23510, 23525 (Apr. 17, 2023).

violated the law.[240] States and other local governing authorities maintain criminal codes that are distinct and separate from public health reporting laws,[241] although some jurisdictions enforce required public health reporting through criminal statutes. Different governmental bodies are responsible for enforcing these separate codes, and public health officials do not typically investigate activities enforced under criminal statutes or laws.[242] Federal laws also generally treat public health investigations as distinct from criminal investigations.[243] Maintaining a clear distinction between public health investigations and criminal investigations serves HIPAA's broader purposes.[244]

The Department concludes that neither section 1178(b) nor the Privacy Rule's permissions to use and disclose PHI for the ''public health'' activities of surveillance, investigation, or intervention include conducting criminal, civil, or administrative investigations into, or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care, including reproductive health care, nor do they include the identification of any person for such purposes. Such actions are not public health activities. As described above, this distinction between public health activities and other investigation and enforcement activities is not limited to reproductive health care. Public health surveillance, investigations, or interventions ensure the health of the community as a whole by addressing ongoing or prospective population-level issues such as the spread of communicable diseases, even where they involve interventions involving specific individuals. Such surveillance systems provide the necessary data to examine and potentially develop interventions to improve the public's health, such as providing education or resources to support individuals' access to health care and improve health outcomes and are not affected by this final rule.[245] U.S. states, territories, and Tribal governments participate in bilateral agreements with the Federal Government to share data on conditions that affect public health.[246] The CDC's Division of Reproductive Health collects reproductive health data in support of national and state-based population surveillance systems to assess maternal complications, mortality and pregnancy-related disparities, and the numbers and characteristics of individuals who obtain legal induced abortions.[247] This final rule does not affect CDC's ability to collect this information now or in the future. Importantly, disclosures to public health authorities permitted by the Privacy Rule are limited to the ''minimum necessary'' to accomplish the public health purpose.[248] In some cases, regulated entities need disclose only de-identified data [249] to meet the public health purpose.

By contrast, efforts to conduct criminal, civil, and administrative investigations or impose criminal, civil, and administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care generally target specific persons for particular conduct; they are not designed to address population-level health concerns and are not limited to information authorized to be collected by a public health or similar government authority for a public health activity. Thus, the exceptions in section 1178(b) for ''public health'' investigations, interventions, or surveillance do not limit the Department's ability to prohibit uses or disclosures of PHI for other purposes, such as judicial and administrative proceedings or law enforcement purposes. While the Department has chosen as a policy matter to continue to permit uses or disclosures of PHI for law enforcement and other purposes in certain contexts, it is adopting a different balance where such uses or disclosures are about reproductive health care that is lawful under the circumstances in which it was provided.

While retaining the focus on activities to prevent disease and promote the health of populations, this final rule clarifies that population-level activities ''include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information.'' This clarification addresses commenters' concerns that regulated entities would no longer be able to report information that states need to conduct public health functions intended to protect against prospective or ongoing threats at the population level, even if at times they necessarily will focus on individuals while doing so (through contact tracing, quarantine or isolation, and the like). The Department does not intend this clarification to prevent disclosures of PHI from covered entities to public health authorities for public health activities that have long been and continue to be permitted under the Privacy Rule. These changes clarify that public health, as used in the specified terms, broadly includes activities to prevent disease in and promote the health of populations. The changes also confirm that the Department does not require a public health authority to supply an attestation to a covered entity to receive PHI of an individual where that disclosure is intended to prevent disease in or promote the health of populations.

The intended purpose of including ''population-level'' was to facilitate

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[240] *See Miguel M.* v. *Barron* at 111, *supra* note 239 (concluding that ''[t]o disclose private information about particular people, for the purpose of preventing those people from harming themselves or others, effects a very substantial invasion of privacy without the sort of generalized public benefit that would come from, for example, tracing the course of an infectious disease.'').

[241] For example, traditional public health reporting laws grew from colonial requirements that physicians report disease. These requirements transitioned to state regulatory requirements imposed by public health departments on authority granted to them by states. *See* Ctrs. for Disease Control and Prevention, ''Public Health Law 101, Disease Reporting and Public Health Surveillance,'' at 12 and 14 (Jan. 16, 2009), *https://www.cdc.gov/phlp/docs/phl101/PHL101-Unit-5-16Jan09-Secure.pdf. See also, e.g.,* Code of Georgia 31–12–2 (2021) (authority to require disease reporting).

[242] *See* ''Public Health,'' *supra* note 235 (''Many cities have a 'public health department' or other agency responsible for maintaining the public health; Federal laws dealing with health are administered by the Department of Health and Human Services.''); *see also* ''Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations,'' *supra* note 237, at 689.

[243] *See Camara* v. *Municipal Ct. of City & Cty. of S.F.,* 387 U.S. 523, 535–37 (1967) (discussing administrative inspections under the Fourth Amendment, such as those aimed at addressing ''conditions which are hazardous to public health and safety,'' and not ''aimed at the discovery of evidence of crime''); 42 U.S.C. 241(d)(D) (prohibiting disclosure of private information from research subjects in ''criminal'' and other proceedings); 42 U.S.C. 290dd–2(c) (prohibiting substance abuse records from being used in criminal proceedings).

[244] *See* ''Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations,'' *supra* note 237, at 687 (discussing reasons why ''an association of public health with law enforcement'' may be ''to the detriment of routine public health practice''). *See also* 45 CFR 164.512(b)(1)(i) (including ''public health investigations'' as an activity carried out by a public health authority that is authorized by law to carry out public health activities).

[245] *See* ''Improving the Role of Health Departments in Activities Related to Abortion,'' Am. Pub. Health Ass'n (Oct. 26, 2021), *https://www.apha.org/Policies-and-Advocacy/Public-Health-Policy-Statements/Policy-Database/2022/01/07/Improving-Health-Department-Role-in-Activities-Related-to-Abortion.*

[246] *See* ''Reportable diseases,'' *supra* note 215. *See also* ''What is Case Surveillance?,'' *supra* note 215.

[247] *See* ''Reproductive Health, About Us,'' Ctrs. for Disease Control and Prevention (Apr. 20, 2022), *https://www.cdc.gov/reproductivehealth/drh/about-us/index.htm; and* ''Reproductive Health, CDCs Abortion Surveillance System FAQs,'' Ctrs. for Disease Control and Prevention (Nov. 17, 2022), *https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm.*

[248] *See* 45 CFR 164.502(b).

[249] *See* 45 CFR 164.514(a).

public health activities that protect large numbers of people from epidemics, environmental hazards, and the like. However, we believe that the language that clarifies that population-level activities ''include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information,'' sufficiently serves this purpose of addressing uses and disclosures of PHI that are necessary to accomplish the overarching goals of public health.

The last sentence of the proposed definition, which described what are not public health activities, is also revised in the final rule for consistency with the general distinction between activities of public health surveillance, investigation, and intervention and activities of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying a person for such activities, as well as the standard the Department is adopting at 45 CFR 164.502(a)(5)(iii), which is discussed further in that section of this rule. Thus, while a state might assert that investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating health care satisfies the definition of ''public health,'' their interpretation would not supersede the definition of ''public health'' in the context of public health surveillance, investigations, or interventions that the Department is adopting under its own Federal statutory authority to administer the HIPAA Rules.

Comment: A few organizations expressed support for the proposed definition of ''public health'' without further elaboration. Several commenters expressed support for the proposed definition of ''public health'' because it would prevent PHI from being disclosed for a prohibited purpose. A few commenters expressed support for the proposal because they believed that information reported for public health purposes could be requested, re-identified (in the case of de-identified information), or further disclosed to law enforcement for purposes for which the Department proposed to prohibit uses and disclosures.

Several commenters expressed support for the proposed definition of ''public health'' and the existing standard that limits public health disclosures of PHI to the minimum necessary information to achieve the purpose.

Response: Consistent with the NPRM, the Department agrees with the commenters who stated that it is important to define ''public health'' in the context of public health surveillance, investigation, or intervention to ensure that PHI is not disclosed for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). Disclosures of PHI for public health purposes continue to be subject to the minimum necessary standard, which limits the use and disclosure of PHI to the minimum necessary to achieve the specified purpose; in some circumstances, de-identified information may suffice. However, many public health activities do require identifiable data, such as for interventions involving individuals, to protect against prospective or ongoing threats to health or safety at the population level, and the Privacy Rule does not prohibit such uses and disclosures.

When making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose, regulated entities are permitted, but not required, to rely on that representation, if such reliance is reasonable under the circumstances.[250] Such reliance may not be reasonable where the request appears to be overly broad when compared to the stated purpose of the request (*e.g.,* where a public health authority requests the disclosure of PHI of all individuals who received treatment for uterine bleeding when the stated purpose is to investigate infection control practices by an obstetrician/gynecologist in a state where law enforcement has publicly announced its intention to investigate individuals for traveling out of state to seek or obtain reproductive health care that is lawful under the circumstances in which it is provided).

Comment: A few commenters asserted that law enforcement generally interprets public health investigations to include criminal investigations and prosecutions and the NPRM proposed definition would complicate such investigations by limiting the amount of PHI that could be disclosed to law enforcement.

Response: The Department has adopted a definition of ''public health'' in the context of public health surveillance, investigation, and intervention that sets clear parameters between such activities and law enforcement activities conducted to impose liability for the mere act of seeking, obtaining, providing, or facilitating health care. Public health surveillance, investigation, and intervention do not include efforts to attach liability to persons for specific acts of seeking, obtaining, providing, or facilitating health care.

This definition is consistent with the longstanding distinction made by the Department between public health activities and law enforcement activities as described above.

Comment: Several commenters expressed support for the Department's proposal generally but recommended further clarifications or revisions to it, especially regarding the limitation to ''population-level'' activities. A few commenters raised questions about the difference between the proposed definition of ''public health'' and the permission for public health activities under 45 CFR 164.512(b)(1)(i) and recommended that the Department clarify the definition to ensure that public health agencies are able to obtain health information for administrative or civil proceedings, such as quarantine or isolation in cases involving infectious diseases.

Response: The Department has modified the definition of ''public health'' in the context of public health surveillance, investigation, or intervention to clarify that such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of PHI. This change addresses commenters' concerns that under the proposed definition, regulated entities would no longer be able to report PHI that is required to address population-level concerns.

Comment: Several commenters raised concerns that the proposed definition of ''public health'' would circumvent states' interests related to public health. A few commenters expressed opposition to the Department's clarification of public health because they believed that states should have the ability to conduct surveillance, investigations, or interventions concerning certain types of health care for public health purposes. Several commenters asserted that the proposal would frustrate the ability of states to enforce their laws prohibiting access to certain types of health care. Conversely, a commenter requested that the Department explicitly exclude reproductive health care from the proposed definition of ''public health,'' so it would not be reportable to public health agencies.

Response: We disagree with commenters' assertions that this final rule will prevent the reporting of vital statistics or other public health

[250] 45 CFR 164.514(d)(3)(iii)(A); *see also* 45 CFR 164.514(h)(2)(ii) and (iii).

activities. A covered entity may continue to use or disclose PHI for all the public health activities and purposes listed in section 1178(b). We also decline to explicitly exclude reproductive health care from the definition of ''public health'' because doing so could hinder beneficial public health activities. Instead, this definition supports this final rule's prohibition against certain uses and disclosures of PHI by clarifying that public health surveillance, investigation, and intervention exclude conducting a criminal, civil, or administrative investigation into any person, or the imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying any person for such activities. Such excluded activities include those with the purposes that are prohibited at 45 CFR 164.502(a)(5)(iii).

Comment: A few commenters believed that defining ''investigation,'' ''intervention,'' or ''surveillance'' was unnecessary or recommended against doing so and requested that the Department clarify that such terms do not encompass any prohibited purposes. One commenter requested that the Department define these terms to expressly exclude information related to reproductive health care.

Response: We are not defining the terms ''investigation,'' ''intervention,'' or ''surveillance'' in this rule. However, we are providing extensive interpretation in the preamble to clarify that such activities in the public health context do not encompass conducting a criminal, civil, or administrative investigation into any person, or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying any person for such activities, including those for which use or disclosure of PHI is prohibited by 45 CFR 164.502(a)(5)(iii).

Reporting of Child Abuse

In accordance with section 1178(b) of HIPAA, the Privacy Rule permits a regulated entity to use or disclose PHI to report known or suspected child abuse or neglect if the report is made to a public health authority or other appropriate government authority that is authorized by law to receive such reports.[251] The Privacy Rule limits disclosures of PHI made pursuant to this permission to the minimum necessary to make the report.[252]

As the Department explained in the 2023 Privacy Rule NPRM, at the time HIPAA was enacted, ''most, if not all, states had laws that mandated reporting of child abuse or neglect to the appropriate authorities.'' [253] Additionally, when Congress enacted HIPAA, it had already addressed child abuse reporting in other laws, such as the Victims of Child Abuse Act of 1990 [254] and the Child Abuse Prevention and Treatment Act.[255] For example, 34 U.S.C. 20341(a)(1), a provision of the original Victims of Child Abuse Act of 1990 that is still in place today, requires certain professionals to report suspected abuse when working on Federal land or in a federally operated (or contracted) facility.[256] As used in these statutes, the term ''child abuse'' does not include activities related to reproductive health care, such as abortion.

In the 2023 Privacy Rule NPRM, the Department discussed that it has long interpreted ''child abuse,'' as used in the Privacy Rule and section 1178(b) of HIPAA, to exclude conduct based solely on a person seeking, obtaining, providing, or facilitating reproductive health care.[257] This interpretation is consistent with the public health aims of improving access to health care for individuals, including reproductive health care, and with relevant statutes at the time HIPAA was enacted, as described above. The Department also stated that this interpretation prohibits a regulated entity from disclosing PHI in reliance on the permission for reporting ''child abuse'' where the alleged victim does not meet the definition of ''person'' or ''child,'' consistent with both 1 U.S.C. 8 and section 1178(b). Additionally, consistent with previous rulemaking under HIPAA, the Department clarified in the preamble that it did not intend for the interpretation to disrupt longstanding state or Federal child abuse reporting requirements that apply to regulated entities.[258]

The Department also made several clarifications in preamble concerning our interpretation of section 1178(b) and the Privacy Rule's public health permission and how we distinguish between public health reporting and disclosures for law enforcement purposes or judicial and administrative proceedings.

Comment: Many commenters supported the Department's clarification and agreed that it would preserve trust between individuals and health care providers, but also requested additional clarification from the Department on its implementation. Few opposed the clarification; those who did expressed concerns about the potential for the clarification to prevent state-mandated reporting in certain circumstances. Many commenters expressed mixed views about the Department's interpretation.

Response: The Department is moving forward with its interpretation as described in the NPRM. As noted above, this final rule does not alter the Privacy Rule's reliance on other applicable law with respect to determining who has the authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, including lawful reproductive health care.[259] The Privacy Rule does not permit a regulated entity to disclose PHI as part of a report of suspected child abuse based solely on the fact that a parent seeks reproductive health care (*e.g.,* treatment for a sexually transmitted infection) for a child. However, the regulated entity is permitted to make such disclosure where there is suspicion of sexual abuse that could be the basis of permitted reporting.

Congress defined the term ''child'' in 1 U.S.C. 8, and the term ''child'' in the Privacy Rule is consistent with that definition. As such, the Department believes that to the extent this clarification prohibits a regulated entity from disclosing PHI to report ''child abuse'' under this permission in the Privacy Rule where the alleged victim does not meet the definition of ''person,'' it is consistent with both 1 U.S.C. 8 and section 1178(b).

The Department also reaffirms its clarification that the Privacy Rule permission to report known or suspected child abuse or neglect permits a disclosure only for the purpose of making a report, and the PHI disclosed must be limited to the minimum necessary information for the purpose of making a report.[260] These provisions do not permit the covered entity to disclose PHI in response to a request for the use or disclosure of PHI to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on a

[251] *See* 45 CFR 164.512(b)(1)(ii).

[252] *See* 45 CFR 164.502(b) and 164.514(d).

[253] 65 FR 82462, 82527 (Dec. 28, 2000).

[254] Public Law 101–647, 104 Stat. 4789 (codified at 18 U.S.C. 3509).

[255] Public Law 93–247, 88 Stat. (codified at 42 U.S.C. 5101 note).

[256] *See* 34 U.S.C. 20341(a)(1), originally enacted as part of the Victims of Child Abuse Act of 1990 and codified at 42 U.S.C. 13031, which was editorially reclassified as 34 U.S.C. 20341, Crime Control and Law Enforcement. For the purposes of such mandated reporting, *see* 34 U.S.C. 20341(c)(1) for definition of ''child abuse.''

[257] 88 FR 23506, 23526 (Apr. 17, 2023).

[258] 65 FR 82462, 82527 (Dec. 28, 2000).

[259] *See* 45 CFR 164.502(g).

[260] *See* 45 CFR 164.502(b) and 164.514(d).

person based on suspected child abuse. Instead, as we explained in the 2023 Privacy Rule NPRM, any disclosure of PHI in response to this type of request from an investigator, must meet the applicable Privacy Rule conditions for disclosures for judicial and administrative proceedings or law enforcement purposes, as applicable.[261] That is the case whether such disclosure is in follow up to the report made by the covered entity (other than to clarify the PHI provided on the report) or part of an investigation initiated based on an allegation or report made by a person other than the covered entity.[262]

Moreover, this clarification does not affect the ability of state authorities to invoke other permissions for disclosure under the Privacy Rule, such as the permission for disclosures for law enforcement purposes, where they are seeking PHI related to unlawful reproductive health care.[263] Thus, the Department's interpretation of ''child abuse'' continues to support the protection of children while also serving HIPAA's objectives of protecting the privacy of PHI to promote individuals' trust in the health care system and preserving the relationship between individuals and their health care providers.

Comment: A few commenters recommended that the Department expand the clarification of child abuse to broadly address providing or facilitating all health care, rather than just reproductive health care.

Response: It is beyond the scope of this rule making to expand the clarification to include the provision or facilitation of all lawful health care. We appreciate the recommendations of commenters and will take them under advisement for potential future rulemaking.

3. Adding a Definition of ''Reproductive Health Care''

Section 160.103 of the HIPAA Rules defines ''health care'' as ''care, services, or supplies related to the health of an individual.'' [264] The definition clarifies that the term ''includes but is not limited to'' several identified types of care, services, and procedures [265] and includes examples such as therapeutic, rehabilitative, or maintenance care, as well as sale or dispensing of drugs or devices.

The Department proposed to add and define a new term, ''reproductive health care,'' that would be a subset of the term ''health care.'' [266] The Department proposed to define ''reproductive health care'' as ''care, services, or supplies related to the reproductive health of the individual.'' The Department noted in the NPRM preamble that the HIPAA Rules define ''health care'' broadly.[267]

Consistent with the definition of ''health care'' in the HIPAA Rules, the proposed definition of ''reproductive health care'' would have applied broadly and included not only reproductive health care and services furnished by a health care provider and supplies furnished in accordance with a prescription, but also care, services, or supplies furnished by other persons and non-prescription supplies purchased in connection with an individual's reproductive health. The Department proposed to use the term ''reproductive health care'' rather than ''reproductive health services'' to ensure that the term was interpreted broadly to capture all health care that could be furnished to address reproductive health, including the provision of medications and devices, whether prescription or over-the-counter.

The Department discussed in preamble some of the types of care, services, and supplies that were included in the proposed term. In keeping with the Department's intention for ''reproductive health care'' to be inclusive of all types of health care related to an individual's reproductive system, the 2023 Privacy Rule NPRM preamble indicated that the term would include, but not be limited to: contraception, including emergency contraception; pregnancy-related health care; fertility or infertility-related health care; and other types of care, services, or supplies used for the diagnosis and treatment of conditions related to the reproductive system. We also provided a non-exhaustive list of examples of health care within each of these categories of reproductive health care.

Consistent with the definition of ''health care'' adopted in 2000 in the HIPAA Rules, the Department did not propose a specific definition of ''reproductive health'' but invited comment on whether including a particular definition of ''reproductive health'' would be beneficial.

Many commenters supported the proposal and agreed that it would provide the necessary protections for individuals and others. Some referenced existing definitions used by other legal authorities and recommended the Department consider adopting or incorporating them in some manner.

Some commenters opposed the proposal to provide an inclusive definition of reproductive health care. Some commenters asserted that the proposal lacked clarity and was too open-ended, making it difficult to operationalize. Other commenters expressed concern that the proposed definition would permit minors to consent to reproductive health care without parental consent.

The final rule adopts the new term ''reproductive health care'' and definition with three modifications. First, we replace ''care, services, or supplies related to the reproductive health of the individual'' with ''health care'' and add a citation to the HIPAA Rules' definition of that term to clarify that reproductive health care is a subset of ''health care.''

Second, we specify that the term means health care ''that affects the health of the individual in all matters relating to the reproductive system and to its functions and processes.'' In keeping with the Department's intention for ''reproductive health care'' to be interpreted broadly and inclusive of all types of health care related to an individual's reproductive system, this additional language clarifies that the definition encompasses the full range of health care related to an individual's reproductive health.

Third, we add a statement reaffirming that the definition should not be construed to establish a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

As discussed in the NPRM, this approach is consistent with the approach the Department took when it adopted the definition of ''health care'' in the HIPAA Rules. At that time, the Department explained that listing specific activities would create the risk that important activities would be left out and could also create confusion.[268]

By describing more fully the breadth of reproductive health care, the definition may decrease the perceived burden to regulated entities of complying with the rule by helping them determine whether a request for

[261] *See* 45 CFR 164.512(e) and (f).

[262] *See* 45 CFR 164.512(e) and (f).

[263] 65 FR 82462, 82527 (Dec. 28, 2000).

[264] 45 CFR 160.103 (definition of ''Health care'').

[265] These groupings are (1) ''[p]reventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body'' and (2) ''[the s]ale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.'' It would also include supplies purchased over the counter or furnished to the individual by a person that does not meet the definition of a health care provider under the HIPAA Rules. 45 CFR 164.103 (definition of ''Health care provider'').

[266] 88 FR 23506, 23527–28 (Apr. 17, 2023).

[267] 88 FR 23506, 23527 (Apr. 17, 2023).

[268] 65 FR 82571 (Dec. 28, 2000).

the use or disclosure of PHI includes PHI that is implicated by this final rule.

To further clarify what is included in reproductive health care for regulated entities, we provide a non-exclusive list of examples that fit within the definition: contraception, including emergency contraception; preconception screening and counseling; management of pregnancy and pregnancy-related conditions, including pregnancy screening, prenatal care, miscarriage management, treatment for preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination; fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components [269] (*e.g.,* in vitro fertilization (IVF)); diagnosis and treatment of conditions that affect the reproductive system (*e.g.,* perimenopause, menopause, endometriosis, adenomyosis); and other types of care, services, and supplies used for the diagnosis and treatment of conditions related to the reproductive system (*e.g.,* mammography, pregnancy-related nutrition services, postpartum care products).

Additionally, the language in the definition stating that the definition should not be construed to set forth a standard of care or regulate what constitutes clinically appropriate reproductive health care should not be read as limiting ''reproductive health care'' to only health care that is determined to be appropriate by a health care professional. Rather, it may be the individual who determines whether the health care they receive, such as over-the-counter contraceptives, is appropriate. Like the definition of ''health care,'' the definition of reproductive health care is intended to be broad. Finally, we clarify that meeting the definition is not sufficient for information about such health care to be protected under the HIPAA Rules or this final rule. Rather, the information about such health care still needs to meet the definition of PHI.[270]

Comment: Some commenters expressed support for the proposed definition of ''reproductive health care.'' Several commenters specifically expressed their support for a broad definition of the term for various reasons, including: ensuring that providers of reproductive health care can continue to serve vulnerable communities and reduce health care disparities; providing clarity; and mitigating the need for clinical expertise and interpretation for each request for reproductive health information. Other commenters expressed support for the term because it would improve access to care and better reflect the breadth of services that support an individual's reproductive health, enable health care providers to continue to maintain appropriate data safeguards, and enable individuals to feel comfortable disclosing their information without fear of incrimination.

Many other commenters expressed opposition to the proposed definition because it was too expansive and would encompass procedures that they did not consider to be reproductive health care. Many commenters explicitly requested that the definition exclude certain types of health care. A few commenters recommended that the Department narrow the proposed definition to apply only to records directly involving certain specified services and clarify that the final definition does not include other procedures or treatments related to pregnancy or contraception. Another commenter expressed opposition to the proposed definition of ''reproductive health care'' because they believe that reproductive health information is no more sensitive than other medical information and should not be treated differently.

One commenter opposed the proposed definition of ''reproductive health care'' because they thought it would prevent health care providers from disclosing PHI to other health care providers for treatment, which would erode individual trust.

Several commenters requested that the Department expand the proposed definition, be more specific in its meaning (*e.g.,* provide additional information about the types of care, services, or supplies included in the definition), or replace it with a more expansive term (*e.g.,* ''sensitive personal health care'' meaning ''care, services, or supplies related to the health of the individual which could expose any person to civil or criminal liability for the mere act of seeking, obtaining, providing, or facilitating such health care''). A commenter urged the Department to define the term ''sexual and reproductive health care'' to ensure that individuals have reproductive health care privacy, regardless of their sexual orientation or gender identity.

Commenters offered several alternative definitions or terms, such as ''including but not limited to services related to contraception, sterilization, preconception care, maternity care, abortion care, and counseling regarding reproductive health care''; the definition of ''reproductive health care services'' at 18 U.S.C. 248(e)(5); ''reproductive and sexual health care services'' as defined in California Health and Safety Code section 1367.31; and limiting the definition to capture only health care that is at risk of being investigated or prosecuted because of *Dobbs.* Other commenters requested additional precision or clarity in the definition. For example, a commenter recommended that the definition include the specific codes and data points that would constitute reproductive health care that would be prohibited from disclosure under the proposed rule (*e.g.,* International Classification of Diseases (ICD) codes related to reproductive health, ABO blood type and Rh factor).

Several commenters urged the Department to narrow the proposed definition because of operational concerns, including the redirection of resources to making or obtaining legal determinations about whether a particular type of care was reproductive health care. Some explained that health information management staff generally do not have the clinical expertise to determine what would constitute ''reproductive health care,'' while another stated that physicians would also have trouble discerning what health care would meet the proposed definition. Another commenter recommended that the Department include only PHI that is already reliably segregated in EHRs in the definition.

Many commenters requested that the Department further explain the proposed definition either in preamble or the regulatory text. One commenter suggested that in lieu of a definition of ''reproductive health care,'' the Department include an extensive discussion of examples in the preamble and provide entities flexibility to implement policies or procedures that may be affected by the definition of ''reproductive health care'' in accordance with their operational structures. A few commenters also recommended that the Department provide examples in preamble discussion, rather than regulatory text. One commenter recommended that the Department provide specific examples to illustrate its meaning where there could be ambiguity. Several commenters recommended that examples be included in the regulatory text and provided specific examples of the types

[269] *See* ''What is Assisted Reproductive Technology?'' Centers for Disease Control and Prevention (Oct. 8, 2019), *https://www.cdc.gov/art/whatis.html* and ''Fact Sheet: In Vitro Fertilization (IVF) Use Across the United States,'' U.S. Dep't of Health and Human Servs. (Mar. 13, 2024), *https://www.hhs.gov/about/news/2024/03/13/fact-sheet-in-vitro-fertilization-ivf-use-across-united-states.html.*

[270] 45 CFR 160.103 (definition of ''Protected health information'').

of health care they thought should be included. Some commenters recommended the Department include examples but did not specify whether they should be in the preamble or in the regulatory text, while other commenters requested that the Department include a non-exhaustive list of examples of reproductive health care in both the regulation and preamble.

Response: After consideration, we have finalized a definition grounded in the Privacy Rule's long-established term ''health care.'' We provide a non-exhaustive list of examples in preamble above. We do not explicitly address all of the many types of health care suggested in comments to avoid creating the impression of a complete list. This is also consistent with our approach regarding the definition of ''health care.'' We emphasize that this definition does not set or affect standards of care, nor does it affect uses and disclosures of PHI for treatment purposes. Operational concerns expressed by some commenters are addressed in response to comments on the prohibition.

4. Whether the Department Should Define Any Additional Terms

The Department requested comments about whether it would be helpful for the Department to define ''reproductive health'' or any additional terms.[271]

Comment: Several commenters recommended that the Department define ''reproductive health'' because it would ensure that all covered entities would be required to implement changes, or that the PHI of individuals receiving certain types of health care would not be disclosed to states where individuals who receive such health care is being penalized.

Several commenters urged the Department to add the definition of reproductive health adopted by the United Nations and World Health Organization, while others recommended the adoption of the definition articulated by the International Conference on Population and Development in 1994. One commenter expressed opposition to adding a definition of reproductive health as unnecessary, and another instead recommended adoption of a precise definition of ''reproductive health care.''

Another commenter recommended expanding the definition of PHI to include certain digital data of entities not regulated under HIPAA (*e.g.,* information from period tracking apps). One commenter recommended revising the definition of ''health oversight agency'' to exclude agencies that investigate or prosecute activities related to reproductive health care. Some commenters requested that the Department define additional terms or clarify existing terms.

Rather than define additional terms, one commenter recommended that the Department ensure that all the proposed definitions would be aligned with the Office of the National Coordinator for Health Information Technology (ONC) and CMS-mandated data elements for Certified Electronic Health Record Technology products and in the electronic clinical quality measures that health care providers are required to report to CMS.

Response: We appreciate the feedback from commenters, but upon further consideration, have concluded that defining any of the additional terms or clarifying additional existing ones is not necessary to support the implementation of this final rule. We also clarify that because HIPAA only authorizes the Department to protect IIHI used or disclosed by covered entities and their business associates, we are not able to regulate information that individuals themselves store and share using consumer health apps.

B. Section 164.502—Uses and Disclosures of Protected Health Information: General Rules

Section 164.502 of the Privacy Rule contains the general rules governing uses and disclosures of PHI. Paragraph (a)(1) of this section sets forth the list of permitted uses and disclosures.

1. Clarifying When PHI May Be Used or Disclosed by Regulated Entities

Section 164.502(a)(1)(iv) generally permits a regulated entity to use or disclose PHI pursuant to and in compliance with a valid authorization under 45 CFR 164.508, except for uses and disclosures of genetic information by a health plan for underwriting purposes prohibited under 45 CFR 164.502(a)(5)(i). Thus, an authorization that purports to allow a health plan to use or disclose PHI for that prohibited purpose is not valid under the Privacy Rule.

The Department proposed to modify 45 CFR 164.502(a)(1)(iv) to incorporate an additional limitation on the ability of a regulated entity to use and disclose PHI pursuant to an individual's authorization.[272] Specifically, the Department's proposal would prohibit a regulated entity from using or disclosing PHI pursuant to an individual's authorization where the purpose of the disclosure is for a criminal, civil, or administrative investigation or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, or to identify any person for the purpose of initiating such activities. As explained in the 2023 Privacy Rule NPRM, the proposed modification was intended to prevent the misuse of the general permission for a regulated entity to use or disclose PHI pursuant to an individual's authorization to bypass the proposed prohibition against using and disclosing PHI for purposes that would be prohibited by proposed 45 CFR 164.502(a)(5)(iii).

The Department explained in the proposed rule that this change to the authorization permission was necessary to protect individuals' privacy by precluding any possibility that a third party, such as a law enforcement official, could coerce or attempt to coerce an individual into signing an authorization, thereby enabling the third party to circumvent the prohibition proposed at 45 CFR 164.502(a)(5)(iii).

The Department also proposed to modify the general rules in 45 CFR 164.502(a)(1)(vi) to expressly condition certain uses and disclosures made under 45 CFR 164.512 on the receipt of an attestation pursuant to proposed 45 CFR 164.509, which is discussed below in greater detail. For clarity, the Department proposed to revise 45 CFR 164.502(a)(1)(vi) by replacing the sentence containing the conditions for certain permitted uses and disclosures with a lettered list.

Public comments about the use of authorization to use and disclose PHI for the purposes the Department proposed to prohibit in the 2023 Privacy Rule NPRM were generally divided between opposing views and supportive views, although only a few comments expressed full support for the proposal, as drafted. While many commenters shared the Department's concerns about the potential for individuals to be coerced into providing an authorization, some of these commenters nonetheless opposed the proposal because it could limit beneficial disclosures, cause uncertainty about the validity of an authorization, increase the burden on regulated entities, or seem to conflict with state laws that permit the disclosure of certain health information with the individual's explicit written consent.

The Department received no comments on its proposal to replace the

[271] 88 FR 23506, 23528 (Apr. 17, 2023).

[272] 88 FR 23506, 23528–29 (Apr. 17, 2023).

sentence at 45 CFR 164.502(a)(1)(vi) with a lettered list. Comments on the Department's proposal to condition certain disclosures made under 45 CFR 164.512 on the receipt of an attestation as required by proposed 45 CFR 164.509 are discussed below in greater detail.

The Department is not finalizing its proposal to prohibit a regulated entity from using or disclosing an individual's PHI for the specified purposes pursuant to and in compliance with an individual's authorization. We agree with the majority of public comments discussed in detail below that generally expressed the view that the Privacy Rule's authorization requirements empower individuals to make decisions about who has access to their PHI. We acknowledge that maintaining the permission for regulated entities to obtain an individual's authorization to use and disclose PHI could leave an individual exposed to the potential for duress or coercion by a third party. It could also expose a health care provider or other person who provides or facilitates reproductive health care to liability in the event the authorization is used to affect a disclosure for a prohibited purpose in connection with lawful reproductive health care. However, we believe that continuing to permit uses and disclosures pursuant to an individual's authorization best preserves individual autonomy concerning uses and disclosures of their PHI. Consistent with our practice described above, the Department will monitor closely the interaction of the revised Privacy Rule and the evolving legal landscape to ensure an appropriate balance of protecting the privacy interests of individuals and permitting access to PHI for non-health care purposes.

As we discussed in the proposed rule, there is a relationship between the provision allowing an individual to authorize a regulated entity to use or disclose the individual's PHI to a third party and the HITECH Act requirement that a regulated entity comply with an individual's direction to transmit to another person an electronic copy of the individual's PHI in an EHR (''individual access right to direct'').[273] Both enhance an individual's autonomy by providing them with the ability to determine who can access the individual's PHI as specified in the authorization or access request. Both also create an opportunity for coercion or attempted coercion of an individual by another person (*e.g.,* a law enforcement official could attempt to coerce an individual into providing the law enforcement official with access to the individual's PHI by offering the individual a reduced sentence for an alleged crime). And while we remain concerned about the potential for coercion or attempted coercion, even if the Department were to finalize the proposed limitation on uses and disclosures with an authorization, the individual would retain the individual access right to direct, which is enshrined in statute. We also believe it would be inconsistent with the spirit of individual access right to direct for the Department to limit the ability of an individual to authorize a regulated entity to disclose their PHI to another person.

For the foregoing reasons, we are not finalizing this proposal, and the language in 45 CFR 164.502(a)(1)(iv) remains unchanged.

Comment: While some commenters expressed concern about the potential for coercion described in the proposed rule, they did not all agree that it would be appropriate to address this concern by prohibiting such disclosures pursuant to an authorization. Some commenters asserted that coercion concerns would not be eliminated by curtailing the ability of individuals to authorize disclosures of their PHI in certain circumstances.

Some commenters explained that prohibiting individuals from requesting disclosures of their PHI pursuant to an authorization for prohibited purposes would create a significant burden for regulated entities, primarily because of the frequent failure of persons requesting the use or disclosure of PHI to provide sufficient detail regarding the purpose of the request to allow them to determine if it would be for a prohibited purpose.

A few commenters asserted that a HIPAA authorization is the safest approach to ensuring an individual is aware of and agrees to the use or disclosure of their PHI. One of those commenters recommended that the Department permit a regulated entity to disclose PHI pursuant to a valid authorization unless the covered entity has actual knowledge that an authorization was not voluntary. A commenter recommended adding a disclaimer or warning to the authorization to provide assurances that an individual was not coerced into disclosing their PHI to law enforcement or other third party that might seek to use the PHI for improper purposes. Still another commenter recommended that the Department require the authorization to indicate the types of sensitive information the individual intends to share. One commenter recommended that certain disclosures be accompanied by a notice of the individual's rights under the Privacy Rule.

Response: We appreciate comments concerning this proposal and the restriction of individuals' ability to maintain control over their PHI by prohibiting the use of written authorization. The Privacy Rule's written authorization requirements are the most objective means by which an individual can provide direction to a regulated entity about the use and disclosure of their PHI known to a regulated entity. The right of individuals to access their PHI and choose to disclose their PHI to another person is a cornerstone of HIPAA, and as such, we are not proceeding with this proposal. The Department will continue to monitor complaints we receive and the outcome of enforcement actions to identify potential coercion and the effect of permitting individuals to authorize the disclosure of PHI for purposes that are prohibited under 45 CFR 164.502(a)(5)(iii) on the relationship between health care providers and individuals.

We also appreciate the comments that asserted that restricting the ability of regulated entities to use an authorization to obtain PHI for the purposes prohibited in this rulemaking could create a burden for the regulated entities.

To the extent that individuals wish to authorize the use and disclosure of their PHI, particularly when a request is not clear, or when a request seeks only partial parts of a record, a written authorization provides the regulated entity with the opportunity to clarify, with both the individual and the person requesting the disclosure, the PHI that will be disclosed. State laws that require regulated entities to obtain an individual's written consent are generally considered more privacy protective, and thus are not preempted.

Comment: Several commenters expressed support for eliminating the ability of regulated entities to use or disclose PHI pursuant to an authorization in certain circumstances because of the potential for harm to individuals as proposed. One commenter described the potential negative effects of permitting uses and disclosures pursuant to an authorization in certain circumstances on individuals from historically marginalized communities. Another commenter asserted that individuals frequently do not read consent forms provided to them for signature for a variety of reasons, including proficiency. Some commenters expressed concerns that individuals who are the subject of a

[273] 42 U.S.C. 17935(e).

criminal investigation or prosecution would be placed in situations where it would not be possible to obtain a voluntary authorization (*e.g.,* a custodial situation), or that law enforcement could seek to persuade an individual to provide them with access to the individual's PHI through improper means.

Response: We continue to share the concern expressed by commenters about the potential for coercion or harassment of individuals, particularly those in marginalized or underserved communities, to provide authorization for the use or disclosure of their PHI. According to many reports and data cited by the Department and commenters, such individuals more often experience negative interactions with law enforcement or other prosecutorial authorities. We urge HIPAA regulated entities to be mindful of Privacy Rule requirements that could help mitigate the potential for harm resulting from coercion or difficulties individuals may experience in understanding an authorization. For example, 45 CFR 164.508(b)(2)(v) holds invalid authorizations that include ''material information [. . .] known by the covered entity to be false''; 45 CFR 164.508(c)(1)(iv) requires that every authorization include a description of each purpose of the requested use or disclosure; and 45 CFR 164.508(c)(3), requires the authorization be written in plain language.[274] The Department will continue to monitor complaints, questions, and enforcement outcomes for potential harm from disclosures resulting from authorizations.

Comment: A few commenters requested clarifications of how the proposal would affect other disclosures made pursuant to the Privacy Rule, including disclosures to the individual's attorney, and whether the Department intended it to apply to other consumer-initiated requests, such as part of an Application Programming Interface (API).

A commenter recommended that health care providers be permitted to refuse to release PHI to any consumer health app when the information could lead to civil or criminal repercussions for the health care provider unless the app developer signs a binding agreement that protects them.

Response: We are not finalizing the proposal, but state here that the Department did not intend to affect or disrupt the ability of covered entities to make other disclosures of PHI pursuant to a written authorization under the Privacy Rule. Additionally, as discussed above, individuals have the right to obtain a copy of their PHI and the individual access right to direct, which could involve releasing PHI to a consumer health app or an API. With respect to EHR and technology vendors and other third parties who facilitate the exchange of PHI on behalf of covered entities, we continue to stress that valid business associate agreements are required by the Privacy Rule and necessary to protect the privacy of the individuals who are the subject of the PHI. ONC also has made clear that it intends to advance technologies that support requirements already extant under the HIPAA Privacy Rule.[275] Additionally, the Department continues to urge covered entities that have direct contact with individuals to educate such individuals on the risks of disclosing their PHI to persons that are not regulated by HIPAA.[276] We will continue to ensure that regulated entities enter into business associate agreements as required by the Privacy Rule.[277] We will continue to monitor complaints, questions, and enforcement outcomes.

Comment: Many commenters addressed the relationship between the Department's proposal to eliminate the option for an individual to request disclosure of their information for the prohibited purposes pursuant to an authorization and the individual right of access, particularly, the right of an individual to direct a regulated entity to transmit to a third party an electronic copy of their PHI in an EHR. Several commenters recommended that the Department curtail the individual access right to direct. Some commenters expressed concern about the potential for individuals to be coerced into providing access to their PHI to third parties. A few commenters expressed concerns that some third parties sell PHI for purposes adverse to individuals' interests, including some of the purposes described in the 2023 Privacy Rule NPRM.

A few commenters provided recommendations for ways to educate individuals regarding their rights under the Privacy Rule.

Response: Although we appreciate the comments on this topic, any modifications to the individual access right to direct are beyond the scope of this rulemaking. We reiterate here that covered entities and their technology vendors that meet the definition of business associates must ensure that valid business associate agreements are in place,[278] and we urge them to facilitate individuals' awareness of the risks of using third-party consumer apps that are not regulated by HIPAA.[279] The Department continues to appreciate the identification of better education resources for individuals and health care providers and commits to providing educational resources through its website, regional offices, and webinars.

2. Adding a New Category of Prohibited Uses and Disclosures

Generally, the Privacy Rule prohibits the use or disclosure of PHI except as permitted or required by the Privacy Rule. Paragraph (a)(5) of section 164.502 contains specific purposes for which the Privacy Rule explicitly prohibits the use and disclosure of PHI. Section 164.502(a)(5)(i) prohibits most health plans from using or disclosing PHI that is genetic information for underwriting purposes, while 45 CFR 164.502(a)(5)(ii) prohibits a regulated entity from selling PHI, except when they have obtained a valid authorization from the individual who is the subject of the PHI.

The Department proposed to add a new paragraph, 45 CFR 164.502(a)(5)(iii), to prohibit regulated entities from using or disclosing an individual's PHI for certain additional purposes, and to describe the scope, applicability, and limitations of the prohibition. Similar to most other

[274] In the preamble to the 2000 Privacy Rule, we explained that a covered entity could meet HIPAA plain language requirements by organizing material to serve the reader; writing short sentences in the active voice; using pronouns; using common, everyday language; and dividing material into short sections. 65 FR 82462, 82548 (Dec. 28, 2000).

[275] 89 FR 1192, 1302 (Jan. 9, 2024). *See also* Off. for Civil Rights, ''Information Blocking Regulations Work In Concert with HIPAA Rules and Other Privacy Laws to Support Health Information Privacy,'' U.S. Dep't of Health and Human Servs. (Apr. 12, 2023), *https://www.healthit.gov/buzz-blog/information-blocking/information-blocking-regulations-work-in-concert-with-hipaa-rules-and-other-privacy-laws-to-support-health-information-privacy.*

[276] *See, e.g.,* Off. for Civil Rights, ''Resource for Health Care Providers on Educating Patients about Privacy and Security Risks to Protected Health Information when Using Remote Communication Technologies for Telehealth,'' U.S. Dep't of Health and Human Servs., *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/resource-health-care-providers-educating-patients/index.html.*

[277] *See* 45 CFR 164.502(a)(3) and (e). *See also* 45 CFR 164.504(e).

[278] For information about what a business associate is and the requirements for business associate agreements, *see* Off. for Civil Rights, ''Business Associate Contracts,'' U.S. Dep't of Health and Human Servs. (Jan. 25, 2013), *https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html.*

[279] Off. for Civil Rights, ''Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet,'' U.S. Dep't of Health and Human Servs. (June 29, 2022), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.*

prohibitions within the Privacy Rule, this prohibition would be purpose-based, rather than a blanket prohibition against uses and disclosures of certain types of PHI.[280] The Department's rationale for this approach was four-fold: (1) to be consistent with the existing Privacy Rule permissible use and disclosure structure with which regulated entities are familiar, including the permission to disclose to law enforcement for certain purposes; (2) to avoid imposing a requirement on regulated entities that would necessitate the adoption and implementation of costly technology upgrades to enable data segmentation; [281] (3) to recognize that PHI about an individual's reproductive health care may be used or disclosed for a wide variety of purposes, and permitting the use or disclosure of PHI for some of those purposes would erode individuals' ability to trust in the health care system; and (4) to avoid any misperception that the Department is setting a standard of care or substituting its judgment for that of individuals and licensed health care professionals.

Proposed 45 CFR 164.502(a)(5)(iii)(A) would establish a new prohibition against the use or disclosure of PHI. Section (a)(5)(iii)(A)(*1*) would prohibit the use or disclosure of PHI where the use or disclosure is for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care. Section 164.502(a)(5)(iii)(A)(*2*) would prohibit the use or disclosure of PHI to identify any person for the purpose of initiating a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care.

The Department proposed 45 CFR 164.502(a)(5)(iii)(B) to explain that ''seeking, obtaining, providing, or facilitating'' would include, but not be limited to, expressing interest in, inducing, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same. As the Department explained in the 2023 Privacy Rule NPRM, the proposed prohibition would apply to any request for PHI to facilitate a criminal, civil, or administrative investigation or proceeding against any person, or to identify any person to initiate an investigation or proceeding, where the basis for the investigation, proceeding, or identification is that the person sought, obtained, provided, or facilitated reproductive health care that is lawful under the circumstances in which such health care is provided. The Department further explained that, consistent with its HIPAA authority, the prohibition would preempt state or other laws requiring a regulated entity to use or disclose PHI in response to a court order or other type of legal process for a purpose prohibited under the proposed rule. Conversely, the prohibition would not preempt laws that require the use or disclosure of PHI for other purposes, such as: public health activities; [282] investigations of sexual assault committed against an individual where such use or disclosure is conditioned upon the receipt of an attestation; or investigations into human and sex trafficking, child abuse, or professional misconduct or licensing inquiries.[283]

The Department also proposed to subject this prohibition to a Rule of Applicability in 45 CFR 164.502(a)(5)(iii)(C). As the Department explained, the proposed prohibition in 45 CFR 164.502(a)(5)(iii) would prohibit a regulated entity from using or disclosing PHI for certain purposes against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is ''lawful under the circumstances in which such health care is provided.'' [284] The Department further explained that it proposed a framework for regulated entities to determine whether the reproductive health care at issue was lawful under the circumstances in which such health care was provided. The proposed language of the Rule of Applicability under this rule would apply where one or more of three specified conditions exist.

The first condition, as proposed in 45 CFR 164.502(a)(5)(iii)(C)(*1*), addressed reproductive health care provided outside of the state that authorized the investigation or proceeding where such health care is lawful in the state where it is provided. In the proposed rule, we also clarified that the proposal would apply the prohibition in a situation in which the health care is ongoing, has been completed, or has not yet been obtained, provided, or facilitated. The proposed prohibition would recognize that any interest of society in conducting an investigation or proceeding against a person would require balancing with, and generally be outweighed by, the interests of society in protecting the privacy interests of individuals when they access lawful health care. As discussed above, privacy interests are heightened with respect to reproductive health care that is lawful under the circumstances in which it is provided as compared to the interests of law enforcement, and private parties afforded legal rights of action, in investigating or imposing liability for actions related to lawful reproductive health care.

The second condition, proposed in 45 CFR 164.502(a)(5)(iii)(C)(*2*), addressed reproductive health care protected, required, or authorized by Federal law, regardless of the state in which such health care is provided. It would apply the prohibition to reproductive health care that is lawful under the applicable Federal law and where the investigation or proceeding is against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care. It would apply, for example, where the underlying reproductive health care continues to be protected by the Constitution, such as contraception, or is expressly required or authorized under Federal law.[285]

The third condition, proposed in 45 CFR 164.502(a)(5)(iii)(C)(*3*), would apply the prohibition when the relevant criminal, civil, or administrative investigation or proceeding is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care that is provided in a state consistent with and permitted by the law of that same state.

The Department also proposed a Rule of Construction in 45 CFR 164.502(a)(5)(iii)(D) that provided that the proposed prohibition should not be construed to prohibit a use or disclosure of PHI otherwise permitted by the Privacy Rule unless such use or disclosure is primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.[286] The Department proposed the Rule of Construction to avoid an erroneous interpretation of the prohibition

[280] 88 FR 23506, 23529–33 (Apr. 17, 2023).

[281] The Department does not oppose efforts to implement or employ technology that is capable of segmenting data. Rather, the Department's proposal was informed by the recognition that the technology deployed by most regulated entities today is not capable of doing so.

[282] *See supra* discussion of ''Public health'' for more information on what constitutes a ''public health activity'' under the Privacy Rule.

[283] 88 FR 23506, 23532 (Apr. 17, 2023).

[284] *Id.* at 23510, 23522, and 23531.

[285] *See Griswold* v. *Connecticut,* 381 U.S. 479 (1965); *Eisenstadt* v. *Baird,* 405 U.S. 438 (1972); *Dobbs,* 597 U.S. 345 (Kavanaugh, J., concurring) (*Dobbs* ''does not threaten or cast doubt on'' the precedents providing constitutional protection for contraception).

[286] *See* proposed 45 CFR 164.502(a)(5)(iii)(D). *See also* 88 FR 23506, 23552–53 (Apr. 17, 2023).

standard, which otherwise could have been construed to prevent regulated entities from using or disclosing PHI for the purpose of defending themselves or others against allegations that they sought, obtained, provided, or facilitated reproductive health care that was not lawful under the circumstances in which it was provided.

Most of the comments addressing the proposed prohibition expressed support for the Department's purpose-based approach and the principle that the Privacy Rule should prohibit the use and disclosure of PHI for a criminal, civil, or administrative investigation into or proceeding against any person, or to identify any person to initiate a criminal, civil, or administrative investigation into or proceeding against any person, in connection with seeking, obtaining, providing, or facilitating lawful reproductive health care. At the same time, the Department received many comments that expressed concern about the proposal's clarity and regulated entities' ability to operationalize the Rule of Applicability and Rule of Construction. For example, commenters asserted that to the extent the proposed rule would require regulated entities to determine whether the requested PHI was about reproductive health care that was lawful under the circumstances in which it was provided, making such a determination could be unduly burdensome when the request was about reproductive health care that was not provided by the regulated entity that received the request and could expose them to legal risk in the absence of additional guidance or a safe harbor. Other commenters expressed concern that applying the prohibition would undermine the ability of states to enforce their own health care laws.

Commenters who addressed the proposed Rule of Construction also expressed confusion about how the Department intended ''primarily'' or ''primarily for the purpose of'' to be interpreted. Many either requested examples of uses and disclosures that were ''primarily'' for the underlying prohibited purposes. In lieu of the proposal to avoid liability based on ''the mere act of'' seeking, obtaining, providing, or facilitating reproductive health care, a few commenters suggested expanding the proposed definition or modifying existing permissions to explicitly exclude conduct based solely on seeking, obtaining, providing, or facilitating certain types of health care.

The Department is finalizing the proposed prohibition that restricts the ability of regulated entities to use or disclose PHI for activities with the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it was provided, or to identify any person for such purposes, with modifications to improve clarity and ease implementation for regulated entities.

The Department is retaining its purpose-based approach in the final rule in light of concerns about the ability of regulated entities to segment certain types of data and in recognition that PHI about an individual's reproductive health may be reflected throughout an individual's longitudinal health record, in addition to being maintained by a wide variety of regulated entities.

As we discussed in the 2023 Privacy Rule NPRM, the Department recognizes that diseases and conditions that are not directly related to an individual's reproductive health may be affected by or have bearing on the individual's reproductive health and the reproductive health care they are eligible to receive, and vice versa. Thus, it may be necessary for all types of health care providers to maintain complete and accurate medical records to ensure that subsequent health care providers are adequately informed in making diagnoses or recommending courses of treatment. For example, an individual with a chronic cardiac or endocrine condition may become pregnant, placing additional strain on the individual's cardiovascular or endocrine system. In such cases, it is essential that their cardiologist or endocrinologist be informed of the pregnancy and consulted as necessary to ensure appropriate health care is provided to the individual because such conditions may have bearing on their pregnancy.

Additionally, the final rule revises the prohibition standard at 45 CFR 164.502(a)(5)(iii) by incorporating language from the proposed Rule of Construction to clarify the purposes for which the Department prohibits uses or disclosures of PHI. In 45 CFR 164.502(a)(5)(iii)(A)(*1*) and (*2*), the Department incorporates the ''mere act of'' language of the proposed Rule of Construction to clarify that the prohibited uses and disclosures of PHI are tied to imposing criminal, civil, or administrative liability for the ''mere act of'' seeking, obtaining, providing, or facilitating reproductive care and not just ''in connection to'' such acts.[287]

Section 164.502(a)(5)(iii)(A)(*1*) combines the criminal, civil, or administrative investigations language from the proposed prohibition standard with the proposed Rule of Construction to prohibit regulated entities from using or disclosing PHI for activities conducted for the purpose of a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Section 164.502(a)(5)(iii)(A)(*2*) separates and replaces the ''or proceeding against'' language from the first condition of the proposed prohibition standard with ''to impose criminal, civil, or administrative liability on'' and incorporates language from the proposed Rule of Construction to prohibit regulated entities from using or disclosing PHI for activities conducted for the purpose of imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Similar to proposed 45 CFR 164.502(a)(5)(iii)(A)(*2*), 45 CFR 164.502(a)(5)(iii)(A)(*3*) now addresses the use or disclosure of PHI to identify any person for the activities described in the other conditions of the prohibition standard. To the extent the purpose in 45 CFR 164.502(a)(5)(iii)(A)(*1*) relates to activities conducted for an investigation, the purpose in 45 CFR 164.502(a)(5)(iii)(A)(*2*) relates to the activities to impose liability, including activities that would flow from that investigation, whether it be in the form of proceedings to consider censure, medical license revocation, the imposition of fines or other penalties, or detainment or imprisonment, or the actual imposition of such liability.

The prohibition against the uses and disclosures of PHI finalized in 45 CFR 164.502(a)(5)(iii)(A) is subject to the Rule of Applicability that the Department is finalizing in 45 CFR 164.502(a)(5)(iii)(B). As discussed in the proposed rule and finalized herein, the Rule of Applicability modifies the prohibition standard to make clear that the prohibition encompasses the use or disclosure of PHI for any activities conducted for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that the regulated entity that has received the request for PHI has reasonably determined is lawful under the circumstances in which such health care is provided. The prohibition's

[287] Section 164.502(a)(5)(iii)(A)(*3*) incorporates the same language by reference to 45 CFR 164.502(a)(5)(iii)(A)(*1*) and (A)(*2*).

reference to the ''mere act'' of seeking, obtaining, providing, or facilitating lawful reproductive health care includes the reasons that the reproductive health care was sought or provided (*e.g.,* an investigation into whether a particular abortion was necessary to save a pregnant person's life would constitute an investigation into the ''mere act'' of seeking, obtaining, providing, or facilitating reproductive health care). The reference to ''mere act'' operates the same way with respect to activities conducted to identify any individual for the purposes described above. This includes but is not limited to law enforcement investigations, third party investigations in furtherance of civil proceedings, state licensure proceedings, criminal prosecutions, and family law proceedings. Examples of criminal, civil, or administrative investigations or activities to impose liability for which regulated entities would be prohibited from using or disclosing PHI would also include a civil suit brought by a person exercising a private right of action provided for under state law against an individual or health care provider who obtained, provided, or facilitated a lawful abortion, or a law enforcement investigation into a health care provider for lawfully providing or facilitating the disposal of an embryo at the direction of the individual.

The Department acknowledges that this final rule will not prohibit the use or disclosure of PHI in all instances in which persons request the use or disclosure of PHI for an investigation or to impose liability on a person for seeking, obtaining, providing, or facilitating reproductive health care. As discussed extensively in Section III of this rule, the Privacy Rule has long balanced the privacy interests of individuals with that of society in obtaining PHI for certain non-health care purposes. Accordingly, we acknowledge that in some circumstances, an individual's privacy interest in obtaining lawful care will outweigh law enforcement's interests in the PHI for certain non-health care purposes, while in others, law enforcement's interests in the PHI will outweigh the privacy interests of individuals. As we discussed above in Section III and in the proposed rule, recent developments in the legal landscape have made information about an individual's reproductive health more likely to be sought for punitive non-health care purposes, such as targeting individuals for seeking lawful reproductive health care outside of their home state, and therefore more likely to be subject to disclosure by regulated entities if the requested disclosure is permitted under the Privacy Rule. The Department's approach in this rulemaking limits the application of the prohibition to situations in which reproductive health care meets one of the conditions of the Rule of Applicability. Accordingly, the prohibition applies only where individuals' privacy interests outweigh the interests of law enforcement, and private parties afforded legal rights of action, in obtaining individuals' PHI for the non-health care purpose of investigating or imposing liability for reproductive health care that was not lawful under the circumstances in which it was provided.

We also acknowledge, as we did in the proposed rule, that in some circumstances, the Privacy Rule imposes greater restrictions on uses and disclosures of PHI than state privacy laws, and the prohibition may delay or hamper enforcement of certain other state laws (*e.g.,* laws governing access to reproductive health care). Such circumstances were contemplated by Congress when it enacted HIPAA.[288] For example, a state law might require a covered entity to disclose PHI to law enforcement in furtherance of an investigation, while the final rule may prohibit such a disclosure. In such cases, the provisions of the Privacy Rule would preempt the application of contrary provisions of state law, and the regulated entity could not disclose the PHI.[289] However, as discussed above in section III, we reiterate that not all methods to investigate the lawfulness of reproductive health care are foreclosed by this rule.

The Department emphasizes that the prohibition does not apply in circumstances that fall outside of its terms. Where a person requesting PHI identifies a legal basis for the request beyond the mere act of a person having sought, obtained, provided, or facilitated reproductive health care that was lawful under the circumstances in which it was provided, the prohibition at 45 CFR 164.502(a)(5)(iii) would not apply. Similarly, if a person obtains reproductive health care that was unlawful, such health care would not be lawful under the circumstances in which it was provided, and the prohibition would not apply. Where the prohibition does not apply, the Privacy Rule permits the requested PHI to be used or disclosed, provided that the use or disclosure is otherwise permitted by the Privacy Rule (*i.e.,* the request meets the requirements of an applicable permission and is accompanied by a valid attestation as described by 45 CFR 164.509, where required). The Department reminds the public that persons who request PHI under false pretenses may be subject to criminal penalties under HIPAA.[290]

The Rule of Applicability, as discussed below, vests the determination of whether the reproductive health care was lawful under the circumstances it was provided with the regulated entity that receives the request for PHI and requires that such determination be reasonable. The regulatory presumption, also discussed below, replaces the proposed requirement that a regulated entity make a determination regarding the lawfulness of the reproductive health care where someone other than the regulated entity that receives the request provided such health care. The new language requires that the reproductive health care at issue be presumed lawful under the circumstances in which such health care is provided when provided by a person other than the regulated entity receiving the request. This helps to ensure that the regulated entity is not required to make a determination about the lawfulness of such health care. The presumption may be overcome if certain conditions are met.

In the proposed rule, the Department provided examples that remain helpful in illustrating the operation of the clarified prohibition and how it continues to permit uses and disclosures for legitimate interests.[291] For example, the prohibition does not restrict a regulated entity from using or disclosing PHI to a health oversight agency conducting health oversight activities, such as investigating whether reproductive health care was actually provided or appropriately billed in connection with a claim for such services, or investigating substandard medical care or patient abuse.[292] However, as discussed above, investigating substandard medical care

[288] 42 U.S.C. 1320d–7(a)(1) (providing the general rule that, with limited exceptions, a provision or requirement under HIPAA supersedes any contrary provision of state law); *see also* section 264(c)(2) of Public Law 104–191 (codified at 42 U.S.C. 1320d–2 note) and 45 CFR 160.203.

[289] *See* final 45 CFR 164.509, and discussion below.

[290] *See* 42 U.S.C. 1320d–6.

[291] 88 FR 23506, 23532–33 (Apr. 17, 2023).

[292] *See* 45 CFR 164.512(d)(1)(i) through (iv) for health oversight activities for which the Privacy Rule permits uses and disclosures of PHI. *See also* the National Association of Medicaid Fraud Control Units, described at *https://www.naag.org/about-naag/namfcu/.* All 53 federally certified Medicaid Fraud Control Units voluntarily subscribe to this organization. This final rule does not interfere with any State's ability to meet their statutory obligations to combat health care fraud related to Medicaid.

or patient abuse may not be used as a pretext for investigating reproductive health care for purposes that are otherwise prohibited by this final rule. In another example, the rule does not bar a regulated entity from using or disclosing PHI to investigate an alleged violation of the Federal False Claims Act or a state equivalent based on unusual prescribing or billing patterns for erectile dysfunction medication.

This final rule also does not prohibit the use or disclosure of PHI where the PHI is sought to investigate or impose liability on a person for submitting a false claim for reproductive health care for payment to the government. In such a case, the request is not made for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Instead, the purpose of the request for PHI is to investigate or impose liability on a person for an alleged violation of the Federal False Claims Act or a state equivalent.[293] As another example, the revised prohibition standard generally does not prohibit the disclosure of PHI to an Inspector General where the PHI is sought to conduct an audit aimed at protecting the integrity of the Medicare or Medicaid Program where the audit is not inconsistent with this final rule. This is because the request is generally not being made for the purpose of investigating or imposing liability on a person for the mere act of providing the reproductive health care itself. The prohibition also makes clear that the use or disclosure of PHI is permitted where the purpose of the use or disclosure is to investigate alleged violations of Federal nondiscrimination laws or abusive conduct, such as sexual assault, that may occur in connection with reproductive health care. The prohibition likewise makes clear that the use or disclosure of PHI is permitted where the purpose of the use or disclosure is to penalize the provision of reproductive health care that is not lawful, as defined by the Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B), as long as a Privacy Rule permission applies.

Under the prohibition, a regulated entity could respond to a request for relevant records in a criminal or civil investigation pursuant to 18 U.S.C. 248 regarding freedom of access to clinic entrances. Investigations under this provision are conducted for the purpose of determining whether a person physically obstructed, intimidated, or interfered with persons providing ''reproductive health services,'' [294] or attempted to do so. Thus, they do not involve investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that was reasonably determined to be lawful under the circumstances in which such health care was provided by the regulated entity that received the request for PHI.

The final rule retains the proposal's prohibition against the use or disclosure of PHI for activities conducted for the purpose of investigating or imposing liability on ''any person'' for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, or for identifying ''any person'' for such activities. ''Any person'' means, based on the HIPAA Rules' definition of ''person,'' [295] that the prohibition is not limited to use or disclosure of PHI for use against the individual; rather, the prohibition applies to the use or disclosure of PHI against a regulated entity, or any other person, including an individual or entity, who may have obtained, provided, or facilitated lawful reproductive health care.[296]

The Department has always and continues to recognize that there may be a public interest and benefit in disclosing PHI for limited non-health care purposes, including enforcing duly enacted laws. The Department has also always sought to balance competing interests in individual privacy and the use and disclosure of PHI for particular purposes in the Privacy Rule. We balance these competing interests by considering both the harm to individuals that results from the use or disclosure of PHI (*e.g.,* loss of trust in the health care system, potential for financial liability or detainment) and the countervailing interests in disclosure. As discussed above, the Department finds that the final rule reflects the appropriate balance between these interests by prohibiting the use and disclosure of PHI for activities conducted for the purpose of investigating or imposing liability on ''any person'' for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, or for identifying ''any person'' for such activities.

Accordingly, the final rule adopts, with modifications discussed below, the proposed Rule of Applicability and re-designates it as 45 CFR 164.502(a)(5)(iii)(B). The final rule text also adds the word ''only'' in 45 CFR 164.502(a)(5)(iii)(B) to make clear that the prohibition's application is limited to the use or disclosure of PHI ''only'' where one or more of the conditions set forth in the Rule of Applicability exists.

To address concerns from commenters about how to determine whether reproductive health care is ''lawful,'' the Department finalizes a revised Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B). Specifically, the Rule of Applicability, as finalized, requires that a regulated entity that receives a request for PHI make a reasonable determination about the lawfulness of the reproductive health care in the circumstances in which such health care was provided, where lawfulness is described by 45 CFR 164.502(a)(5)(iii)(B)(*1*)–(*3*). Thus, a regulated entity that receives the request for PHI must decide whether it would be reasonable for a similarly situated regulated entity to determine, as provided in the Rule of Applicability, that the reproductive health care is lawful under the circumstances in which such health care is provided.

To make the reasonableness determination, that is, to determine whether it would be reasonable for a similarly situated regulated entity to determine that one or more of the conditions of the Rule of Applicability applies, a regulated entity receiving the request for PHI must evaluate the facts and circumstances under which the reproductive health care was provided. Such facts and circumstances include but are not limited to the individual's diagnosis and prognosis, the time such health care was provided, the location where such health care was provided, and the particular health care provider who provided the health care. This approach is consistent with the current and longstanding practice under the Privacy Rule, whereby a covered entity is responsible for determining whether a requested use or disclosure is permitted under one or more of the permissions set forth in the Privacy Rule. For example, a regulated entity is permitted to make a use or disclosure of PHI where ''required by law'' pursuant to 45 CFR 164.512(a). To make a use or disclosure under that permission, the regulated entity cannot rely on assertions from the person making the request, but rather, must itself evaluate the relevant law to determine whether

[293] 31 U.S.C. 3729–3733.

[294] 18 U.S.C. 248(e)(5) (definition of ''Reproductive health services'').

[295] 45 CFR 160.103 (definition of ''Person'').

[296] Note that in Section V.A.1, the Department is clarifying the definition of ''person,'' although that clarification does not affect the analysis in this paragraph.

the use or disclosure is ''required by law'' and thus permitted under that permission. As discussed above, the Department recognizes that this approach may prevent uses or disclosures in support of some law enforcement investigations (*e.g.,* where a health care provider reasonably determines that its provision of reproductive health care was lawful, but where law enforcement reasonably disagrees or does not provide sufficient factual information for a regulated entity to determine that there is a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided). However, we believe that, in these narrow circumstances, the interests of law enforcement, and private parties afforded legal rights of action, are outweighed by privacy interests and that the current approach strikes the appropriate balance between these competing interests.

The Department is retaining the proposed framework for identifying the circumstances in which reproductive health care is lawful, and thus the prohibition applies. However, we are modifying the regulatory text of the Rule of Applicability to clarify its conditions. As revised, the regulatory text combines the first and third conditions of the Rule of Applicability into a revised 45 CFR 164.502(a)(5)(iii)(B)(*1*) that focuses on whether the reproductive health care at issue is lawful under the circumstances in which such health care is provided. Under the revised condition, the circumstances in which the prohibition applies are determined by the law of the state in which the health care is provided.

As proposed in the 2023 Privacy Rule NPRM, the first and third conditions, when considered together, would have given the impression that the Department was drawing a distinction between reproductive health care provided in-state or out-of-state, although outcomes would have been the same. As the Department explained in the proposed rule, both the first and third conditions would have prohibited a regulated entity from using or disclosing PHI where the reproductive health care was permitted by the law of the state in which it was provided (*e.g.,* for pregnancy termination that occurs before a state-specific gestational limit or under a relevant exception in a state law restricting pregnancy termination such as when the pregnancy is the result of rape or incest or because the life of the pregnant individual is endangered, for reproductive health care that is generally permitted but must be provided by a specific type of health care professional or in a certain place of service). The outcome of the analysis remains the same under this final rule, which combines the first and third conditions of the Rule of Applicability into one condition. Thus, the revision improves the clarity of the Rule of Applicability by focusing solely on whether the reproductive health care was lawful under the circumstances in which it was provided.

Additionally, the final rule modifies the regulatory text in 45 CFR 164.502(a)(5)(iii)(B)(*2*) to include an express reference to the U.S. Constitution as a source of Federal law for determining whether reproductive health care is lawful under the circumstances in which such health care is provided. The Department has always intended to include the U.S. Constitution as a source of Federal law, and the final regulatory text now explicitly reflects this. The regulatory text also makes clear that the U.S. Constitution is not the sole source of Federal law and that Federal statutes, regulations, and policies may be the relevant legal authority for determining whether the reproductive health care is protected, required, or authorized under Federal law. This final rule in no way supersedes applicable state law pertaining to the lawfulness of reproductive health care.

To address commenters' concerns about obligating regulated entities to determine whether reproductive health care that occurred outside of the regulated entity is lawful, the Department is adding a new presumption provision at 45 CFR 164.502(a)(5)(iii)(C). It presumes the reproductive health care at issue was lawful under the circumstances in which such health care was provided when it was provided by a person other than the regulated entity receiving the request. The presumption can be overcome where the regulated entity has either actual knowledge, or factual information supplied by the person requesting the use or disclosure, that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided. The first ground to overcome the presumption—concerning ''actual knowledge''—accounts for situations where the regulated entity has actual knowledge that the reproductive health care was not lawful. The second ground to overcome the presumption—concerning ''factual information''—accounts for situations where the person making the request has demonstrated to the regulated entity that there is a substantial factual basis that the reproductive health care was unlawful under the circumstances in which such health care was provided. To satisfy the second ground, the regulated entity must obtain from the person making the request sufficient threshold factual evidence that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided.

For example, an investigator requests information from a health plan about claims for coverage of certain reproductive health care provided by a particular health care provider. The health plan must presume that the reproductive health care was lawful unless the health plan has actual knowledge that the reproductive health care was not lawful or the investigator supplied information that demonstrates a substantial factual basis to believe that the reproductive health care was not lawful under these circumstances. The latter condition could be met where the investigator provides the regulated entity with various types of documentation. For example, persons requesting PHI could provide the regulated entity with affidavits supplied by complainants that contain the circumstances under which the reproductive health care was provided. In this example, the presumption would be overcome, and the health plan would be permitted to use or disclose the PHI, assuming that all applicable conditions of the Privacy Rule were otherwise met. In contrast, if the investigator requests the same information but only provides an anonymous report of a particular health care provider providing reproductive health care that is not lawful under the circumstances in which it is provided, the health plan would not have a substantial factual basis to believe that the reproductive health care was not lawful. Accordingly, this final rule would prohibit the health plan from disclosing the requested PHI unless the investigator provides sufficient information to overcome the presumption and the use or disclosure is otherwise permitted by the Privacy Rule. The conditions of making the use or disclosure would include, as described elsewhere in this final rule, obtaining a valid attestation if the relevant permission requires one.

The Department emphasizes that, as demonstrated by the numerous comments on this issue, this regulatory presumption is necessary for workability by the regulated entities subject to this final rule. We recognize that when a regulated entity did not provide the reproductive health care at

issue, it may not have access to all of the relevant information, including medical records with the necessary information, to determine whether prior reproductive health care obtained by an individual was lawful. We clarify that regulated entities are not expected to conduct research or perform an analysis of an individual's PHI to determine whether prior reproductive health care was lawful under the circumstances in which it was provided when such health care was provided by someone other than the regulated entity that receives the request for the use or disclosure of PHI.

We also reiterate that this final rule is intended to support and clarify the privacy interests of individuals availing themselves of lawful reproductive health care, and not to thwart the interests of states in conducting lawful investigations or imposing liability on the provision of unlawful reproductive health care. While this new regulatory presumption may make it more difficult for a state to investigate whether reproductive health care was unlawful under the circumstances in which it was provided (*e.g.,* when other sources of information that is not PHI are unavailable), as discussed above, the Department has considered those interests and determined that the effects are justified by countervailing privacy benefits. Moreover, as also explained above, society's interest in obtaining PHI in such circumstances is reduced, particularly in light of its continued ability to obtain information from other sources. The Department also emphasizes that it is not applying a blanket presumption that all reproductive health care reflected in a regulated entity's records was lawful under the circumstances in which it was provided. Instead, the presumption applies only where the reproductive health care at issue is provided by someone other than the regulated entity that received the request for the use or disclosure of PHI, and it may be overcome in the circumstances identified above.

In contrast, where a request for PHI is made to the regulated entity that provided the relevant reproductive health care, the regulated entity is responsible for determining whether it provided reproductive health care that was lawful under the circumstances in which it was provided, including, as discussed above, a review of all available relevant evidence bearing on whether the reproductive health care was lawful under the circumstances in which it was provided. If the regulated entity reasonably determines that the health care was lawfully provided, the prohibition applies, and the regulated entity may not make the use or disclosure.

To illustrate how the presumption would apply, consider a hospital that has PHI about the provision of reproductive health care by a different facility. The hospital is not expected to conduct research or perform analysis into whether reproductive health care obtained at a different facility from another health care provider was lawful under the circumstances in which such health care was provided. Accordingly, the regulated entity, if they receive a request for PHI to which the prohibition at 45 CFR 164.502(a)(5)(iii) may apply, is not expected to review the individual's PHI to determine the lawfulness of the prior reproductive health care. In such situations, the regulated entity is also not expected to research other states' laws to determine whether the reproductive health care was lawful under the circumstances in which it was provided, nor are they expected to consult with an attorney to do the same. Rather, the presumption standard allows the regulated entity to limit their review to information supplied by the person making the request for the use or disclosure of PHI where the request addresses reproductive health care provided by someone other than the regulated entity receiving the request. Thus, a regulated entity that did not provide the reproductive health care must presume that the reproductive health care was lawful under the circumstances in which it was provided unless the conditions of rebutting the presumption are met.

Consider a different example in which a law enforcement official from State A issues a subpoena to a hospital in State A to request the PHI of an individual from State A who is suspected of obtaining reproductive health care in State B that would have been unlawful under the law of State A if provided there. The hospital did not provide the reproductive health care in question, nor did the individual provide information to the hospital about who may have provided such health care. At the time the law enforcement official issues the subpoena, the individual is no longer in the hospital, nor is the individual receiving treatment at the hospital. Additionally, the law enforcement official provided no information in the subpoena that would make it reasonable for the hospital to determine that the reproductive health care at issue was not lawful in the circumstances in which it was provided, that is, to determine that the reproductive health care was not lawful under the law of State B or was not protected, required, or authorized by Federal law. In this case, the hospital did not have actual knowledge that, nor did the information supplied to it by the law enforcement official making the request demonstrate to the hospital a substantial factual basis that, the individual had previously received unlawful reproductive health care; therefore, the reproductive health care is presumed to have been provided under circumstances in which it was lawful to provide such health care. Accordingly, this final rule would prohibit the hospital from disclosing the requested PHI unless the law enforcement official provides sufficient information to overcome the presumption and the use or disclosure is otherwise permitted by the Privacy Rule. This includes, as described elsewhere in this final rule, receipt of a valid attestation if the relevant permission requires one.

Conversely, if the hospital is provided with factual information that demonstrates a substantial factual basis that the reproductive health care at issue was not lawful under the specific circumstances in which such health care was provided, the presumption would be overcome. When a presumption is overcome or rebutted, the Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B) cannot be satisfied (*i.e.,* the regulated entity has actual knowledge, or has received factual information from the person requesting the PHI to determine that there is substantial factual basis to believe, that the reproductive health care was not lawful under the circumstances in which it was provided), and thus, the use or disclosure would not be prohibited under the final rule. As such, the Privacy Rule would permit, but would not require, the hospital to disclose the PHI in response to the subpoena where the use or disclosure meets the requirements of an applicable permission, including the receipt of a valid attestation where required.

In another example, a law enforcement agency presents a covered entity's business associate, such as a cloud service provider, with a subpoena for the PHI of an individual who received reproductive health care as part of its investigation into the health care provider who provided such health care for the provision of that health care. The PHI is encrypted, and the business associate does not have the key to decrypt it or is not permitted under the terms of its business associate agreement with the covered entity to decrypt the PHI. Thus, the business associate lacks a complete view of the individual's PHI and did not provide

the underlying reproductive health care. Additionally, the business associate has no actual knowledge that the reproductive health care was unlawful, nor did the person requesting the PHI supply it with information that demonstrates to the business associate a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. In such a case, the presumption that the reproductive health care at issue was lawful applies. If the law enforcement agency does not present more information to overcome the presumption, the Privacy Rule prohibits the business associate from disclosing the requested PHI in response to the subpoena, even if the law enforcement agency has provided an attestation; in this circumstance, the attestation would not be valid because the disclosure is for a purpose that is prohibited by 45 CFR 164.502(a)(5)(iii).

The presumption serves a different purpose than the attestation, which is required when there is a request for PHI potentially related to reproductive health care for certain permitted purposes under the Privacy Rule, as discussed further below. In contrast with the attestation, the presumption applies only where a request for PHI involves a purpose prohibited under 45 CFR 164.502(a)(5)(iii) and the reproductive health care at issue was provided by someone other than the regulated entity that received the request for PHI, so the regulated entity does not have first-hand knowledge of the circumstances in which the reproductive health care was provided. Because the situations in which the presumption applies involve purposes prohibited under 45 CFR 164.502(a)(5)(iii), it is not reasonable for a regulated entity to rely, without additional information, on a statement from the person requesting the use or disclosure, including the statement required in the attestation by 45 CFR 164.509(b)(1)(ii), that the request is not made for a prohibited purpose or that the underlying reproductive health care was unlawful. Thus, such statement alone does not satisfy 45 CFR 164.502(a)(5)(iii)(C)(*2*). However, if a person requesting the use or disclosure of PHI provides the regulated entity with sufficient information, separate and distinct from the attestation itself, that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided, the presumption would be overcome; in this scenario, the Privacy Rule would permit, but would not require, the regulated entity to disclose the PHI in response to the subpoena. The presumption may also be overcome by, for example, a spontaneous statement from the individual about the circumstances under which they obtained reproductive health care.

As we explained above, this final rule, consistent with the Department's longstanding approach to the Privacy Rule, balances competing interests between the privacy expectations of individuals and society's interests in PHI for certain non-health care purposes. For example, since its inception, the Privacy Rule has permitted a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).[297] Elsewhere in the Privacy Rule, covered entities are required to make a determination of whether it is ''reasonable under the circumstances'' to rely on documentation, statements, or representations from a person requesting PHI to verify the identity of the person requesting PHI and the authority of the person to access the PHI.[298] In the case of public officials, we have previously explained that covered entities must verify the identity of the request by examination of reasonable evidence, such as written statement of identity on agency letterhead, an identification badge, or similar proof of official status. In addition, where explicit written evidence of legal process or other authority is required before disclosure may be made, a public official's proof of identity and oral statement that the request is authorized by law are not sufficient to constitute the required reasonable evidence of the legal process or authority.[299] In both instances, the Privacy Rule permits regulated entities to rely on representations made by public officials where it is reasonable to do so but makes clear that in some instances, documentary or other evidentiary proof is needed.[300]

In this final rule, the Department has enshrined the requirement that a regulated entity make a reasonable determination of whether PHI should be disclosed in response to a request from law enforcement, or other official, in regulatory text and determined that is not reasonable to rely solely on representations of law enforcement or other officials without a written attestation. This approach is due to the high potential for harm to the individual who is the subject of the PHI or to persons who are subject to liability for the mere act of seeking, obtaining, providing or facilitating reproductive health care.

Further, as we discussed above, even in the scenario where a state official seeks PHI to investigate whether the underlying reproductive health care was unlawful, a regulated entity's reasonable determination that the conditions of the prohibition set forth in the Rule of Applicability are met means that the prohibition applies and the regulated entity is prohibited from using or disclosing the PHI. This does not foreclose the ability of state officials to investigate the circumstances surrounding the provision of the reproductive health care, including through the collection of information from sources that are not regulated under HIPAA, to determine whether a health care provider or other person may have acted unlawfully. Rather, this final rule prohibits the use or disclosure of PHI when it is being used to investigate or impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care, or to identify any person to initiate such activities. Indeed, the individual's privacy interests are especially strong where individuals seek lawful reproductive health care and risk either avoiding such lawful health care or being less than truthful with their health care providers because they fear that their PHI will be disclosed.

The Department is re-designating proposed 45 CFR 164.502(a)(5)(iii)(B) as 45 CFR 164.502(a)(5)(iii)(D) and modifying it in response to the

[297] *See* 45 CFR 164.514(d)(3)(iii)(A) and 65 FR 82462, 82545, and 82547 (Dec. 28, 2000).

[298] 45 CFR 164.514(h)(2) and 65 FR 82462, 82546–47 (Dec. 28, 2000).

[299] *See* 45 CFR 164.514(h) and 65 FR 82462, 82546–47 (Dec. 28, 2000).

[300] *See* 65 FR 82462, 82545 (Dec. 28, 2000) (''[. . .] covered entities making disclosures to public officials that are permitted under § 164.512 may rely on the representations of a public official that the information requested is the minimum necessary.''); *see also id.* at 82547 (further discussing verification of identity and authority of persons requesting PHI in 45 CFR 164.514(h) and the requirements in 45 CFR 164.512 for the circumstances under which covered entities must make reasonable determinations about the sufficiency of proof of identify and authority based on documentary evidence, contrasted with a reasonable reliance on verbal representations when necessary to avert a pending emergency or imminent threat to the health or safety of a person or the public pursuant to 45 CFR 164.512(j)(1)(i)).

commenters who provided examples of situations where they could reasonably expect to receive a request for PHI that might relate to ''seeking, obtaining, providing, or facilitating reproductive health care.'' To address these concerns, the Department is revising the list of activities in 45 CFR 164.502(a)(5)(iii)(D) that explain the scope of actions taken by persons that the Department is protecting against impermissible requests for PHI. Specifically, the Department is adding the terms ''administering,'' ''authorizing,'' ''providing coverage for,'' ''approving,'' and ''counseling about'' to the current list of descriptive activities in the proposed rule and removing ''inducing'' from the list. We are removing ''inducing'' from the list in response to concerns from commenters that the prohibition might apply in circumstances where individuals are coerced to obtain reproductive health care. It was never the Department's intention for the prohibition on the use or disclosure of PHI to apply in such circumstances. Rather, we intended it to refer to situations in which a health care provider ''induces'' labor under circumstances in which such health care is lawful; however, we believe our intended meaning of ''inducing'' is encompassed in other terms in the list. The revised list better explains the type of activities in which a person may be engaged and about which the Department intends to prevent the use or disclosure of PHI.

The Department is not finalizing a separate Rule of Construction because the need is obviated by incorporating the key content into the prohibition itself at 45 CFR 164.502(a)(5)(iii). The Department proposed the Rule of Construction to clarify that 45 CFR 164.502(a)(5)(iii) should not be construed to prohibit a use or disclosure of PHI otherwise permitted by the Privacy Rule unless such use or disclosure is ''primarily for the purpose of'' investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. By incorporating the Rule of Construction into the main standard and removing the proposed ''primarily for the purpose of'' language, the Department now more clearly conveys its intent to prohibit the use and disclosure of PHI for the specified purposes only when it relates to the ''mere act of'' seeking, obtaining, providing, or facilitating reproductive health care. As discussed in greater detail below in our responses to comments, this change is designed to reduce confusion for regulated entities about how to reconcile and apply the Rule of Construction with the main prohibition standard and does not change the scope of the prohibition as proposed. The revisions and restructuring of regulatory text formerly included in the Rule of Construction improve readability and reduce redundancy. Likewise, the final rule incorporates other minor wording changes to improve readability and updates regulatory text references to other paragraphs to accurately reflect the organization of this section.

Comment: Many commenters expressed support for the Department's proposal to create a new category of prohibited uses and disclosures about reproductive health care. A few of these commenters explained the rationale for their support as based on the proposed approach's balance of preventing harm to individuals from certain uses and disclosures and permitting beneficial uses and disclosures, while providing regulated entities with clarity with respect to when uses and disclosures of PHI would be permitted.

A few commenters agreed with the Department's view that a purpose-based prohibition is preferable to other approaches to protecting the privacy of individuals that would require labeling or segmenting of PHI. Other commenters focused on how the proposal would better facilitate HIPAA's goals of providing high-quality health care and encouraging the flow of information to covered entities.

Response: The approach we are taking in this final rule preserves the ability of regulated entities to use and disclose PHI for permitted purposes while also enhancing protections for PHI, to strike the appropriate balance between privacy interests and other societal interests, including law enforcement. As discussed above, the Department's approach will lead to numerous benefits associated with enhanced privacy protections.

Comment: A few commenters asserted that the Department's proposal would provide a consistent standard for all states to follow.

Response: The Department believes this final rule will provide clear standards for regulated entities, especially health care providers, by incorporating the prohibition into the Privacy Rule. However, we stress that the prohibition attaches to only requests for uses and disclosures that are for a prohibited purpose where the reproductive health care is lawful under the circumstances in which such health care is provided. Different states and localities have promulgated different standards for the lawfulness of reproductive health care.

Comment: A few commenters expressed their appreciation that the proposal encompassed a broad range of reproductive health care and explained the importance of ensuring that a final rule protects any health information about reproductive health care.

Response: As the Department acknowledged in the 2023 Privacy Rule NPRM, many routine medical examinations and treatments could involve PHI about an individual's reproductive health or reproductive organs and systems. This final rule is not limited to PHI about abortion. The Department recognized the impracticability of attempting to parse out the types of reproductive health care that should be subject to the prohibition and those that should not be. For this reason, and in keeping with the existing scheme of the Privacy Rule, the Department proposed and is finalizing a purpose-based approach to prohibiting the use and disclosure of any PHI for use against any person for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. A regulated entity that receives a request for PHI is charged with making a reasonable determination of whether the conditions of lawfulness set forth in the Rule of Applicability apply. To further assist regulated entities in understanding the broad scope of ''reproductive health care,'' we provide in the preamble a non-exclusive list of examples that fit within the definition.

Comment: Some commenters expressed opposition to this proposal, asserting that the proposed new category would interfere with the enforcement of state laws that restrict or regulate abortion or that the proposal would make it more difficult for regulated entities to determine whether a requested use or disclosure of PHI is permitted under the Privacy Rule because it lacked sufficient specificity.

Response: The Department is finalizing a narrowly tailored prohibition that will only apply when an individual's privacy interest in lawfully obtained reproductive health care outweighs society's interest in obtaining PHI for non-health care purposes. As discussed above, the Department has adopted an approach that strikes the appropriate balance between privacy interests and other interests, including law enforcement interests in accessing PHI to investigate or impose liability on persons for seeking, obtaining, providing, or facilitating reproductive health care that

is unlawful under the circumstances in which such health care is provided. To help regulated entities operationalize the prohibition, the Department is finalizing an attestation requirement in 45 CFR 164.509 in which persons requesting PHI under a permission that is mostly likely to be used to request PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) must attest that the request is not subject to the prohibition. The Department acknowledges that requests for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) may be made pursuant to another applicable permission and reminds regulated entities that they must evaluate all requests made by a third party for the use or disclosure of PHI to ensure that they are not for a prohibited purpose. Requests not subject to the prohibition would still be subject to the conditions of the relevant permissions in the Privacy Rule. When requests for PHI meet the conditions for permissions in the Privacy Rule, including conditions specified in 45 CFR 164.512, regulated entities are permitted to use and disclose PHI in accordance with such permissions.

Moreover, as we describe above, the Department is modifying the final rule to clarify that the prohibition restricts the use and disclosure of PHI for the enumerated purposes when connected to the ''mere act of'' seeking, obtaining, providing, or facilitating reproductive health care. Thus, the prohibition does not prevent the use or disclosure of the PHI about reproductive health care obtained by an individual in all circumstances. Rather, it prevents the use or disclosure of PHI when the purpose of the disclosure is to investigate or impose liability on a person because they sought, obtained, provided, or facilitated reproductive health care that was lawful under the circumstances in which such health care was provided, as determined by the regulated entity that received the request for PHI. For example, a regulated entity would not be prohibited from disclosing an individual's PHI when subpoenaed by law enforcement for the purpose of investigating allegations of sexual assault by or of the individual, assuming that law enforcement provided a valid attestation and met the other conditions of the permission under which the request was made.

Comment: A commenter expressed opposition to the proposal and asserted that it relied on the assumption that it would be readily apparent or ascertainable whether particular reproductive health care was lawfully provided. According to this commenter, persons who violate the law have an interest in concealing their activity, and the proposal would impede law enforcement investigations to determine whether lawbreaking has occurred. Additionally, the commenter expressed their concern that the proposal would represent a departure from the Privacy Rule's existing approach to law enforcement investigations and proceedings.

Response: The Department is finalizing a regulatory presumption to address the narrow circumstance of when lawfulness is not readily apparent to a regulated entity who is the recipient of a request for the use or disclosure PHI when the regulated entity did not provide the underlying reproductive health care. As we explained above, this final rule is intended to support and clarify the privacy interests of individuals availing themselves of lawful reproductive health care, and not to thwart the interests of states and the Federal government in conducting lawful investigations or imposing liability on the provision of unlawful reproductive health care. While this new regulatory presumption may make it more difficult for law enforcement officials to investigate whether reproductive health care was unlawful under the circumstances in which it was provided (*e.g.,* when other sources of information that is not PHI are unavailable), the Department has considered those interests and determined that the effects are justified by countervailing privacy benefits. We also reiterate here that the presumption is not a blanket presumption. It only applies where the reproductive health care at issue is provided by someone other than the regulated entity that received the request for the use or disclosure of PHI, and it may be overcome in the circumstances identified above.

We note that the Privacy Rule has always and continues to permit regulated entities to disclose PHI for law enforcement purposes, subject to certain conditions or limitations. In this final rule, the Department has found that changes in the legal landscape now necessitate codifying a prohibition against uses and disclosures for the purposes specified in 45 CFR 164.502(a)(5)(iii)(A), subject to the Rule of Applicability in 45 CFR 164.502(a)(5)(iii)(B). The Department is not otherwise changing the existing permissions in the Privacy Rule that permit regulated entities to use or disclose PHI for law enforcement purposes and other important non-health care purposes, except as discussed elsewhere in this rule. These purposes include when PHI is required by law to be disclosed for purposes other than those prohibited by this final rule, for public health and health oversight activities, for other law enforcement purposes not in conflict with this rulemaking, for reports of child abuse, about decedents when not prohibited by this final rule, and other purposes specified in the Privacy Rule.

In particular, in the 2023 Privacy Rule NPRM, the Department discussed the interaction of this rule with HIPAA's statutory preemption provisions [301] and explained that it was necessary to preempt state laws that require the use and disclosure of PHI for the purposes prohibited by this rule to give effect to the prohibition consistent with HIPAA. As discussed above, to achieve the purpose for which HIPAA was enacted, to enable the electronic exchange of identifiable health information, we must protect the privacy of that information to further individuals' trust in the health care system. As finalized, the prohibition is limited only to circumstances in which the privacy interests of an individual and the interests of society in an effective health care system outweigh society's interest in obtaining PHI for non-health care purposes.

Comment: A commenter stated that, to the extent the ability of a state to determine whether to investigate or bring a proceeding is based on information in the possession of a regulated entity, the proposed rule did not adequately address a state's need to regulate the medical profession and health care facilities.

Response: As finalized, the prohibition prevents the use and disclosure of PHI for certain purposes where a person sought, obtained, provided, or facilitated reproductive health care that is lawful under the circumstances in which such health care is provided. As discussed above, the final rule strikes the appropriate balance between privacy interests and other interests. Public officials remain free to investigate the provision of health care by seeking information from non-covered entities. Moreover, the prohibition does not prevent a state from enforcing its laws. Instead, it protects the privacy of individuals' PHI in certain circumstances.

Comment: A few commenters expressed concern that the proposed prohibition may also affect the enforcement of Federal laws.

Response: The Department has consulted extensively with other Federal agencies and officials in the

[301] *See* 88 FR 23506, 23530 (Apr. 17, 2023).

development of this rule, including the Attorney General, and does not believe that this rule will impede the enforcement of Federal laws. As discussed above, this rule carefully balances privacy and other interests, applying only in certain narrowly tailored situations.

Comment: Numerous commenters recommended that the Department expand the scope of the proposed prohibition to include other or all types of stigmatized health care. A few commenters recommended expanding the proposed prohibition to all health care or to provide individuals the ability to prevent the disclosure of their PHI through HIEs.

Generally, commenters supporting expansion of the proposal's scope expressed the belief that it was necessary for HIPAA to promote trust between individuals and health care providers and to improve health care quality and outcomes.

Several commenters explained that persons seeking, obtaining, providing, or facilitating other types of health care are facing the same challenges as described in the proposal with respect to reproductive health care, including health care obtained outside of the health care system, and provided examples of such challenges. Many commenters also made recommendations for how the Department should address those challenges.

Response: The Department is issuing this final rule to protect the privacy of PHI when it is sought for activities to investigate or impose liability on persons for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care. Lawfulness is based on a reasonable determination made by a regulated entity that has received a request for PHI for one of the purposes specified at 45 CFR 164.502(a)(5)(iii)(A) that at least one of the conditions in the Rule of Applicability applies. We are finalizing a prohibition that is not specific to certain procedures, laws, or types of providers. Rather, the prohibition we finalize here requires regulated entities to consider the purpose of the requested use or disclosure. To the extent that the specific types of health care referenced by commenters above meet the definition of reproductive health care, this final rule will prevent the disclosure of PHI where it is sought for activities with the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided. In adopting a purpose-based prohibition, the Department has chosen an administrable standard that reflects the appropriate balance between protecting individuals' privacy interests and allowing the use or disclosure of PHI in support of other important societal interests. Additional privacy protections for information about SUD treatment may be afforded to PHI in Part 2 records under Part 2.[302]

Comment: In response to the Department's specific request about whether it should require a regulated entity to obtain an individual's authorization for any uses and disclosures of ''highly sensitive PHI'' or otherwise address such a defined category of PHI in the Privacy Rule, a few commenters urged the Department to expand the proposed prohibition to protect all people at risk of criminal or other investigation for use of essential health care or care, services, or supplies related to the health of the individual that could expose any person to civil or criminal liability. Several commenters recommended that the Department expand the scope of the proposed prohibition to, variously, all ''highly sensitive health information,'' ''sensitive personal health care,'' ''highly sensitive PHI,'' or ''highly sensitive PHI and restricted health care service'' because of the potential harms that could result if such health information were to be disclosed without stringent privacy safeguards.

Several commenters asserted that creating a category of or separate standard for ''highly sensitive PHI'' would cause significant confusion because it would be difficult to define in a commonly understood manner. According to these commenters, this would make compliance more challenging and costly and further decrease the individual's privacy. A few commenters expressed concern that creating a special category of highly sensitive PHI would further stigmatize certain types of health care.

Several commenters expressed concern that prohibiting or limiting uses or disclosures of highly sensitive PHI for certain purposes may negatively affect efforts to eliminate the need for data segmentation, such as efforts to align the Privacy Rule and Part 2; reduce or eliminate stigmatization of certain health conditions and diagnoses; and improve health care management and health care coordination.

Response: We appreciate these comments and generally agree with commenters who expressed concern that the Privacy Rule should address the shifting legal landscape to ensure that it continues to protect PHI, regardless of how the PHI is transmitted or maintained. We also agree that to the extent possible, the Privacy Rule should promote administrative efficiency and disincentivize adverse actions by health care providers grounded in fear of prosecution or legal risks borne from providing lawful health care to individuals, which may erode patients' trust and confidence in the health care system and deter them from seeking lawful health care. The Department's approach to promulgating a narrowly tailored prohibition focused on clarifying the use and disclosure of PHI for the purposes prohibited by this final rule accomplishes these goals. As we explained in the 2023 Privacy Rule NPRM and re-affirm in this final rule, recent developments in the legal environment have made information about lawful reproductive health care sought by or provided to an individual more likely to be of interest for punitive non-health care purposes, and thus more likely to be used or disclosed if sought for a purpose permitted under the Privacy Rule today. As explained, the Department has identified concerns that the use or disclosure of PHI for the prohibited purposes in this rule would erode individuals' trust in the privacy of legal reproductive health care. Such erosion would negatively affect relationships between individuals and their health care providers, result in individuals forgoing needed treatment, and make individuals less likely to share pertinent health concerns with their health care providers. Modifying the Privacy Rule to focus on and address this shifting landscape is the most efficient way to return to a regulatory landscape that is balanced and consistent with the goals of HIPAA.

We do not believe that it is necessary to modify the Privacy Rule to prohibit the use and disclosure of PHI for any criminal, civil, or administrative investigation or effort to impose criminal, civil, or administrative liability related to all health care, services, or supplies. Sections 164.512(e) and (f) already set forth the specified conditions under which regulated entities may disclose PHI for judicial and administrative proceedings and law enforcement purposes.

We decline to modify the prohibition to apply it to the use and disclosure of ''highly sensitive PHI.'' We are persuaded by commenters who voiced concern about the feasibility of defining the phrase such that regulated entities would be able to understand and

[302] *See* 42 CFR part 2 and the 2024 Part 2 Rule for more information about Part 2 and the protections afforded to Part 2 records.

operationalize it. We also find persuasive comments about the compliance burden that would result from implementing such a prohibition. While PHI about reproductive health care may be found throughout an individual's record and may be collected or maintained by multiple types of providers, the term ''reproductive health care'' is defined in a manner that is clearly connected to the reproductive system, its functions, and processes.[303]

In contrast, applying the prohibition to all ''highly sensitive PHI'' or any use or disclosure of PHI that results in harm, stigma, or adverse result for an individual would be unworkable because of lack of consensus about how to define such categories and would likely create the issues with segmentation and care coordination discussed above. As discussed above, the purpose of this final rule and narrowly crafted prohibition is to adopt the appropriate balance in the Privacy Rule between protecting individuals' privacy and permitting PHI to be used and disclosed for other societal benefits. The commenters' objectives reflect a desire to protect individuals, but their discussion does not properly account for other societal interests that are supported by certain disclosures of PHI, interests that the Privacy Rule has balanced since its inception.

Comment: A commenter requested that the Department clarify that state laws may protect the privacy of health information when the Privacy Rule does not apply, such as when individuals' health information is in the possession of a person that is not a regulated entity, such as a friend or family member, or is stored on a personal cellular phone or tablet.

Response: HIPAA provides the Department with the authority to protect the privacy and security of IIHI that is maintained or transmitted by covered entities, and in some cases, their business associates. Other laws may apply where the HIPAA Rules do not. Guidance on protecting the privacy and security of health information when using a personal cell phone or tablet is available on OCR's website.[304]

Comment: Many commenters cited potential operational challenges with the proposed prohibition and confirmed that current health IT generally does not provide regulated entities with the ability to segment PHI into specific categories afforded special protections. A few commenters recommended that the Department work with EHR vendors to modernize health care data management platforms to better address data segmentation, while others recommended that the Department ensure interagency coordination of data segmentation policies and provide individuals with granular level of control over their PHI.

A few commenters requested that the Department address concerns about the interaction between the minimum necessary standard and this final rule.

A commenter asserted that privacy protections that do not account for individual privacy preferences would result in individuals withholding information from their health care providers, and some health care providers electing not to generate or document certain information from or about individuals.

Response: The prohibition, as finalized, should not implicate additional data segmentation concerns beyond those that already exist. We acknowledge the low adoption rate of data segmentation standards and challenges related to the technical and administrative feasibility of data segmentation (*e.g.,* costs), and as discussed above, are finalizing a purpose-based approach to address such concerns. The Department continues its active engagement, particularly through ONC, to identify robust data sharing standards that facilitate appropriate privacy controls.

With respect to concerns about the Privacy Rule minimum necessary standard, we do not anticipate that this final rule will affect the ability of regulated entities subject to the standard to comply. First, the prohibition is applicable only for the purposed uses and disclosures specified in 45 CFR 164.502(a)(5)(iii). Regulated entities must make reasonable efforts to limit the use or disclosure of PHI pursuant to 45 CFR 164.512, other than 45 CFR 164.512(a), to the minimum amount of PHI necessary to accomplish the intended purpose of the use, disclosure, or request.[305] Regulated entities are required to have in place policies and procedures that outline how the entity complies with the standard.[306]

Comment: A few commenters requested that the Department clarify the roles and responsibilities of covered entities and business associates with respect to compliance with the proposed prohibition and attestation requirements and whether business associate agreements would need to be amended to reflect the requirements of the final rule.

Response: The prohibition standard finalized in 45 CFR 164.502(a)(5)(iii)(A) applies directly to all regulated entities; meaning, all HIPAA covered entities and business associates. We also note that the finalized presumption of lawfulness for the underlying health care, when applicable, directly applies to business associates, as does the attestation requirement in 45 CFR 164.509. As such, business associates of covered entities that hold PHI by virtue of their business associate relationship with the covered entity are subject to the express prohibition on using or disclosing PHI for the specified purposes, regardless of whether the prohibition is specified in the business associate agreement. The attestation requirement and its application to business associates are discussed in greater detail below.

Comment: A commenter expressed support for the application of the proposal to health care providers, but also recognized states' interest in ensuring that health care providers render health care in accordance with the standard of care in that state. Another commenter questioned the Department's authority under HIPAA to implement this provision.

Response: The Department is modifying the proposed definition of ''Reproductive health care'' to explicitly clarify that the definition does not set a standard of care for or determine what constitutes clinically appropriate reproductive health care. Additionally, as discussed above, the application of this rule is limited to reproductive health care that is lawful under the circumstances in which such health care is provided as described at 45 CFR 164.502(a)(5)(iii)(B). Lawfulness is determined by the regulated entity that receives the request for PHI, after a reasonable determination that at least one of the conditions in the Rule of Applicability apply. As explained above, the prohibition is carefully tailored to protect the privacy of individuals' health information in circumstances where the reproductive health care at issue was lawful under the circumstances such care was provided, reflecting the appropriate balance between privacy interests and other societal interests.

Comment: Many commenters recommended alternative or additional

[303] *See* the finalized definition of ''Reproductive health care'' at 45 CFR 160.103.

[304] *See* Off. for Civil Rights, ''Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet,'' U.S. Dep't of Health and Human Servs. (June 29, 2022), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.*

[305] *See* 45 CFR 164.502(b). Uses and disclosures of PHI pursuant to 45 CFR 164.512(a) are limited to the relevant requirements of such law. 45 CFR 164.512(a)(1).

[306] 45 CFR 164.514(b).

approaches to the purpose-based prohibition, such as eliminating or narrowing the permissions for use or disclosure of PHI without an individual's authorization or limiting disclosures to third parties subject to an individual's authorization.

A few commenters recommended that the Department revise specific Privacy Rule permissions to clarify the use and disclosure of PHI for certain administrative or law enforcement requests, instead of promulgating a new prohibition.

Response: The Department's approach to prohibit the uses and disclosures of PHI for the purposes described in this final rule is consistent with the Privacy Rule's longstanding balancing of individual privacy interests with society's interests in PHI for non-health care purposes. Adopting the correct balance is necessary to preserve and promote trust between individuals and health care providers. Instead of modifying specific permissions at 45 CFR 164.512, we are finalizing modifications that prohibit the use or disclosure of PHI to ensure the correct balance, instead of modifying specific permissions at 45 CFR 164.512. Recognizing that requests that fall under these permissions represent important public policy objectives (*e.g.,* health oversight, law enforcement, protection of individuals subject to abuse), the Department is imposing a new attestation requirement, as described in greater detail below, to protect against harm that may arise from the use or disclosure of PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii), which is more likely to occur when a person requesting the use or disclosure of PHI relies on certain permissions. The new attestation condition will also provide a mechanism that will enable a regulated entity to better evaluate the request. The Department declines to make additional changes at this time and will consider these topics for future guidance. The Department also declines to finalize its proposal to prevent an individual from requesting that a regulated entity use or disclose PHI pursuant to a valid authorization.

Comment: A few commenters questioned the ability of regulated entities to use or disclose PHI in compliance with mandatory reporting laws, such as laws requiring the reporting of suspected child abuse or domestic violence.

A few of these commenters questioned whether mandatory reporting requirements would change a regulated entity's duty to apply the minimum necessary standard.

A few commenters asserted that mandatory reporting laws dissuade individuals from seeking health care, prevent the development of trust between individuals and health care providers, and generally are implemented in an inequitable fashion that disproportionately apply to individuals from marginalized or historically underserved communities or communities of color.

Response: The Department acknowledges that there may be some mandatory reporting laws that require a regulated entity to determine whether a request for PHI is for a purpose prohibited by this rule. However, whether in response to a mandatory reporting law or routine request, the final rule's operation remains the same, that is, it prohibits a regulated entity from using or disclosing PHI for a prohibited purpose when the reproductive health care under investigation or at the center of the activity to impose liability is lawful under the circumstances that it was provided.

To the extent mandatory reporting requirements apply to the reporting of PHI to public health authorities for public health purposes, including PHI about reproductive health care, this final rule does not prevent a regulated entity from complying with such mandate.

To aid stakeholders in understanding how the prohibition operates with respect to public health reporting, the Department is clarifying that the term ''Public health,'' as used in public health surveillance, investigation, and intervention, includes identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of PHI. In so doing, we are clarifying that public health surveillance, investigation, and intervention are outside of the scope of activities prohibited by 45 CFR 164.502(a)(5)(iii). These changes will offer additional protection to individuals who would otherwise be subject to having their PHI disclosed for a prohibited purpose because the underlying mandatory reporting requirement did not clearly specify its relationship to public health. This final rule does not change the minimum necessary standard or the circumstances in which the Privacy Rule requires a regulated entity to apply the minimum necessary standard.

Comment: Many commenters expressed concern that the purposes for which the Department proposed to prohibit uses or disclosures would interfere with the ability of law enforcement to conduct investigations, including into coercion, child abuse, and sex trafficking and assault, would prevent states from verifying state licensure requirements, and would hamper the ability of health care professionals to report illegal behavior by other health care professionals.

Response: As discussed above, the prohibition applies only to activities conducted for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is provided under circumstances in which such health care is lawful. A regulated entity is permitted to disclose PHI to a person who requests PHI for other purposes if a permission applies and the underlying conditions of the relevant permission are met, including the attestation condition, if applicable.

Comment: A few commenters recommended that the Department establish a safe harbor for the use or disclosure of PHI by regulated entities for TPO.

Response: We appreciate the comment but do not believe such a safe harbor is necessary. The Privacy Rule permits the disclosure of an individual's PHI for TPO when the conditions set forth in the TPO provisions of the rule are met.[307] The prohibited uses and disclosures codified in this rulemaking would rarely intersect with uses and disclosures that qualify as TPO activities. As explained above, to the extent a person requesting the use or disclosure of PHI reasonably articulates a basis for a request that is not related to the mere act of seeking, obtaining, providing, or facilitating reproductive health care, a regulated entity may use or disclose the PHI where otherwise permitted by the Privacy Rule.

Comment: A commenter recommended that the Department clarify that the prohibition applies to the activities of insurers and third-party administrators of self-funded plans by adding ''administering, authorizing, covering, approving, or gathering or providing information about'' to the explanation of ''seeking, obtaining, providing, or facilitating.''

Response: The prohibition applies to all activities that a person could reasonably be expected to engage in with a regulated entity that could result in a use or disclosure of PHI that might be sought for prohibited purposes, including activities conducted or performed by or on behalf of a health

[307] *See* 45 CFR 164.506.

plan, including a group health plan.[308] Accordingly, the Department has modified the scope of activities initially proposed in the 2023 Privacy Rule NPRM to better explain what it meant by seeking, obtaining, providing, or facilitating reproductive health care. The modified text is finalized at 45 CFR 164.502(a)(5)(iii)(D),[309] and adds administering, authorizing, providing coverage for, approving, counseling about to the non-exhaustive list of example activities.

Comment: Several commenters expressed support for the proposed Rule of Applicability. A few commenters expressed support for the proposed Rule of Applicability because it would reassure residents of the state in which the lawful health care is provided and individuals who travel to such states for lawful health care that their medical records will not be disclosed for prohibited purposes.

Response: We are finalizing a modified Rule of Applicability as described above.

Comment: Some comments expressed varying levels of support for the Department's references to ''substantial interests'' by states or superseding state laws. A few commenters disagreed with the Department's assertion that states lack a legitimate interest in conducting a criminal, civil, or administrative investigation or proceeding into lawful reproductive health care where the investigation is based on the mere fact that reproductive health care was or is being provided. Others asserted that the proposed rule would be unworkable and would assign health care providers and the Department the power to determine whether reproductive health care was provided lawfully, thereby affording them the authority to enforce certain state laws.

Response: As explained above, the Rule of Applicability reflects the Department's careful balancing of privacy interests and other societal interests. For the reasons explained above, the Department has determined that the privacy interest of an individual and the interest of society in an effective health care system outweigh the interests of society in seeking the use of PHI for non-health care purposes that could result in harm to the individual where a regulated entity that receives a request for PHI reasonably determines that at least one of the conditions in the Rule of Applicability applies. To help clarify this discussion further, the Department provides examples where the Rule of Applicability applies in this section of this final rule.

Comment: Several commenters recommended that the Department eliminate the distinction between health care that is lawful and health care that is not and that all forms of reproductive health care should be protected from criminalization and government investigation.

Several commenters stated that the term ''lawful'' would incorrectly suggest that *receiving* certain types of reproductive health care could be unlawful, even though most prohibitions on reproductive health care apply to *providing* or *performing* the health care, rather than receiving it. They also questioned whether the proposed Rule of Applicability would protect individuals who obtained reproductive health care in another state.

Response: We are finalizing a Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B) that ensures the privacy of PHI when it is sought to conduct an investigation into or impose liability on any person for the mere act of seeking, obtaining, providing or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, consistent with applicable Federal or state law. A regulated entity that receives a request for PHI must make a reasonable determination that at least one of the conditions in the Rule of Applicability applies. As discussed above, this approach reflects a careful balance between privacy interests and other societal interests.

Comment: Some commenters asserted that medical records should not be used for purposes outside of the health care setting in ways that could harm the subject of the records, particularly for law enforcement or other governmental purposes. One commenter expressed concern that disclosures of PHI would not be limited for all purposes, and that the proposal would not prevent a state from pursuing actions where the health care is later found to be unlawful. Another commenter asserted that disclosing PHI to law enforcement in connection with an investigation into reproductive health care is a secondary use of PHI that would be directly at odds with the purpose for which the PHI was collected, while others stated that the proposal risks deterring individuals from seeking or obtaining necessary health care.

A few commenters expressed concerns that health care providers could be inhibited from providing necessary health care, fully educating individuals about their options, or documenting the health care provided.

Response: When the Department promulgated the 2000 Privacy Rule, we acknowledged that the rule balanced the privacy interests of individuals with the interests of the public in ensuring PHI was available for non-health purposes. As we explained in the 2023 Privacy Rule NPRM, ''individuals' right to privacy in information about themselves is not absolute. It does not, for instance, prevent reporting of public health information on communicable diseases or stop law enforcement from getting information when due process has been observed.'' [310] At the same time, in the 2023 Privacy Rule NPRM, the Department acknowledged that adverse consequences do result when individuals question the privacy of their health information and explained that the purpose of HIPAA is to protect the privacy of information and promote trust in the health care system to ensure that individuals do not forgo lawful health care when needed or withhold important information that may affect the quality of their health care.[311]

Accordingly, the Privacy Rule provides a clear framework to operationalize these principles, and this final rule is intended to balance these interests. The Privacy Rule does not protect information received or maintained by entities other than those that are regulated under HIPAA, including information that is used for a purpose other than the purpose for which it was initially requested. This final rule provides heightened protection, as necessary, to the privacy of PHI where its use or disclosure may result in harm to a person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. With respect to other disclosures to law enforcement or to other governmental interests, the Privacy Rule includes other carefully crafted permissions that specify the conditions under which such disclosures must be made to ensure a reasonable balance between privacy and the public policies that disclosure would serve.

Comment: Several commenters asserted that the proposed Rule of Applicability would not protect all PHI pertaining to lawful health care. For example, commenters suggested that the proposed Rule of Applicability would be unlikely to protect individuals who

[308] *See* 45 CFR 160.103 (definitions of ''health plan'' and ''group health plan'').

[309] In the 2023 Privacy Rule NPRM, we proposed the Scope of prohibition in 45 CFR 164.502(a)(5)(iii)(B).

[310] 88 FR 23506, 23509 (Apr. 17, 2023) (*citing* 65 FR 82464 (Dec. 28, 2000)).

[311] *Id.*

obtain care outside of the health care system and urged the Department to clarify the final rule to strengthen protections for individuals who receive care in this manner. As another example, a commenter expressed concern that the proposal would not protect PHI for individuals who obtain legal reproductive health care, but as a result of complications, subsequently access health care in a state where the same reproductive health care is illegal.

Response: The definition of ''reproductive health care'' is discussed in greater detail above. As noted above, this final rule does not establish a standard of care, nor does it regulate what constitutes clinically appropriate health care.

Commenters who point out that different results may arise in different states are correct, but this has been true since the inception of the Privacy Rule because it sets a national floor for privacy standards, rather than a universal rule. The prohibition applies, and therefore liability attaches, when the prohibition is violated, based on the ''circumstances in which such health care is provided.'' Thus, a regulated entity is not permitted to disclose PHI about reproductive health care that was provided in another state where such health care was provided under circumstances in which it was lawful to provide such health care, even where the individual subsequently accesses related health care in a state where it would have been unlawful to provide the underlying health care under the circumstances in which such health care was provided. HIPAA liability attaches in cases where attempts to circumvent the Privacy Rule result in impermissible or wrongful uses or disclosures.[312]

We remind regulated entities that the Privacy Rule permits the use or disclosure of PHI, without an individual's signed authorization, only as expressly permitted or required by the Privacy Rule. For example, where state or other applicable law prohibits certain reproductive health care but does not expressly require a regulated entity to report that an individual obtained the prohibited health care, the Privacy Rule would not permit a disclosure to law enforcement or other investigative body pursuant to the ''required by law'' permission (but could potentially allow it pursuant to other provisions).[313]

Comment: One commenter recommended the Department add language to the proposed Rule of Applicability or elsewhere to ensure that there would be protections for PHI where a health care provider believes the health care is legal, even when the person requesting the use or disclosure of PHI disputes the legality. A few commenters asserted that the health care provider making the decision could be a party to the reproductive health care at issue, making it a conflict of interest for the health care provider to make the determination regarding the lawfulness of the reproductive health care.

Response: We do not believe additional language is necessary because, under the prohibition, the regulated entity—and not the person making the request—is responsible for reasonably determining whether health care was lawful before making a disclosure. As explained above, this framework is consistent with how the Privacy Rule's permissions are administered, whereby regulated entities must determine whether a use or disclosure is permitted under the relevant permission. For example, when evaluating whether a use or disclosure of PHI is permitted because the use or disclosure is required by law, the regulated entity must look to the relevant law to determine whether the use or disclosure falls within that permission.[314] Furthermore, as with other use and disclosure provisions in the Privacy Rule, regulated entities remain subject to HIPAA liability for impermissible or wrongful disclosures. Neither the statute nor the Privacy Rule provides an exception to such liability for circumstances involving conflicts of interest.

Comment: Many commenters expressed concern regarding the burden imposed upon and resources that would be required for regulated entities to determine whether the reproductive health care at issue was lawful if they did not provide the health care at issue, particularly considering the evolving nature of state law in this area. Several commenters expressed concern that the proposal incorrectly assumes that regulated entities would know where the reproductive health care at issue occurred and inquired about specific scenarios, such as where requests for PHI are received by clinical laboratories that have no face-to-face interaction with individuals and that rely on information provided by other covered entities. A few commenters asserted that requiring regulated entities to make the required legal determinations would not be conducive to building a trusting relationship between individuals and health care providers.

Some commenters offered recommendations to the Department, such as providing guidance for health care providers regarding their rights and responsibilities under a final rule, revising the proposal to clarify that there would be a presumption that reproductive health care occurred under lawful circumstances, absent compelling evidence to the contrary, particularly when an individual travels for health care, and clarifying the Rule of Applicability by including examples in the regulatory text.

Some commenters asserted that regulated entities in different states or with different interpretations of certain state requirements could reach different determinations about whether the reproductive health care was provided lawfully, in part because of the lack of clarity or consistency in the interpretation in these laws. Yet another commenter recommended that the Department add an express directive that, in the event of any ambiguity or unsettled law, the scope of what is considered lawful should be interpreted consistently with the intent of the rule to protect the privacy of PHI to the maximum extent possible. A commenter recommended that where the regulated entity decides in good faith, it should not be subject to penalties or enforcement action if their determination is incorrect or if the Department disagrees with the determination. Another commenter recommended that the Department clarify that regulated entities may use a reasonableness standard when making the determination about whether state laws conflict with the Privacy Rule and are therefore preempted by HIPAA.

A few commenters expressed concern about the potential interpretation or application of the proposed Rule of Applicability, particularly when the laws at issue are ambiguous. Commenters recommended inclusion of language that PHI need not be disclosed to a government agency or law enforcement if the health care provider deems, in good faith, that the reproductive health care is lawful under the circumstances in which it is provided, and that the Department clarify the application of preemption or provide in preamble examples of each condition of the proposed Rule of Applicability.

Response: We appreciate the many comments the Department received in response to its inquiry asking whether the proposed Rule of Applicability would be sufficiently clear to individuals and covered entities, and

[312] *See* 42 U.S.C. 1320d–5 and 6.

[313] *See* 45 CFR 164.512(a).

[314] *See* 45 CFR 164.512(a).

whether the provision should be made more specific or otherwise modified. Considering the many comments expressing concern about the burden associated with, the difficulty of, or the liability that could attach when someone other than the person who provided the health care must determine whether the underlying reproductive health care is lawful, the Department is adding a regulatory presumption in the final rule.

As discussed above, the regulatory presumption in 45 CFR 164.502(a)(5)(iii)(C) will permit a regulated entity receiving a PHI request that may be subject to the prohibition to presume the reproductive health care at issue was lawful under the circumstances in which such health care was provided when provided by a person other than the regulated entity receiving the request. The presumption includes a knowledge requirement such that the regulated entity must not have actual knowledge that the reproductive health care was unlawful under the circumstances in which such health care was provided or factual information supplied by the person requesting the use or disclosure of PHI that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

Comment: A commenter asserted that the proposed rule would unlawfully thwart enforcement of Federal criminal laws on reproductive health care because the proposed rule would be limited to circumstances where reproductive health care is permitted by state law, thereby prohibiting disclosures for the purpose of enforcing Federal laws pertaining to reproductive health care when they conflict with state law. A few commenters expressed their support for the Department's proposal that the prohibition against the use or disclosure of PHI apply where certain Federal laws apply. A few commenters requested greater specificity with respect to the application of Federal and state laws on abortion.

Response: Federal laws that involve reproductive health care form the underlying basis for examining whether reproductive health care was protected, required, or authorized by Federal law under the circumstances in which it was provided, pursuant to the 45 CFR 164.502(a)(5)(iii)(B)(*2*). Under this final rule, Federal and state authorities retain the ability to investigate or impose liability on persons where the investigation or imposition of liability is centered upon the provision of reproductive health care that is unlawful under the circumstances in which it is provided. As discussed above, this rule reflects a careful balance between privacy interests and other societal interests, and the prohibition is tailored to cover situations where the reproductive health care was lawfully provided, whether state or Federal law is at issue.

Comment: A few commenters provided examples of and expressed concerns about the electronic availability of PHI about health care lawfully provided in one state to health care providers in another state where such health care would not have been lawful.

A few commenters requested that the Department clarify that clinical laboratory testing involving a validated laboratory-developed test used within a single laboratory certified pursuant to the Clinical Laboratory Improvement Amendments of 1988 [315] (CLIA) and the implementing regulations, an in vitro diagnostic test cleared or approved by the Food and Drug Administration (FDA), or a validated laboratory-developed test that is an in vitro diagnostic test cleared or approved by the FDA and used within a single CLIA-certified laboratory would fall within the scope of reproductive health care that would be ''authorized by Federal law'' for the purposes of the Rule of Applicability. The commenters also recommended that a clinical laboratory test furnished under the authority of a state with legal requirements that are equal to or more stringent than CLIA's statutory and regulatory requirements, and is therefore exempt from CLIA requirements, also be considered ''authorized by Federal law'' for the purposes of the Rule of Applicability.

Response: We interpret the language ''authorized by Federal law'' in the Rule of Applicability to include activities, including clinical laboratory activities, that are conducted as allowed under applicable Federal law, in circumstances where there is no conflicting state restriction on the Federally authorized activity or where applicable Federal law preempts a contrary state restriction. In such circumstances, these activities are lawfully conducted because there either is no relevant state restriction or Federal law preempts a contrary state restriction. This provision thus reflects the Department's careful balancing of privacy interests and other societal interests in disclosure. As explained above, in circumstances where reproductive health care is lawfully provided, privacy interests are heightened while other societal interests in disclosure are reduced. This final rule and the operation of HIPAA's general preemption authority do not supersede applicable state law pertaining to the lawfulness of reproductive health care.

Comment: One commenter expressed support for including the phrase ''based primarily'' to clarify that the proposed Rule of Construction would only address situations where the purpose of the disclosure is to investigate or impose liability because reproductive health care was provided, rather than for an issue related to, but not focused on the provision of such health care, such as the quality of the health care provided or whether claims for certain health care were submitted appropriately.

All other commenters recommended removing ''primarily'' to ensure that there is consistent implementation. In the alternative, the commenters recommended that the Department provide additional examples of scenarios in which a situation would and would not be considered ''primarily for the purposes of'' or ''primarily based on'' the provision of reproductive health care. One commenter asserted that the definition is uncertain and could be interpreted as permitting secondary or additional uses or disclosures. Another commenter explained that permitting a use or disclosure where conducting the investigation or imposing liability is only for a secondary or incidental purpose would create too much risk for individuals and health care providers and would undermine the intent of the proposed prohibition. And another stated it is foreseeable that a requesting entity could still use the PHI for one of the purposes for which the Department proposed to prohibit uses or disclosures of PHI once they have it if it was not the primary purpose of their request. A commenter expressed concern that the language could be exploited to manufacture a ''primary'' purpose that would be permissible to permit PHI to be used or disclosed for a prohibited purpose, particularly because the PHI would lose the protections of the Privacy Rule once it is disclosed to another person, unless that person is also a regulated entity. Another commenter asserted that the proposed rule did not define ''primarily'' or ''mere act,'' nor did it provide sufficient examples to provide regulated entities with sufficient information to understand the proposal.

A commenter explained that a request for PHI is often for multiple purposes

[315] Public Law 100–578, 102 Stat. 2903 (Oct. 31, 1988) (codified at 42 U.S.C. 201 note).

and recommended that the Department revise the proposed Rule of Construction to allow the proposed prohibition to apply where at least one of the purposes for which PHI is sought is to use or disclose the information for a prohibited purpose. Similarly, this commenter recommended the proposed attestation requirement in 45 CFR 164.509(b)(1) be revised to state that ''one of the uses or disclosures'' is not prohibited by 45 CFR 164.502(a)(5)(iii).

Response: We agree with the commenter that explained that a request for PHI may be multi-purposed. We also agree with commenters that pointed out that as proposed, the regulatory Rule of Construction appeared to create a secondary standard to consider whether a regulated entity should be prohibited from using or disclosing PHI. As discussed above, the Department is not finalizing a separate Rule of Construction and is not incorporating the phrase ''primarily for the purpose of'' originally proposed in 45 CFR 164.502(a)(5)(iii)(D) into the final prohibition standard. The modified prohibition standard more clearly conveys that it only prohibits the use and disclosure of PHI for the specified purposes when it relates to the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care in certain circumstances.

Comment: Commenters also recommended that the proposed Rule of Construction prohibit health care providers from reporting individuals for the sole reason of having received health care in a state where it was not lawful. They described concerns about the effect of interoperability and data sharing rules that give health care providers ready access to individuals' full medical records and urged the Department to expand the proposed Rule of Construction to mitigate the risks created by the electronic exchange of PHI.

Response: The prohibition, as finalized, is narrowly tailored to operate in a manner that protects the interests of individuals and society in protecting the privacy of PHI while still allowing the use or disclosure of PHI for certain non-health care purposes. We remind regulated entities that they are generally prohibited from disclosing PHI unless there is a specific provision of the Privacy Rule that permits (or, in limited instances, requires) such disclosure. For example, the Privacy Rule permits but does not require regulated entities to disclose PHI about an individual, without the individual's authorization, when such disclosure is required by another law and the disclosure complies with the requirements of the other law.[316] The permission to disclose PHI as ''required by law'' is limited to a ''mandate contained in law that compels an entity to use or disclose PHI and that is enforceable in a court of law.'' [317] Further, where a disclosure is required by law, the disclosure is limited to the relevant requirements of such law.[318] Disclosures that do not meet the ''required by law'' definition of the HIPAA Rules,[319] or that exceed what is required by such law,'' [320] are not permissible disclosures under the required by law permission. Accordingly, regulated entities are prohibited from proactively disclosing PHI under the required by law permission at 45 CFR 164.512(a) absent a law requiring mandatory reporting of such PHI.

Comment: A few commenters asserted that the Department should modify the regulatory text of the proposed prohibition to eliminate the need for the proposed Rule of Construction because it is confusing and appears to set forth two different standards.

Response: For the reasons discussed above, we agree and have incorporated the Rule of Construction into the prohibition standard as described above.

Comment: A commenter expressed concerns that beneficial uses or disclosures, such as for conducting investigations into health care fraud, would be too limited and would not address criminal, civil and administrative proceedings, which are not related to receiving, obtaining, facilitating, or providing reproductive health services where the receipt or provision of these services could serve as evidence of another crime.

Response: We disagree with concerns that beneficial uses or disclosures would be too limited under the changes. If PHI is requested for a purpose that is not prohibited and the request complies with the conditions of an applicable permission, including the requirements of the attestation condition are met, where applicable, the regulated entity is permitted to comply with the request.

Comment: Another commenter cited studies to assert that the proposed Rule of Construction would continue to permit health care providers to proactively report on individuals. The commenter also stated that the proposed rule would not clarify how it would interact with mandatory reporting laws that could expose individuals and health care providers to investigations based on the provision of reproductive health care.

Response: The Privacy Rule does not permit a regulated entity to disclose PHI for law enforcement purposes, proactively or otherwise, without an individual's authorization when the disclosure is not made pursuant to process or as otherwise required by law.[321] This is true currently and remains true under this final rule.

As discussed above, HIPAA generally preempts state laws requiring the use or disclosure of PHI, except in limited circumstances. Where such mandatory reporting laws are not preempted by HIPAA, regulated entities are limited to disclosing the minimum amount of PHI necessary to comply with the mandatory reporting requirement or the relevant requirements of such law.[322]

Comment: Several commenters responded to the question about whether it would be beneficial for the Department to further clarify or provide examples of uses or disclosures of PHI that would be permitted under a final rule. All of these commenters agreed that it would be beneficial for the Department to do so. Of those, several commenters specified that the Department should provide such examples in the final regulatory text. A few commenters who requested examples be provided within the regulatory text also recommended that the language make clear that the examples are illustrative.

Response: The Department declines to include examples of uses or disclosures of PHI that would be permitted in this rule, in regulatory text. We have provided illustrative examples above.

3. Clarifying Personal Representative Status in the Context of Reproductive Health Care

Section 164.502(g) of the Privacy Rule contains the standard for personal

[316] *See* 45 CFR 164.512(a)(1).

[317] *See* 45 CFR 164.103 (definition of ''Required by law''). The definition provides additional explanation about what constitutes a mandate contained in law.

[318] *See* 45 CFR 164.512(a)(1).

[319] *See* 45 CFR 164.103 (definition of ''Required by law'').

[320] The Privacy Rule permits but does not require covered entities to disclose PHI in response to an order of a court or administrative tribunal. The Privacy Rule also permits but does not require covered entities to disclose PHI in response to a subpoena, discovery request, or other lawful process, but only when certain conditions are met. *See* 45 CFR 164.512(e)(1). These provisions cannot be used to make disclosures to law enforcement officials that are restricted by 45 CFR 164.512(f). *See* 45 CFR 164.512(e)(2).

[321] 45 CFR 164.512(f)(1).

[322] Whether the regulated entity is limited by the minimum necessary standard or the relevant requirements of the law that requires the reporting depends upon whether the regulated entity is making the disclosure pursuant to 45 CFR 164.512(a) or some other permission under 45 CFR 164.512. *See* 45 CFR 164.502(b)(v).

representatives and generally requires a regulated entity to treat an individual's personal representative as the individual if that person has authority under applicable law (*e.g.,* state law, court order) to act on behalf of the individual in making decisions related to health care.[323] For example, the Privacy Rule would treat a legal guardian of an individual who has been declared incompetent by a court as the personal representative of that individual, if consistent with applicable law.[324] In this and certain other provisions, the Department seeks to maintain the longstanding balance HIPAA strikes between the interest of a state or other authorities to regulate health and safety and protect vulnerable individuals [325] with the goal of maintaining the privacy protections established in the Privacy Rule.[326]

In the 2023 Privacy Rule NPRM, the Department expressed concern that some regulated entities may interpret the Privacy Rule as providing them with the ability to refuse to recognize as an individual's personal representative a person who makes reproductive health care decisions, on behalf of the individual, with which the regulated entity disagrees.[327] Under these circumstances, current section 45 CFR 164.502(g)(5) of the Privacy Rule could be interpreted to permit a regulated entity to assert that, by virtue of the personal representative's involvement in the reproductive health care of the individual, the regulated entity believes that the personal representative is subjecting the individual to abuse. Further, this regulated entity might exercise its professional judgment and decide that it is in the best interest of the individual to not recognize the personal representative's authority to make health care decisions for that individual.

To protect the balance of interests struck by the Privacy Rule, the Department proposed to modify 45 CFR 164.502 by adding a new paragraph (g)(5)(iii). Proposed 45 CFR 164.502(g)(5)(iii) would ensure that a regulated entity could not deny personal representative status to a person where such status would otherwise be consistent with state and other applicable law primarily because that person provided or facilitated reproductive health care for an individual. The Department expressed its belief that this proposal was narrowly tailored and respected the interests of states and the Department by not unduly interfering with the ability of states to define the nature of the relationship between an individual and another person, including between a minor and a parent, upon whom the state deems it appropriate to bestow personal representative status. The proposal would, however, maintain the existing HIPAA standard by ensuring personal representative status, when otherwise consistent with state law, would not be affected by the type of underlying health care sought.

Several commenters supported the Department's proposal to clarify that the covered entity's reasonable basis for electing not to treat a person as a personal representative of an individual, despite state law or other requirements of the Privacy Rule, cannot be primarily because the person has provided or facilitated reproductive health care. Other commenters expressed concern about their ability to determine what constitutes reproductive health care, as would be required to ascertain whether the covered entity had a reasonable basis to elect not to treat a person as an individual's personal representative. These commenters requested that the Department provide additional clarity in regulatory text or through examples. Other commenters questioned how the Department's proposal would align with existing state law on parental rights.

As discussed throughout this final rule, reproductive health care is uniquely sensitive and must be treated accordingly. Thus, we are finalizing 45 CFR 164.502(g)(5) with additional modifications as follows. This final rule precludes the denial of personal representative status where the basis of the denial is that the person provided or facilitated reproductive health care instead of the proposed standard that would have precluded denial ''primarily'' based on these actions. This change clarifies that the covered entity does not have to determine whether the reproductive health care is the ''primary'' basis for denying a person personal representative status. Additionally, the final rule adds the term ''reasonable'' before ''belief'' to align with 45 CFR 164.502(g)(5)(i)(A), clarifying that the basis of the covered entity's belief must be reasonable in the circumstances. We are also renumbering paragraphs. Collectively, these changes clarify that it is not reasonable to elect not to treat a person as an individual's personal representative because the person provides or facilitates reproductive health care for and at the request of the individual. The Department is making these changes in response to comments received on the 2023 Privacy Rule NPRM, which are further discussed below.

Comment: Several commenters supported the Department's proposal to clarify that the covered entity's basis for electing not to treat a person as a personal representative of an individual, despite state law or other requirements of the Privacy Rule, cannot be primarily because the person has provided or facilitated reproductive health care.

Response: As explained throughout this final rule, reproductive health care is uniquely sensitive and must be treated as such. Accordingly, we are finalizing this proposal with modifications as described above.

Comment: A commenter expressed concerns that regulated entities would have difficulty determining whether the ''primary'' basis for the belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by such person, or that treating such person as the personal representative could endanger the individual related to the provision or facilitation of the reproductive health care, in some circumstances. The commenter requested that the Department provide additional clarity in the regulatory text or through examples.

Response: As discussed above, we have removed the term ''primary'' before ''basis'' and reorganized the provision. We believe this change clarifies that the covered entity does not have to determine whether the provision or facilitation of reproductive health care is the ''primary'' basis for believing that a person who is an individual's personal representative under applicable law has abused, neglected, or endangered the individual, or may do so in the future, such that the covered entity would be permitted to deny the person personal representative status.

Comment: A few commenters requested that the Department clarify that other existing provisions pertaining to personal representatives continue to apply, including the provision that a covered entity should not treat a parent or guardian as a personal representative where state law does not require a minor to obtain parental consent to lawfully obtain health care.

Response: As discussed above, the Privacy Rule generally requires a covered entity to treat a person who, under applicable law, has the authority to act on behalf of an individual in making decisions related to health care

[323] *See* 45 CFR 164.502(g).

[324] *See* 45 CFR 164.502(g)(3)(i). *See also* Off. for Civil Rights, ''Personal Representatives,'' U.S. Dep't of Health and Human Servs., *https://www.hhs.gov/hipaa/for-individuals/personal-representatives/index.html.*

[325] *See, e.g.,* 45 CFR 164.510(b)(3) and 164.512(j)(1)(i)(A).

[326] *See* 65 FR 82462, 82471 (Dec. 28, 2000).

[327] 88 FR 23506, 23533–34 (Apr. 17, 2023).

as the individual's personal representative with respect to PHI relevant to such personal representation, with limited exception.[328] In this final rule, we are clarifying those limited exceptions apply to this general rule.[329] We did not propose, nor are we making any additional changes to the Privacy Rule's provisions on personal representatives. Nothing in this final rule is intended to alter any other use or disclosure permissions for personal representatives, nor does it interfere with the ability of states to define the nature of the relationship between a minor and a parent or guardian.

Comment: A commenter asserted that the proposal could lead to situations in which someone pretending to be a personal representative of the individual would consent to reproductive health care for the individual. According to a few commenters, the proposal would make it easier for a person abusing an individual to obtain access to an individual's PHI because of the limits imposed on the reasonable belief provisions by the proposal. Another commenter asserted that the proposal would hinder state investigations into crimes that affect an individual's reproductive health where such crimes are committed by a person meeting a state's definition of a personal representative.

Response: The Department has no reason to believe, and commenters provided no evidence to suggest, that the final rule will lead to abuse or undermine parental consent. Rather, the final rule will protect sensitive PHI by clarifying that a regulated entity must treat a person as a personal representative of an individual with respect to PHI relevant to such personal representation if such person is, under applicable law, authorized to act on behalf of the individual in making decisions related to health care. This includes a court-appointed guardian, a person with a power of attorney, or other persons with legal authority to make health care decisions. Further, under 45 CFR 164.514(h), a covered entity must verify the identity of a person requesting PHI and the authority of any such person to have access to PHI, if the identity is not already known to the covered entity.

Additionally, the final rule allows a covered entity to elect not to treat a person as a personal representative of an individual if the covered entity, in the exercise of professional judgment, has a reasonable belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by such person, or that treating such person as the personal representative could endanger the individual. The final rule only clarifies that the reasonable basis cannot be the provision or facilitation of reproductive health care by the person authorized by applicable law.

Comment: A few commenters recommended that the Department define and interpret personal representative status in the context of reproductive health care consistent with its current interpretation.

Response: We appreciate the comments but decline to specifically define ''personal representative'' in the context of reproductive health care. We are reducing compliance burdens by eliminating the need for covered entities to determine whether the provision or facilitation of reproductive health care was the ''primary'' basis for their belief that an individual has been or may be subjected to domestic violence, abuse, or neglect, or may be endangered by a person authorized by applicable law to act as an individual's personal representative if the covered entity treats the person as such, with respect to PHI relevant to such personal representation.

Comment: A covered entity recommended that the Department set reasonable threshold standards that covered entities would be required to meet if they deny personal representative status to a person because of any legal, social, or professional liability that could attach based on such denials. The commenter further recommended that the Department set objective universal thresholds for denials that are clear, concise, and easily defined.

Response: We appreciate the comment but decline to set a reasonable threshold standard that covered entities would be required to meet if they deny personal representative status to a person. As discussed above, the Department gives covered entities discretion to elect not to treat a person as a personal representative of an individual if the covered entity has a reasonable belief that the individual has been subjected to domestic violence, abuse, or neglect by or would be in danger from a person seeking to act as the personal representative, except where the basis of the denial is that the person provided or facilitated reproductive health care.

Response: As discussed above, a personal representative, with authority under applicable law, stands in the shoes of the individual and has the ability to act for the individual and exercise the individual's rights. Thus, with very limited exceptions, covered entities must provide the personal representative access to the individual's PHI in accordance with 45 CFR 164.524 to the extent such information is relevant to such representation.

4. Request for Comments

The Department requested comment on whether to eliminate or narrow any existing permissions to use or disclose ''highly sensitive PHI.'' [330] Most of the comments on this question are discussed in the context of the prohibition.

C. Section 164.509—Uses and Disclosures for Which an Attestation Is Required

1. Current Provision

The Privacy Rule currently separates uses and disclosures into three categories: required, permitted, and prohibited. Permitted uses and disclosures are further subdivided into those to carry out TPO; [331] those for which an individual's authorization is required; [332] those requiring an opportunity for the individual to agree or object; [333] and those for which an authorization or opportunity to agree or object is not required.[334] For an individual's authorization to be valid, the Privacy Rule requires that it contain certain specific information to ensure that an individual authorizing a regulated entity to use or disclose their PHI to another person knows and understands to what it is they are agreeing.[335]

2. Proposed Rule

As we described in the 2023 Privacy Rule NPRM, a regulated entity presented with a request for PHI would need to discern whether using or disclosing PHI in response to the request would be prohibited. To facilitate compliance with the proposed prohibition at 45 CFR 164.502(a)(5)(iii) while also providing a pathway for regulated entities to disclose PHI for certain permitted purposes, the Department proposed to require that a covered entity obtain an attestation from a person requesting the use or disclosure of PHI in certain circumstances.[336]

[328] *See* 45 CFR 164.502(g).

[329] *See* 45 CFR 164.502(g)(3)(i).

[330] 88 FR 23506, 23534 (Apr. 17, 2023).

[331] 45 CFR 164.506.

[332] 45 CFR 164.508.

[333] 45 CFR 164.510.

[334] 45 CFR 164.512.

[335] 45 CFR 164.508(b).

[336] 88 FR 23506, 23534–37 (Apr. 17, 2023).

Specifically, the Department proposed to add a new section 45 CFR 164.509, ''Uses and disclosures for which an attestation is required.'' This proposed condition would require a regulated entity to obtain certain assurances from the person requesting PHI potentially related to reproductive health care before the PHI is used or disclosed, in the form of a signed and dated written statement attesting that the use or disclosure would not be for a purpose prohibited under 45 CFR 164.502(a)(5)(iii), where the person is making the request under the Privacy Rule permissions at 45 CFR 164.512(d) (disclosures for health oversight activities), (e) (disclosures for judicial and administrative proceedings), (f) (disclosures for law enforcement purposes), or (g)(1) (disclosures about decedents to coroners and medical examiners).

The proposed new section included a description of the proposed attestation contents, including a statement that the use or disclosure is not for a purpose the Department proposed to prohibit as described at 45 CFR 164.502(a)(5)(iii). The 2023 Privacy Rule NPRM also included a discussion about how the Department anticipated the proposed attestation requirement would work in concert with Privacy Rule permissions. Additionally, the proposed attestation provision would also include the general requirements for a valid attestation, and defects of an invalid attestation.[337] The Department also proposed to require that an attestation be written in plain language [338] and to prohibit it from being ''combined with'' any other document. Further, the Department's proposal would explicitly permit the attestation to be in an electronic format, as well as electronically signed by the person requesting the disclosure.[339] Under the proposal, the attestation would be facially valid when the document meets the required elements of the attestation proposal and includes an electronic signature that is valid under applicable Federal and state law.[340]

Additionally, the proposal specified that each use or disclosure request would require a new attestation.

The Department proposed that a regulated entity would be able to rely on the attestation provided that it is objectively reasonable under the circumstances for the regulated entity to believe the statement required by 45 CFR 164.509(c)(1)(iv) that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), rather than requiring a regulated entity to investigate the validity of an attestation.[341] We explained that it would not be objectively reasonable for a regulated entity to rely on the representation of the person requesting PHI about whether the reproductive health care was provided under circumstances in which it was lawful to provide such health care. This is because we believed that the regulated entity, not the person requesting the disclosure of PHI, has the information about the provision of such health care that is necessary to make this determination. Therefore, we explained that this determination would need to be made by the regulated entity prior to using or disclosing PHI in response to a request for a use or disclosure of PHI that would require an attestation under the proposal.

The attestation proposal also would require a regulated entity to cease use or disclosure of PHI if the regulated entity develops reason to believe, during the course of the use or disclosure, that the representations contained within the attestation were materially incorrect, leading to uses or disclosures for a prohibited purpose.[342] Relatedly, the 2023 Privacy Rule NPRM included a discussion of the consequences of material misrepresentations that cause the impermissible use or disclosure of IIHI relating to another individual under HIPAA.

To reduce the burden on regulated entities implementing this proposed attestation, the Department requested comment on whether it should develop a model attestation that a regulated entity may use when developing its own attestation templates. The Department did not propose to require that regulated entities use the model attestation.

3. Overview of Public Comments

Most commenters expressed support for the proposal to require an attestation for certain uses and disclosures. Some commenters questioned why the Department did not extend the attestation requirement directly to business associates, consistent with the general prohibition and recommended that the attestation requirements be applied to business associates.

Some of those commenters that supported the proposal to require an attestation expressed concern or made additional recommendations about its components, content, and scope, and the consequences for covered entities that make inadvertent disclosures of PHI without an attestation. A small number of opposing commenters also expressed concerns about the effectiveness and administrative burden of the proposed attestation requirement.

About half of the commenters concerned about the administrative burden of the attestation expressed support for limiting the applicability of the proposed attestation to certain types of uses and disclosures of information, while the other half recommended expanding the scope of the proposed attestation requirement to mitigate burdens on covered entities or to increase privacy protections for individuals.

Many commenters expressed concern about the Department's statement in the 2023 Privacy Rule NPRM that it would not be objectively reasonable for a regulated entity to rely on the representation of a person requesting the use or disclosure of PHI about whether the PHI sought was related to lawful health care. Specifically, commenters asserted that regulated entities may have difficulties determining whether an attestation is ''objectively reasonable'' and were unlikely to possess the information necessary to determine the purpose of a person's request for the use or disclosure of PHI.

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[337] Pursuant to 45 CFR 164.530(j), regulated entities would be required to maintain a written or electronic copy of the attestation.

[338] The Federal plain language guidelines under the Plain Writing Act of 2010 only applies to Federal agencies, but it serves as a helpful resource. *See* 5 U.S.C. 105 and ''Federal plain language guidelines,'' U.S. Gen. Servs. Admin., *https://www.plainlanguage.gov/guidelines/*.

[339] Proposed 45 CFR 164.509(b)(1)(iv) and (c)(1)(iv).

[340] While not explicitly stated in the Privacy Rule, the Department previously issued guidance clarifying that authorizations are permitted to be submitted and signed electronically. *See* Off. for Civil Rights, ''Is a copy, facsimile, or electronically transmitted version of a signed authorization valid under the Privacy Rule?,'' U.S. Dep't of Health and Human Servs., HIPAA FAQ #475 (Jan. 9, 2023), *https://www.hhs.gov/hipaa/for-professionals/faq/475/is-a-copy-of-a-signed-authorization-valid/index.html* and Off. for Civil Rights, ''How do HIPAA authorizations apply to an electronic health information exchange environment?,'' U.S. Dep't of Health and Human Servs., HIPAA FAQ #554 (July 26, 2013), *https://www.hhs.gov/hipaa/for-professionals/faq/554/how-do-hipaa-authorizations-apply-to-electronic-health-information/index.html.*

[341] This approach is consistent with 45 CFR 164.514(h), which requires a regulated entity to verify the identity and legal authority of a public official or a person acting on behalf of a public official, and describes the type of documentation upon which a regulated entity may rely, if such reliance is reasonable under the circumstances, to do so. *See also* 45 CFR 164.514(d)(3)(iii)(A), which permits a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).

[342] Proposed 45 CFR 164.509(d).

Most commenters urged the Department to expand the proposal beyond requests for PHI potentially related to reproductive health care to requests for any PHI because of the associated administrative burden of identifying and segmenting PHI about reproductive health care from other types of PHI. These commenters asserted that the burden would be significant because such PHI can be found throughout the medical record. Commenters also expressed concerns about the ability of EHRs to segment data.

Most commenters recommended that the Department add to or modify the content of the proposed attestation, including to add a statement that the recipient pledges not to redisclose PHI to another party for any of the prohibited purposes or that the request is for the minimum amount of information necessary. Many supported the inclusion of a signed declaration under penalty of perjury and a statement regarding the penalties for perjury to add a layer of accountability.

4. Final Rule

As we explained in the 2023 Privacy Rule NPRM, it may be difficult for regulated entities to distinguish between requests for the use and disclosure of PHI based on whether the request is for a permitted or prohibited purpose, which could lead regulated entities to deny use or disclosure requests for permitted purposes. Additionally, absent an enforcement mechanism, it is likely that persons requesting the use or disclosure of PHI could seek to use Privacy Rule permissions for purposes that are prohibited under the new 45 CFR 164.502(a)(5)(iii). Accordingly, the Department is finalizing the proposed attestation requirement, with modification, as described below. We intend to publish a model attestation prior to the compliance date for this final rule.

First, the Department is renumbering the attestation provision such that the requirement is now 45 CFR 164.509(a)(1) and modifying that requirement to hold business associates directly liable for compliance with the attestation requirement. This change was made to address concerns raised by commenters who questioned why the Department did not extend the attestation requirement directly to business associates, consistent with the general prohibition and with revisions made to the HIPAA Rules in the 2013 Omnibus Rule, as required by the HITECH Act. The Department has authority to take enforcement action against business associates only for requirements for which the business associate is directly liable.[343] Thus, under the proposed attestation requirement, a business associate would only have been required to comply with the proposed 45 CFR 164.509 if such obligation was explicitly included within its business associate agreement.[344]

Both covered entities and business associates process requests for PHI. The Privacy Rule permits regulated entities to determine whether a business associate can respond to such requests or whether they are required to defer to the covered entity.[345] As noted by commenters, while many PHI requests processed by a business associate pursuant to 45 CFR 164.512(d)–(g)(1) are processed on behalf of the covered entity, persons may elect to request PHI directly from the business associate. Thus, the Department has determined that it is appropriate to hold both covered entities and business associates directly liable for compliance with the attestation requirement. Expanding the attestation requirement to apply to business associates will ensure that the business associate is directly liable for compliance with it, regardless of whether compliance with 45 CFR 164.509 is explicitly included in a BAA.

The Department is also adopting the proposed attestation requirement that a regulated entity obtain an attestation only for PHI ''potentially related to reproductive health care.'' As discussed in the 2023 Privacy Rule NPRM, this will limit the number of requests that require an attestation, and therefore, the burden of the attestation requirement on regulated entities and persons requesting PHI. The Department reminds regulated entities that they are permitted, but not required, to respond to law enforcement requests for PHI where the purpose of the request is not one for which regulated entities are prohibited from disclosing PHI. By narrowing the scope of the attestation to PHI ''potentially related to reproductive health care,'' the attestation requirement will not unnecessarily interfere with or delay law enforcement investigations that do not involve PHI ''potentially related to reproductive health care.'' While in practice this scope may be wide, we believe the privacy interests of individuals who have obtained reproductive health care necessitates the inclusion of ''potentially related'' PHI. We are concerned that extending the attestation requirement to all PHI could unnecessarily delay law enforcement investigations that are not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). We acknowledge commenters' concerns about the ability of regulated entities to operationalize the attestation condition and note that the requirement to obtain an attestation applies where the request is for PHI ''potentially related to reproductive health care,'' as opposed to PHI ''related to reproductive health care.'' Consistent with the Department's instructions to regulated entities since the Privacy Rule's inception, we have taken a flexible approach to allow scalability based on a regulated entity's activities and size. All regulated entities must take appropriate steps to address privacy concerns. Regulated entities should weigh the costs and benefits of alternative approaches when determining the scope and extent of their compliance activities, including when developing policies and procedures to comply with the Privacy Rule.[346] The Department will assess the progress of regulated entities' compliance with this requirement and promulgate guidance as appropriate. The Department also notes that with limited exceptions, the Privacy Rule generally permits but does not require the use or disclosure of PHI when the conditions set by the Privacy Rule for the specific use or disclosure of PHI are met.

The Department is adopting the proposed requirement that an attestation be obtained where a request is made under the Privacy Rule permissions at 45 CFR 164.512(d) (disclosures for health oversight activities), (e) (disclosures for judicial and administrative proceedings), (f) (disclosures for law enforcement purposes), or (g)(1) (disclosures about decedents to coroners and medical examiners). This requirement will help ensure that these Privacy Rule permissions cannot be used to circumvent the new prohibition at 45

[343] Business associates became directly liable for compliance with certain requirements of the HIPAA Rules under the HITECH Act. Consistent with the HITECH Act, the 2013 Omnibus Rule identified the portions of the HIPAA Rules that apply directly to business associates and for which business associates are directly liable. Prior to the HITECH Act and the Omnibus Rule, these requirements applied to business associates and their subcontractors indirectly through the requirements under 45 CFR 164.504(e) and 164.314(a), which require that covered entities by contract require business associates to limit uses and disclosures and implement HIPAA Security Rule-like safeguards. *See* 78 FR 5566 (Jan. 25, 2013). *See also* Off. for Civil Rights, ''Direct Liability of Business Associates Fact Sheet,'' U.S. Dep't of Health and Human Servs. (July 16, 2021), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html.*

[344] 45 CFR 164.504(e) and 164.314(a).

[345] 45 CFR 164.504(e)(2)(i)(E).

[346] 65 FR 82462, 82471, and 82875 (Dec. 28, 2000).

CFR 164.502(a)(5)(iii) and continue permitting essential disclosures, while also limiting the attestation's burden on regulated entities by providing a standard mechanism by which the regulated entity can ascertain whether a requested use or disclosure is prohibited under this final rule. The attestation requirement is intended to reduce the burden of determining whether the PHI request is for a purpose prohibited under 45 CFR 164.502(a)(5)(iii), but it does not absolve regulated entities of the responsibility of making this determination, nor does it absolve regulated entities of the responsibility for ensuring that such requests meet the other conditions of the relevant permission.

We are modifying the proposal by revising 45 CFR 164.509(a)(1) to clarify that a regulated entity may not use or disclose PHI where the use or disclosure does not meet all of the Privacy Rule's applicable conditions, including the attestation requirement. While this is consistent with the existing requirements of the Privacy Rule, we determined that it was necessary to reiterate this requirement here based on comments we received. Thus, when this final rule is read holistically, a regulated entity is not permitted to use or disclose PHI where such disclosure does not meet all of the Privacy Rule's applicable conditions, including the attestation requirement.

We are also modifying the proposal by adding 45 CFR 164.509(a)(2) to clarify that the use or disclosure of PHI based on a defective attestation does not meet the attestation requirement. For example, the attestation requirement would not be met if a regulated entity relies on an attestation where it is not reasonable to do so because the attestation would be defective under 45 CFR 164.509(b)(2)(v). Accordingly, it would be a violation of the Privacy Rule if the regulated entity makes a use or disclosure in response to a defective attestation.

The Department is modifying the proposal to prohibit inclusion in the attestation of any elements that are not specifically required by 45 CFR 164.509(c). This provision addresses concerns that regulated entities might require persons requesting PHI to provide information beyond that which is required under 45 CFR 164.509(c). Such additional requirements could make it burdensome for persons requesting PHI to submit a valid attestation when they make a request pursuant to 45 CFR 164.512(d), (e), (f), or (g)(1). Additionally, a person requesting PHI is not required to use the specific attestation form provided by a regulated entity, as long as the attestation provided by such person is compliant with the requirements of 45 CFR 164.509.

Additionally, the Department is modifying the proposed prohibition on compound attestations. Specifically, the final rule prohibits the attestation from being ''combined with'' any other document. The modification clarifies that while an attestation may not be combined with other ''forms,'' additional documentation to support the information provided in the attestation may be submitted. This additional documentation may not replace or substitute for any of the attestation's required elements. The attestation itself must be clearly labeled, distinct from any surrounding text, and completed in its entirety, but documentation to support the statement at 45 CFR 164.509(c)(1)(iv) or to overcome the presumption at 45 CFR 164.502(a)(5)(iii)(C) may be appended to the attestation. Thus, a regulated entity must ensure that the required elements of the attestation are met, and should review any additional documents provided by the person making the request when making the required determinations.

A regulated entity may use this information—the information on the attestation combined with any additional documentation provided by the person making the request for PHI—to make a reasonable determination that the attestation is true, consistent with 45 CFR 164.509(b)(2)(v). For example, an attestation would not be impermissibly ''combined with'' a subpoena if it is attached to it, provided that the attestation is clearly labeled as such. As another example, an electronic attestation would not be impermissibly ''combined with'' another document where the attestation is on the same screen as the other document, provided that the attestation is clearly and distinctly labeled as such.

The Department is finalizing the proposed content requirements with modifications as follows. Specifically, the Department is finalizing the proposal that an attestation must include that the person requesting the disclosure confirm the types of PHI that they are requesting; clearly identify the name of the individual whose PHI is being requested, if practicable, or if not practicable, the class of individuals whose PHI is being requested; and confirm, in writing, that the use or disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). For purposes of the ''class of individuals'' described in 45 CFR 164.509(c)(1)(i)(B), the Department clarifies that the requesting entity may describe such a class in general terms—for example, as all individuals who were treated by a certain health care provider or for whom a certain health care provider submitted claims, all individuals who received a certain procedure, or all individuals with given health insurance coverage.

As we proposed, we are finalizing a requirement that the attestation include a clear statement that the use or disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). This requirement may be satisfied with a series of checkboxes that identifies why the use or disclosure is not prohibited under 45 CFR 164.502(a)(5)(iii) (*i.e.,* the use or disclosure is not for a purpose specified in 45 CFR 164.502(a)(5)(iii)(A); or the use or disclosure is for a purpose that would be prohibited under 45 CFR 164.502(a)(5)(iii)(A), but the reproductive health care at issue was not lawful under the circumstances in which it was provided so the Rule of Applicability is not satisfied, and thus the prohibition does not apply).

The Department is adding another new required element, a statement that the attestation is signed with the understanding that a person who knowingly and in violation of HIPAA obtains or discloses IIHI relating to another individual, or discloses IIHI to another person, may be subject to criminal liability.[347] We believe that adding this language satisfies the intent that led us to consider including a penalty of perjury requirement and with applicable law. The statement does not impose new liability on persons who sign an attestation; instead, including the statement in the attestation ensures that persons who request the use or disclosure of PHI for which an attestation is required are on notice of and acknowledge the consequences of making such requests under false pretenses.

The Department is also finalizing the proposed requirement that the attestation must be written in plain language. Additionally, the Department is finalizing its proposal to permit the attestation to be in electronic format and for it to be electronically signed by the person requesting the disclosure where such electronic signature is valid under applicable law.[348] The Department declines to mandate a specific electronic format for the attestation.

As we proposed, an attestation will be limited to the specific use or disclosure. Accordingly, each use or disclosure

[347] *See* 42 U.S.C. 1320d–6(a).

[348] 45 CFR 164.509(b)(1)(iii) and (c)(1)(vi).

request for PHI will require a new attestation.

There is no exception to the minimum necessary standard for uses and disclosures made pursuant to an attestation under 45 CFR 164.509.[349] Thus, a regulated entity will have to limit a use or disclosure to the minimum necessary when provided in response to a request that would be subject to the proposed attestation requirement, unless one of the specified exceptions to the minimum necessary standard in 45 CFR 164.502(b)(2) applies. Where the person requesting the PHI is also a regulated entity, that person will also need to make reasonable efforts to limit their request to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.[350]

The Department is not requiring a regulated entity to investigate the validity of an attestation provided by a person requesting a use or disclosure of PHI. Rather, a regulated entity is generally permitted to rely on the attestation if, under the circumstances, a regulated entity reasonably determines that the request is not for investigating or imposing liability for the mere act of seeking, obtaining, providing, or facilitating allegedly unlawful reproductive health care. In addition, a regulated entity is generally permitted to rely on the attestation and any accompanying material if, under the circumstances, a regulated entity reasonably could conclude (*e.g.,* upon examination of adequate supporting documentation provided by the person making the request) that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), consistent with the approach taken in the Privacy Rule [351] and elsewhere in this final rule. If such reliance is not reasonable, then the regulated entity may not rely on the attestation. This is a change from the proposed language, which permitted reliance based on an ''objectively reasonable'' standard. The proposed standard was modified because a reasonable person standard is inherently objective.[352] Thus, including ''objectively'' in the description of the standard was redundant.

For requests involving allegedly unlawful reproductive health care, the extent to which a regulated entity may reasonably rely on an attestation depends in part on whether the regulated entity provided the reproductive health care at issue. Under the final rule, it would not be reasonable for a regulated entity to rely on the representation made by a person requesting the use or disclosure of PHI that the reproductive health care was unlawful under the circumstances in which it was provided unless such representation meets the conditions set forth in the presumption at 45 CFR 164.502(a)(5)(iii)(C). As discussed above, under the presumption, reproductive health care is presumed to be lawful under the circumstances in which such health care is provided unless a regulated entity has actual knowledge, or information from the person making the request that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. Where the reproductive health care at issue was provided by a person other than the regulated entity receiving the request for the use or disclosure of PHI and the presumption is overcome, the regulated entity is permitted to use or disclose PHI in response to the request upon receipt of an attestation where it is reasonable to rely on the representations made in the attestation. It is not reasonable for the regulated entity to rely solely on a statement of the person requesting the use or disclosure of PHI that the reproductive health care was unlawful under the circumstances in which such health care was provided. Instead, the person requesting the use or disclosure of PHI must provide the regulated entity with information such that it would constitute actual knowledge or that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. A regulated entity that receives a request for PHI involving reproductive health care provided by that regulated entity should review the relevant PHI in its possession and other related information (*e.g.,* license of health care provider that provided the health care, operating license for the facility in which such health care was provided) to determine whether the reproductive health care was lawful under the circumstances in which it was provided prior to using or disclosing PHI in response to a request for PHI that requires an attestation. Where the request is about reproductive health care that is provided by the regulated entity receiving the request, it would not be reasonable for a regulated entity to automatically rely on a representation made by a person requesting the use or disclosure of PHI about whether the reproductive health care was provided under the circumstances in which it was lawful to provide such health care. Rather, the regulated entity must review the individual's PHI to consider the circumstances under which it provided the reproductive health care to determine whether such reliance is reasonable. Therefore, where the request involves the use or disclosure of PHI potentially related to reproductive health care that was provided by the recipient of the request, the regulated entity must make the determination about whether it provided the health care lawfully prior to using or disclosing PHI in response to a request that requires an attestation.

For example, if a law enforcement official requested PHI potentially related to reproductive health care to investigate a person for the mere act of seeking, obtaining, providing or facilitating allegedly unlawful reproductive health care, it would not be reasonable for a regulated entity that receives such a request to rely solely on a signed attestation that states that the reproductive health care was not lawful under the circumstances in which it was provided, as set forth in 45 CFR 164.502(a)(5)(iii)(B), and therefore, that the requested disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii)(A). This is regardless of whether the regulated entity receiving the request for PHI provided the reproductive health care at issue. Assuming that the attestation is not facially deficient, a regulated entity must consider the totality of the circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances. To determine whether it is reasonable to rely on the attestation, a regulated entity should consider, among other things: who is requesting the use or disclosure of PHI; the permission upon which the person making the request is relying; the

[349] 45 CFR 164.502(b). The minimum necessary standard of the Privacy Rule applies to all uses and disclosures where a request does not meet one of the specified exceptions in paragraph (b)(2).

[350] 45 CFR 164.502(b)(1).

[351] This approach is consistent with 45 CFR 164.514(h), which requires a covered entity to verify the identity and legal authority of a public official or a person acting on behalf of the public official and describes the type of documentation upon which regulated entities can rely, if such reliance is reasonable under the circumstances, to do so. *See also* 45 CFR 164.514(d)(3)(iii)(A), which permits a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).

[352] *E.g.,* Restatement (Second) Torts § 283, comment b (Am. L. Inst. 1965).

information provided to satisfy other conditions of the relevant permission; the PHI requested and its relationship to the stated purpose of the request; and, where the reproductive health care was supplied by another person, whether the regulated entity has: (1) actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided; or (2) factual information supplied by the person requesting the use or disclosure of PHI that would demonstrate to a reasonable regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

For example, a regulated entity receives an attestation from a Federal law enforcement official, along with a court ordered warrant demanding PHI potentially related to reproductive health care. The law enforcement official represents that the request is about reproductive health care that was not lawful under the circumstances in which such health care was provided, but the official will not divulge more information because they allege that doing so would jeopardize an ongoing criminal investigation. In this example, if the regulated entity itself provided the reproductive health care and, based on the information in its possession, reasonably determines that such health care was lawful under the circumstances in which it was provided, the regulated entity may not disclose the requested PHI.

If the regulated entity did not provide the reproductive health care, it may not disclose the requested PHI absent additional factual information because the official requesting the PHI has not provided sufficient information to overcome the presumption at 45 CFR 164.502(a)(5)(iii)(C). Further, it also would not be reasonable under the circumstances for the regulated entity to rely on the attestation that the information would not be used for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) because of the presumption that the reproductive health care was lawfully provided.

However, in cases where the presumption of lawfulness applies, the regulated entity would be permitted to make the disclosure, for example, where the law enforcement official provides additional factual information for the regulated entity to determine that there is a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided. As another example, a regulated entity could rebut the presumption of lawfulness by relying on a sworn statement by a law enforcement official that the PHI is necessary for an investigation into violations of specific criminal codes unrelated to the provision of reproductive health care (*e.g.,* billing fraud) or an affidavit from an individual that the individual obtained unlawful reproductive health care from a different health care provider and the requested PHI is relevant to that investigation. Similarly, if a regulated entity receives an attestation from a Federal law enforcement official, along with a court-ordered warrant demanding PHI potentially related to reproductive health care, that both specify that the purpose of the request is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), the regulated entity may rely on the attestation and warrant, subject to the requirements of 45 CFR 164.512(f)(1)(ii)(A).

Lastly, this final rule requires a regulated entity to cease use or disclosure of PHI if the regulated entity, during the course of the use or disclosure, discovers information reasonably showing that the representations contained within the attestation are materially incorrect, leading to uses or disclosures for a prohibited purpose.[353] As we explained in the 2023 Privacy Rule NPRM, pursuant to HIPAA, a person who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual or discloses IIHI to another person would be subject to criminal liability.[354] Thus, a person who knowingly and in violation of HIPAA [355] falsifies an attestation (*e.g.,* makes material misrepresentations about the intended uses of the PHI requested) to obtain (or cause to be disclosed) an individual's IIHI could be subject to criminal penalties as outlined in the statute.[356] Additionally, a disclosure made based on an attestation that contains material misrepresentations after the regulated entity becomes aware of such misrepresentations constitutes an impermissible disclosure, which requires notifications of a breach to the individual, the Secretary, and in some cases, the media.[357]

The attestation requirement does not replace the conditions of the Privacy Rule's permissions for a regulated entity to disclose PHI, including in response to a subpoena, discovery request, or other lawful process, or administrative request. Instead, the attestation is designed to work with the permissions and their requirements. If PHI is disclosed pursuant to 45 CFR 164.512(e)(1)(ii) or (f)(1)(ii)(C), a regulated entity will need to verify that the requirements of each provision are met, in addition to satisfying the requirements of the new attestation provision under 45 CFR 164.509. Furthermore, the requirements of 45 CFR 164.528, the right to an accounting of disclosures of PHI made by a covered entity, are not affected by the attestation requirement. Thus, disclosures made pursuant to a permission under 45 CFR 164.512(d), (e), (f), or (g) must be included in the accounting, including when they are made pursuant to an attestation.

5. Responses to Public Comments

Comment: Most commenters supported the proposal to require an attestation for certain uses and disclosures. A few commenters recognized the benefits of the attestation requirement, despite the potential increase in administrative burden for regulated entities.

Many commenters opposed the proposal for what they described as administrative burden, questionable effectiveness, and lack of clarity. A few commenters stated that the requirements imposed an inappropriate compliance burden on covered entities that would need to determine whether a PHI request was ''potentially related'' to sensitive personal health care, and, along with a health care provider who otherwise supported the attestation, they recommended instead that the Department impose requirements on the person requesting the use or disclosure of PHI. Many commenters expressed concerns about the ability of covered entities to operationalize the proposed requirement with the limitation to PHI potentially related to reproductive health care because it would require the ability to segment PHI, which the Department previously acknowledged is generally unavailable. A few commenters questioned the effectiveness of the proposed attestation

[353] 45 CFR 164.509(d).

[354] *See* 42 U.S.C. 1320d–6(a).

[355] A person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d–9(b)(3) of this title) and the individual obtained or disclosed such information without authorization. *Id.*

[356] *See* 42 U.S.C. 1320d–6(b).

[357] 45 CFR 164.400 *et seq.* The HIPAA Breach Notification Rule, 45 CFR 164.400–414, requires HIPAA covered entities and their business associates to provide notification following a breach of unsecured PHI.

requirement, as compared to its potential burden, enforceability, and effects on access to maternal and specialty health care.

Response: We agree with commenters that the attestation requirement will bolster the privacy of PHI and acknowledge that implementation of this important safeguard requires additional administrative activities by regulated entities. The Department considered removing the limitation on the application of the attestation condition to PHI ''potentially related to reproductive health care,'' but we are concerned that expanding it to apply to all requests for PHI made for specified purposes would impose even more burden on regulated entities. The requirement is to determine whether the requested PHI is ''potentially related to reproductive health care,'' not whether it is ''related to reproductive health care.'' Thus, regulated entities are not required to make an affirmative determination that the requested PHI is in fact related to reproductive health care before requiring a person requesting PHI to provide an attestation. We note that the focus of the attestation requirement has been limited to PHI potentially related to reproductive health care because the changes to the legal landscape have heighted privacy concerns about reproductive health care that is lawful under the circumstances in which such health care is provided. We also note that the provision of an attestation itself is not determinant of whether the request is for a prohibited purpose. Rather, regulated entities must consider whether a request for PHI is for a prohibited purpose, regardless of whether the request is made for a purpose for which the Privacy Rule requires an attestation.

The Department is limited to applying the HIPAA Rules to those entities covered by HIPAA (*i.e.,* health plans, health care clearinghouses, and health care providers that conduct covered transactions) and to business associates, as provided under the HITECH Act. Accordingly, the Department is limited to imposing obligations on persons requesting the use or disclosure of PHI to those who are also regulated entities.

The attestation condition has been drafted to promote the privacy of information about lawful reproductive health care, including maternal and specialty health care, while still permitting certain uses of PHI. Regulated entities, including covered entities that specialize in providing reproductive health care may determine, based on their assessment of what PHI is potentially related to reproductive health care, that an attestation must accompany all requests they receive for the use or disclosure of any PHI made pursuant to and in compliance with 45 CFR 164.512(d)–(g)(1). Further, the attestation requirement only applies to the specified requests for PHI and should not affect any intake of new patients or provision of maternal health care.

The Department is not requiring a regulated entity to investigate the veracity of the information provided in support of an attestation because doing so would impose a significant administrative burden on regulated entities and persons requesting the use or disclosure of PHI without proportional benefit. Additionally, requiring such an investigation by the regulated entity may cause unnecessary delays to law enforcement activities. Rather, the Department is finalizing a regulated entity's ability to rely on the attestation provided that it is reasonable under the circumstances for the regulated entity to believe the statement required by 45 CFR 164.509(c)(1)(iv) that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii). If such reliance is not reasonable, then the regulated entity may not rely on the attestation.

A regulated entity that receives a request for PHI potentially related to reproductive health care for purposes specified in 45 CFR 164.512(d), (e), (f), or (g)(1) may accept information, in addition to the attestation, from the person requesting the PHI to support its ability to make the determinations required by 45 CFR 164.502(a)(5)(iii) and 45 CFR 164.509(b)(v).

For example, it likely would not be reasonable for a regulated entity to rely on an attestation from a public official who represents that their request is for a purpose that is not prohibited, if the request for PHI is overly broad for its purported purpose and the public official has publicly stated that they will be investigating health care providers for providing reproductive health care. In such cases, regulated entities should consider the circumstances surrounding an attestation to determine whether they can reasonably rely on the attestation. Although we have modified the regulatory text by removing ''objectively,'' the standard remains unchanged in practice because a reasonableness standard is an objective standard. As we also discussed above, it is not reasonable for a regulated entity that provided the reproductive health care at issue to rely on a representation made by a person requesting the use or disclosure of PHI that the reproductive health care at issue was unlawful under the circumstance in which such health care was provided. A regulated entity that makes a disclosure where it was not reasonable to rely on the representation made by the person requesting the use or disclosure may be subject to enforcement action by OCR.

Additionally, as discussed in greater detail above, a person who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual or discloses IIHI to another person would be subject to criminal liability.[358] We believe that this provision serves as a deterrent for those who otherwise might request PHI in violation of this final rule. It also will continue to permit essential disclosures while ensuring that Privacy Rule permissions cannot be used to circumvent the new prohibition, thereby enhancing the privacy of individuals' PHI and protecting other important interests.

Comment: Several commenters opposed the attestation proposal because they believed that the proposal would make it more difficult for law enforcement to request PHI and for entities to respond to such requests, potentially putting them in situations where they need to choose between complying with a court order and impermissibly disclosing PHI. A few individuals stated that the proposal would have a chilling effect on the ability of a state to conduct investigations or proceedings for which the use or disclosure of PHI could be beneficial, particularly in cases involving rape, incest, sex trafficking, domestic violence, abuse, and neglect.

Response: We acknowledge that the attestation provision may require regulated entities to obtain additional information from persons requesting PHI in certain circumstances. As discussed above, this condition is consistent with the operation of the Privacy Rule since its inception, which has always required regulated entities to obtain additional information from persons requesting PHI in certain circumstances, such as where the use or disclosure is one for which an authorization or opportunity to agree or object is not required.[359] However, as also discussed above, any burden the attestation may impose on persons requesting PHI is outweighed by the privacy interests that this final rule is designed to protect.

A person requesting PHI pursuant to 45 CFR 164.512(d)–(g)(1) may elect to provide an attestation with their request, even if a determination has not

[358] *See* 42 U.S.C. 1320d–6(a).

[359] *See* 45 CFR 164.512.

yet been made concerning whether such request is for PHI potentially related to reproductive health care. Similarly, the Privacy Rule does not require a regulated entity to respond to requests for PHI.

Comment: Some commenters were concerned about the effect of the attestation requirement on the electronic exchange of PHI and recommended approaches for incorporating attestations into a HIE environment. A commenter expressed concern that the requirement for an attestation would delay or prevent automated data exchange using Fast Healthcare Interoperability Resources® (FHIR®) APIs and might impede innovation. They requested guidance on how to implement the attestation condition in an HIE environment without impeding regulated exchanges or industry innovations using extensive data exchange via FHIR APIs. Commenters also recommended that the Department issue guidance on implementing attestation policies in circumstances not required by this rule that would not constitute information blocking. A commenter encouraged the Department to implement processes that limit the liability of health care providers for the actions of third parties. For example, the commenter requested that the Department clarify that a refusal to disclose PHI absent an attestation is protected from a finding of information blocking.

Response: We do not believe that this final rule prevents the disclosure of PHI via a HIE. We disagree that this requirement prevents the exchange of data using FHIR APIs under these permissions or for automated health data exchange more broadly. PHI can be disclosed as requested if the regulated entity obtains a valid attestation and the request meets the conditions of an applicable permission. The attestation requirement does not affect any requests via FHIR API that fall outside of the 45 CFR 164.512(d)–(g)(1) permissions. For example, a disclosure of PHI from a covered health care provider to another health care provider for care coordination purposes would not require an attestation because the disclosure would not be for a purpose addressed by 45 CFR 164.512(d)–(g)(1). The importance of ensuring the protection of an individual's interests in the privacy of their PHI and society in improving the effectiveness of the health care system far outweigh any potential administrative burdens or delays in the electronic exchange of PHI for non-health care purposes. Further, compliance with applicable law does not constitute information blocking.[360] Thus, we do not believe additional regulatory language is necessary at this time. OCR regularly collaborates with other Federal agencies, including ONC, to develop guidance on compliance with Federal standards and to address questions that arise about the ability of regulated entities to comply with applicable laws.

The permissions for which the Department is requiring that a regulated entity obtain an attestation prior to using or disclosing PHI are already conditioned upon meeting certain requirements, which generally require manual review. The Department acknowledges that certain persons may need to adjust their workflows to account for the attestation requirement. While there may be some delays until new processes are implemented, any disruptions will decrease over time. Thus, we do not anticipate that this final rule will contribute to additional delays in the disclosure of PHI.

The Department is finalizing a new regulatory presumption that permits a regulated entity to presume reproductive health care provided by another person was lawful unless the regulated entity has actual knowledge or factual information supplied by the person requesting the use or disclosure of PHI that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. This presumption will facilitate the determination by the regulated entity about whether a request for the use or disclosure of PHI would be subject to the prohibition, and thus will reduce the risk of an impermissible use or disclosure of the requested PHI, thereby reducing the liability of regulated entities that receive requests for PHI to which the prohibition may apply, but where they did not provide the reproductive health care at issue.

Comment: Many commenters questioned the Department's rationale for not extending the attestation requirement directly to business associates, consistent with the general prohibition. Some commenters recommended that the attestation requirement be applied to business associates because persons requesting the use or disclosure of PHI may directly approach a business associate for this PHI (and the business associate agreement may permit such disclosures or be silent regarding whether the business associate may respond to them). Commenters also requested clarification of the responsibilities of business associates with respect to attestations and questioned whether the proposal would require amendment of their business associate agreements.

Response: As discussed above, we agree with the commenters that the attestation requirement should apply directly to business associates because they receive direct requests for PHI and are subject to the general prohibition in the same manner as covered entities. Therefore, we are modifying 45 CFR 164.509 to ensure that it expressly applies to both covered entities and their business associates.

Comment: Although a few commenters expressed support for limiting the attestation condition to requests regarding ''PHI potentially related to reproductive health care,'' many commenters recommended that the proposed requirement to obtain an attestation be broadly applied to requests for any PHI. Many stated that it would be easier and more efficient for regulated entities if all requests related to a prohibited purpose required the attestation, regardless of the PHI being requested. According to these commenters, this would allow the regulated entity to avoid making any determinations regarding the PHI. A few explained that expanding the requirement to all PHI would appropriately place the burden of demonstrating that the requested disclosure was permissible on the person making request.

Several commenters asserted that information related to reproductive health care is potentially found in every department, record, and system, including those that may not have a readily apparent relationship to reproductive health care. As a result, according to these commenters, it would be onerous and costly to separate different types of health information in a medical record. According to other commenters, the volume of records requests received by health systems would render any requirement on a health care provider to redact PHI from an individual's medical record in the absence of an attestation overly burdensome and increase the risk of unauthorized disclosure. Some

[360] *See* 42 U.S.C. 300jj–52(a)(1) (excluding from the definition of ''information blocking'' practices that are likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information if they are ''required by law''; 85 FR 25642, 25794 (May 1, 2020) (explaining that ''required by law'' specifically refers to interferences that are explicitly required by state or Federal law). *See also* 89 FR 1192, 1351 (Jan. 9, 2024) (affirming that where applicable law prohibits access, exchange, or use of information, practices in compliance with such law are not considered to be information blocking and citing to compliance with the Privacy Rule as an example of an applicable law).

commenters explained that staff managing health information generally do not have the legal or medical training to determine whether a PHI request may be for PHI potentially related to reproductive health care, particularly given the breadth of most requests (*e.g.,* for all medical records of an entity, of a particular health care provider or a particular individual). These commenters also raised concerns that the lack of legal or medical training could lead to inconsistent application of the rule, the inadvertent disclosure of PHI potentially related to reproductive health care, or delay the use or disclosure of PHI, even when the individual has not sought or obtained reproductive health care. Many commenters asserted that determining whether a request for the use or disclosure of PHI includes PHI potentially related to reproductive health care is difficult and a significant burden on health information professionals, particularly where the covered entity did not provide or facilitate the health care. According to some commenters, some business associates, such as cloud services providers, may not have the ability to determine whether the PHI that they maintain includes PHI potentially related to reproductive health care.

Some commenters posited that the result of this requirement would be that health care providers would refuse to provide any PHI in response to a request for the use or disclosure PHI on any matter that could possibly be construed as potentially related to reproductive health care. They and others stated that limiting the proposed prohibition to one category of PHI would require regulated entities to label or segment certain PHI within medical records, which would be impractical and costly because EHRs are unable to reliably segregate or flag PHI retrospectively.

Response: We acknowledge the comments from regulated entities that expressed concerns about the effects of the limitation of the attestation requirement to PHI potentially related to reproductive health care. However, the Department is concerned that extending the attestation requirement to all PHI could result in unintended consequences, such as the potential delay of law enforcement investigations that do not require PHI potentially related to reproductive health care. By contrast, an attestation requirement is necessary for PHI potentially related to reproductive health care because of recent changes to the legal landscape that make it more likely that PHI will be sought for punitive non-health care purposes, and thus more likely to be subject to disclosure by regulated entities if the requested disclosure is permissible under the Privacy Rule, thereby harming the interests that HIPAA seeks to protect. Accordingly, the Department is not modifying the attestation requirement that a regulated entity obtain an attestation only for PHI potentially related to reproductive health care.

The Department acknowledges that the attestation requirement may increase the burden on regulated entities, but we disagree that regulated entities are unable to make the required assessments of attestations. Regulated entities currently conduct similar assessments when determining whether PHI may be disclosed to a personal representative, when making disclosures that are required by law or for public health purposes, and for various other permitted purposes. Regulated entities also regularly review medical records to comply with minimum necessary requirements. The Department is cognizant that an expanded attestation requirement could significantly increase burden if it were to expand this requirement to all disclosures in the absence of the sensitivities described in this final rule.

Comment: Many commenters supported the proposal to limit the requirement to obtain an attestation with a request for uses and disclosures for certain permissions, namely that have the greatest potential to be connected with a purpose for which the Department proposed to prohibit the use and disclosure of PHI. Some commenters expressed their belief that the Department had identified the appropriate permissions for which the attestation would provide additional safeguards.

Many commenters suggested modifications, primarily expansions or clarifications of the types of permitted uses and disclosures that would be subject to the attestation. Generally, commenters explained their belief that their recommended modifications would either mitigate the burden of the requirement to ascertain the purposes of the requested disclosure or increase privacy protections for individuals.

Commenters recommended multiple ways to expand the attestation requirement, such as extending it to all permissions in 45 CFR 164.512; disclosures required by law, for public health activities, and to avert a serious threat to health or safety; disclosures for treatment purposes to a person not regulated by HIPAA or disclosures to any person who might use the PHI for a prohibited purpose; and any disclosure at the discretion of the covered entity.

Response: The Department declines to expand the permissions for which an attestation is required at this time. The Department specifically chose to limit the attestation condition to the permissions at 45 CFR 164.512(d)–(g)(1) because these permissions have the greatest potential to result in the use or disclosure of an individual's PHI for a purpose prohibited at 45 CFR 164.502(a)(5)(iii). In the context of other permissions, where the risk of improper use or disclosure is less, the benefits of an attestation condition would be outweighed by the administrative burden of compliance. Accordingly, any disclosures made pursuant to 45 CFR 164.512(b), which includes disclosures for public health surveillance, investigations, or interventions, do not require an attestation. However, we note that requests made pursuant to other permissions of the rule remain subject to and must be evaluated for compliance with the prohibition at 45 CFR 164.502(a)(5)(iii).

Comment: A commenter stated that no attestation should be needed for judicial and administrative proceedings because current requirements are adequate. Instead, the commenter requested that the Department consider expanding procedural protections.

Response: We are finalizing the requirement that regulated entities obtain an attestation as a condition of a use or disclosure of PHI for judicial and administrative proceedings. As previously discussed, the attestation requirement ensures that certain Privacy Rule permissions are not used to circumvent the prohibition. The attestation requirement also reduces the burden on regulated entities because it is specifically designed to facilitate compliance with the prohibition under 45 CFR 164.502(a)(5)(iii) by helping regulated entities determine whether the use or disclosure of the requested PHI is permitted. Although a court order, qualified protective order, satisfactory assurance, or subpoena may have a restriction that prevents information requested from being further disclosed, it protects PHI only after it has been used or disclosed. Thus, the regulated entity's use or disclosure of PHI could still violate the prohibition at 45 CFR 164.502(a)(5)(iii), even if that disclosure is made in response to a court order, qualified protective order, satisfactory assurance, or subpoena. The attestation requirement helps to mitigate the risk of violations in these circumstances.

Comment: A few commenters expressed concerns about their ability to implement the attestation requirement

in circumstances where the use or disclosure is triggered by a mandatory reporting law or verbal request and recommended that no attestation should be required in any case where disclosure of PHI is required by law. According to the commenters, an attestation requirement could require a significant change to operational workflows for permitted disclosures and significantly impede operations for state and local agencies that conduct death investigations and perform public health studies and initiatives.

Response: The Privacy Rule at 45 CFR 164.512(a) permits certain uses and disclosures of PHI that are required by law, including notification of certain deaths by a covered health care provider to a medical examiner, when those uses and disclosures are limited to the requirements of such law. The attestation condition does not apply to the mandatory disclosures made pursuant to 45 CFR 164.512(a). Other mandatory reporting that is subject to 45 CFR 164.512(a)(2) has always been subject to the additional requirements of 45 CFR 164.512(c), (e), or (f). Further, mandatory reporting for public health activities pursuant to 45 CFR 164.512(b) do not require an attestation.

The attestation condition applies if the regulated entity is making a use or disclosure to a coroner or medical examiner pursuant to 45 CFR 164.512(g)(1). We understand that this may require regulated entities to adjust their workflows to comply with this requirement. For example, regulated entities could consider having an electronic attestation form readily available for persons that request the use or disclosure of PHI potentially related to reproductive health care because doing so may reduce delays in the regulated entity's response time related to the attestation condition. Thus, this condition will not significantly impede operations for persons who request information because the interruptions will decrease as they adjust their workflows to accommodate the new condition.

We remind regulated entities that the prohibition in 45 CFR 164.502(a)(5)(iii) applies, regardless of whether the request for PHI is made pursuant to a permission for which an attestation is required or another permission.

Comment: Many commenters urged the Department to implement a reasonable, good faith standard or a safe harbor for situations in which a regulated entity discloses PHI and the person requesting the PHI either uses or rediscloses it for a purpose that would be prohibited under the proposed rule. Some commenters were concerned that a covered entity will be liable for inadvertent disclosures of PHI and sought the benefit of the affirmative defense afforded at 45 CFR 160.410(b)(2).

Response: The Department declines to add a ''good faith'' standard or safe harbor to this final rule. As discussed above, the Department is not finalizing a separate Rule of Construction and is not incorporating the phrase ''primarily for the purpose of'' into the final prohibition standard.

As we explained in the 2023 Privacy Rule NPRM, 45 CFR 164.509 requires a new attestation for each use or disclosure request; a single attestation would not be sufficient to permit multiple uses or disclosures. This requirement is unlike the authorization, where generally, when a regulated entity receives a valid authorization, they may continue to use or disclose PHI to the person requesting the use or disclosure of PHI pursuant to that authorization after the initial disclosure, provided that such subsequent uses and disclosures are valid and related to that authorization. We understand that this may constitute an additional administrative burden for both the regulated entity and the person or entity requesting the information; however, requiring an attestation for each use or disclosure is necessary to ensure that certain Privacy Rule permissions are not used to circumvent the new prohibition at 45 CFR 164.502(a)(5)(iii), and to permit essential disclosures.

Comment: Some commenters expressed support for permitting a regulated entity to rely on an attestation if ''it appears objectively reasonable'' or ''when objectively reasonable'' and not requiring covered entities to investigate the accuracy of an attestation, thereby mitigating liability to the regulated entity, if not fully protecting an individual. Many commenters expressed concern that it would not be objectively reasonable for a regulated entity to rely on a representation made by the person requesting the use or disclosure of PHI that the PHI sought was related to unlawful health care. The commenters requested a guarantee that a health care provider's reliance on a ''facially valid'' attestation would be objectively reasonable without requiring the entity to investigate the intentions of the person requesting the use or disclosure of PHI and the validity of their attestation. A commenter recommended that the final rule direct regulated entities to take attestations at face value and hold harmless regulated entities in the event of a false attestation.

Commenters offered several reasons for these recommendations, including the burden on covered entities where they are required to determine: (1) the veracity of every attestation; (2) whether an attestation is required; and (3) whether the statement that the request for the use or disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) is objectively reasonable.

Response: To assist in effectuating the prohibition, this Final Rule requires an attestation in some circumstances. We recognize the potential burden on regulated entities to investigate the validity of every attestation and do not require that they conduct a full investigation in each instance. However, as discussed above, if an attestation, on its face, meets the requirements at 45 CFR 164.509(c), a regulated entity must consider the totality of the circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances. To determine whether it is reasonable to rely on the attestation, a regulated entity should consider, among other things: who is requesting the use or disclosure of PHI; the permission upon which the person making the request is relying; the information provided to satisfy other conditions of the relevant permission; the PHI requested and its relationship to the purpose of the request (*i.e.,* does the request meet the minimum necessary standard in relation to the purpose of the request); and, where the presumption at 45 CFR 164.502(a)(5)(iii)(C) applies, information provided by the person requesting the use or disclosure of PHI to overcome that presumption.

For example, as discussed above, it may not be reasonable for a regulated entity to rely on an attestation filed by a public official that a request for PHI potentially related to reproductive health care is not for a prohibited purpose when that public official has publicly stated their interest in investigating or imposing liability on those who seek, obtain, provide, or facilitate certain types of lawful reproductive health care. If a regulated entity concludes that it would not reasonable to rely on the attestation in this instance, the regulated entity would be prohibited from disclosing the requested PHI unless and until the public official provided additional information that enables the regulated entity to assess the veracity of its attestation. In contrast, it may be reasonable to rely on the representation of a public official that a request for PHI potentially related to reproductive

health care is not for a prohibited purpose if the stated purpose for the request is to investigate insurance fraud and the public official making the request is expressly authorized by law to conduct insurance fraud investigations as part of their legal mandate. Therefore, as discussed above, the Department is balancing these considerations by finalizing language that generally permits a regulated entity to rely on the attestation if it is reasonable for the regulated entity to believe the statement that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii).[361] To further assist regulated entities in determining whether it is reasonable to rely on the attestation, the requirement that the attestation include a clear statement that the use or disclosure is not for a prohibited purpose under 45 CFR 164.502(a)(5)(iii) may be satisfied with a statement that identifies why the use or disclosure is not prohibited, which could be checkboxes that indicate that the use or disclosure is not for a purpose described in 45 CFR 164.502(a)(5)(iii)(A), or that the reproductive health care does not satisfy the Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B).

Where the request for the use or disclosure of PHI is made of the regulated entity that provided the reproductive health care at issue, the regulated entity should ensure that the reproductive health care was not lawful under the circumstances in which such health care was provided before using or disclosing the requested PHI. If the reproductive health care at issue was provided under circumstances in which such health care was lawful, the regulated entity must obtain an attestation and determine whether it is reasonable to rely on the attestation that the use or disclosure is not being requested to conduct an investigation into or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating such reproductive health care. If the reproductive health care at issue was provided under circumstances in which such health care was unlawful, the regulated entity is permitted, but not required, to disclose the PHI if the disclosure is meets the conditions of an applicable Privacy Rule permission, which may include an attestation.

Regulated entities will not generally be held liable for disclosing PHI to a person who signed the attestation under false pretenses, provided that the requirements of 45 CFR 164.509 are met, and it is reasonable under the circumstances for the regulated entity to believe the statement that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii).

Comment: A commenter recommended that the rule clarify the relationship between the attestation and 45 CFR 164.514(h) regarding verification requirements. They requested that the Department consider making explicit in the Final Rule that reliance on legal process would not be appropriate in the absence of an attestation.

Response: The verification requirement under 45 CFR 164.514(h) [362] is separate from the attestation requirement, and a regulated entity must still comply with 45 CFR 164.514(h) when processing an attestation. The final rule makes clear that the attestation requirement will apply if the request for PHI potentially related to reproductive health care is made pursuant to permissions under 45 CFR 164.512(d)–(g)(1), which may include disclosing PHI pursuant to a legal process.

Comment: Some commenters stated that it is difficult to determine the purpose of a request for the use or disclosure of PHI because many requests include only a general purpose. A commenter asserted that staff would need to screen all incoming requests, a task that may require legal or clinical expertise. Further, some commenters stated that regulated entities may experience conflict with persons requesting the use or disclosure of PHI about signing the form.

Response: This final rule prohibits the use and disclosure of PHI for certain purposes and conditions disclosures for certain purposes upon the receipt of an attestation. Thus, it is incumbent upon the regulated entity receiving the request to determine whether disclosure is in compliance with the Privacy Rule. To help the regulated entity make such a determination, the Department is adding to the required elements of the attestation a description of the purpose of the request that is sufficient for the regulated entity to determine whether the prohibition at 45 CFR164.502(a)(5)(iii) may apply to the request. Requests for the use or disclosure of PHI for the specified purposes are likely subject to heightened scrutiny by the regulated entity currently because of other conditions imposed upon such disclosures by the Privacy Rule, so additional expertise will not always be required when processing a request for the use or disclosure of PHI and the accompanying attestation. For example, under the Privacy Rule, a regulated entity must determine whether a request for the use or disclosure of PHI for a judicial or administrative proceeding made using a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal contains ''satisfactory assurances'' that reasonable efforts have been made by the person making the request either: (1) to ensure that the individual who is the subject of the PHI that has been requested has been given notice of the request; [363] or (2) to secure a qualified protective order that meets certain requirements specified in the Privacy Rule.[364] The Privacy Rule further details how regulated entities are to determine whether they have received ''satisfactory assurances'' for both options described above.[365] Such requirements ensure that a regulated entity must already carefully review requests for such purposes, such that the attestation condition likely poses minimal additional burden for such requests. In any event, the Department believes that these administrative burdens are outweighed by the privacy interests that this final rule seeks to protect.

Comment: Many commenters asserted that it would be reasonable to require affirmative verification under penalty of perjury that the request for the use or disclosure of PHI is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) because it would signal an intent to penalize requests

[361] This approach is consistent with 45 CFR 164.514(h), which requires a regulated entity to verify the identity and legal authority of a public official or a person acting on behalf of the public official and describes the type of documentation upon which the regulated entity can rely, if such reliance is reasonable under the circumstances, to do so. *See also* 45 CFR 164.514(d)(3)(iii)(A), which permits a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).

[362] 45 CFR 164.514(h)(1) requires a regulated entity to verify both the identity of the person requesting PHI and the authority of any such person to have access to PHI, if the identity or authority of such person is not known to the regulated entity. 45 CFR 164.514(h)(2)(ii) describes the information upon which a regulated entity may rely, if such reliance is reasonable under the circumstances, to verify the identity of a public official requesting PHI or a person acting on behalf of a public official, while 45 CFR 164.514(h)(2)(iii) describes the information upon which a regulated entity may rely, if such reliance is reasonable under the circumstances, to verify the authority of the public official requesting PHI or a person acting on behalf of a public official.

[363] 45 CFR 164.512(e)(1)(ii)(A).

[364] 45 CFR 164.512(e)(1)(ii)(B).

[365] 45 CFR 164.512(e)(1)(iii) and (iv).

made to contravene the prohibition; would incentivize persons requesting the use or disclosure of PHI to consider whether their request is for a purpose prohibited under 45 CFR 164.502(a)(5)(iii); deter unlawful ''fishing expeditions'' or conceal improper intent; and add a layer of accountability. Another commenter stated this heightened standard would enable the covered entity to reasonably rely in good faith on the substance of the attestation without further investigation, delay, cost, burden, or dispute. According to the commenter, a person making a request for the use or disclosure of PHI in good faith should have minimal to no concern when providing a statement signed under penalty of perjury. Another commenter supported a requirement that a person requesting the use or disclosure of PHI provide an affirmative verification made under penalty of perjury that the use or disclosure is not for purpose prohibited under 45 CFR 164.502(a)(5)(iii) because it would suggest that evidence obtained falsely would not be admissible in a legal proceeding. A commenter asserted that it is important to ensure that the proposed attestations would be as effective as possible, and including a signed declaration made under penalty of perjury is critical to ensuring their effectiveness in the current legal environment. A commenter endorsed adding a statement regarding perjury to the proposed attestation because it would place the person requesting the use or disclosure of PHI on notice of the criminal penalties if the person were to violate the proposed requirement.

A commenter asserted that the penalty of perjury requirement is a common signature standard for legal and administrative proceedings and expressed support for expanding it to other proceedings. The commenter also expressed support for considering other options because of concerns that the application and consequences of making a statement under a penalty of perjury may lack clarity outside of certain proceedings.

Response: We appreciate commenters' suggestions; however, the Department ultimately decided that the addition of a penalty of perjury would be unnecessary in light of the statutory criminal and civil penalties under HIPAA. 42 U.S.C. 1320d–6 provides that any person who knowingly and in violation of the Administrative Simplification provisions obtains IIHI relating to another individual or discloses IIHI to another person is subject to criminal liability.[366] A regulated entity is also subject to civil penalties for violations of requirements of the HIPAA Rules.[367] Thus, a person that requests PHI who knowingly falsifies an attestation (*e.g.,* makes material misrepresentations as to the intended uses of the PHI requested) to obtain PHI or cause PHI to be disclosed would be in violation of HIPAA and could be subject to criminal penalties.[368]

Comment: Some commenters expressed support for requiring that the attestation include a statement that a person signing an attestation is doing so under penalty of perjury, but they also questioned its ability to prevent a person from requesting the use or disclosure of PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) and recommended additional requirements or alternatives. One commenter expressed concern that there would be no disincentive for the recipient to submit an attestation signed under false pretenses in the absence of enforceable penalties. A different commenter questioned the efficacy of a penalty of perjury requirement because the person requesting the use or disclosure may not be the person that uses the PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii); it might be another person who uses the information for a purpose prohibited under that provision. According to the commenter, no criminal or other penalty would attach because that other person did not sign the attestation. The commenter also expressed concern that an attestation signed on behalf of an entity may not be enforceable because the person who signed the attestation did not have authority to bind the entity.

Commenters variously recommended that the Department include language that the person requesting the use or disclosure of PHI would not further use or disclose the PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) and that the requested information is the minimum necessary, or require a search warrant or data use agreement instead of an attestation. A commenter recommended that the Department provide individuals with an actionable remedy, such as the right to receive a portion of any civil money penalty assessed to the regulated entity or the right to ''claw back'' the disclosure from the receiving entity if the party that signed the attestation later violates its terms.

Response: The Department understands and shares commenters' concerns about redisclosures that would be prohibited by this rule if the disclosure was made by a regulated entity. However, HIPAA limits the Department's authority to regulating PHI maintained or transmitted by a regulated entity, that is a covered entity or their business associate. Accordingly, a person that is not a regulated entity generally may use or disclose such information without further limitation by the HIPAA Rules.

Requiring search warrants or data use agreements as a condition of the use or disclosure of PHI is beyond the scope of this final rule.

With respect to the commenter's concern about situations in which a person who does not have the appropriate authority requests PHI on behalf of a public official, the Privacy Rule generally requires that a regulated entity verify the identity and legal authority of persons requesting PHI prior to making the disclosure.[369] Where a disclosure of PHI is to a public official or person acting on behalf of a public official who has the authority to request the information, a regulated entity may verify the authority of that public official by relying on, if reliance is reasonable under the circumstances, either a written statement of legal authority under which the information is requested (or an oral statement, if the written statement is impracticable).[370] Alternatively, a regulated entity may presume the public official's legal authority if a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or judicial administrative tribunal.[371] We remind regulated entities that a determination that a public official has the authority to make a request for the use or disclosure does not mean that the Privacy Rule permits them to obtain any and all information that the official requests. In such circumstances, the regulated entity should carefully review the conditions of the applicable permission to ensure that they are met. Where the condition involves a warrant, subpoena, or similar instrument, the regulated entity must also review the scope of the authority granted by the warrant, subpoena, or order to determine the extent of the PHI that it is permitted to disclose.[372] Further, a regulated entity may rely, if such reliance is reasonable under the

[366] *See* 42 U.S.C. 1320d–6(a).

[367] *See* 42 U.S.C. 1320d–5. *See also* 45 CFR part 160, subparts A, D, and E.

[368] *See* 42 U.S.C. 1320d–6(b).

[369] *See* 45 CFR 164.514(h); *see also* 65 FR 82462, 82541, and 82547 (Dec. 28, 2000).

[370] 45 CFR 164.514(h)(2)(iii)(A).

[371] 45 CFR 164.514(h)(2)(iii)(B).

[372] 45 CFR 164.512(a)(1).

circumstances, on a requested disclosure by a public official as the minimum necessary if the public official represents that the requested PHI is the minimum necessary for the stated purpose.[373]

HIPAA specifies the remedies available to the Federal Government where persons violate the statute's Administrative Simplification provisions: civil monetary penalties [374] and criminal fines and imprisonment.[375] HIPAA does not include a private right of action.

Comment: One commenter asked the Department to clarify that anyone providing a false attestation would be held accountable for false statements with appropriate or significant civil fines or criminal penalties for the material misrepresentation. Another commenter specifically recommended that the Department consider it a material misrepresentation for a person to sign an attestation without an objectively reasonable basis to suspect that the reproductive health care of interest was unlawful under the circumstances in which such health care was provided. The commenter asserted that the attestation should include specific language that any person who is requesting the use or disclosure of PHI because they believe the reproductive health care was not lawful under the circumstances in which such health care was provided must have a reasonable basis for that belief (*e.g.,* a statement from a witness) and that the absence of an articulable, fact-based reasonable suspicion would constitute a material misrepresentation. According to the commenter, such a requirement would prevent fishing expeditions because persons requesting the use or disclosure of PHI would be required to have an actual, objective reason for believing that a person provided health care in violation of state or Federal law.

Response: The Department agrees that it would be a material misrepresentation if a person who signs an attestation does not have an objectively reasonable basis to suspect that the reproductive health care was provided under circumstances in which it was unlawful, and that an objectively reasonable basis of suspicion requires specific and articulable facts associated with the individual whose PHI is requested and the health care they received. We decline to include a statement of this position on the attestation because it is encompassed in the language that requires persons making a request for PHI to attest that they are not making the request for a prohibited purpose and the language ensuring that persons making such requests are aware of the potential liability for knowingly and in violation of HIPAA obtaining IIHI relating to an individual or disclosing IIHI to another person.

Comment: Some commenters urged the Department to include additional provisions to monitor and enforce the attestation condition, including requiring that a court order, written attestation, or valid authorization accompany requests for the use or disclosure of PHI for legal or administrative proceedings or law enforcement investigations.

Response: The attestation condition does not replace the conditions of the Privacy Rule's permissions for a regulated entity to disclose PHI in response to a subpoena, discovery request, or other lawful process,[376] or administrative request.[377] Instead, it is designed to work with these permissions and associated condition. For PHI to be disclosed pursuant to 45 CFR 164.512(e)(1)(ii) and (f)(1)(ii)(C), a regulated entity must verify that the relevant conditions are met and also satisfy the attestation condition at 45 CFR 164.509. We do not believe it is necessary to include additional requirements to monitor and enforce implementation of the attestation condition because a person who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual or discloses IIHI to another person would be subject to criminal liability.[378]

Comment: Almost all commenters responding to the Department's request for comment expressed support for a Department-developed model attestation or sample language that could be used by regulated entities to reduce the implementation burden of the attestation condition. A large health care provider expressed appreciation for options that would simplify the process for reviewing requests for the use or disclosure of PHI made pursuant to 45 CFR 164.512(d)–(g)(1). Other commenters asserted that a standard form would reduce unnecessary variation, support a consistent approach, decrease implementation costs, and make it easier for a regulated entity to identify requests for the use or disclosure of PHI for purposes prohibited under 45 CFR 164.502(a)(5)(iii).

Several commenters suggested that a universal or standardized attestation form would reduce the burden of the attestation requirement, especially for smaller health care providers, and reduce delays in the disclosure of PHI resulting from the need for legal review or unfamiliarity with the format of an attestation provided by a person requesting the use or disclosure of PHI. One of these commenters stated this would also support electronic data exchange by standardizing attestation fields and the format. Most commenters expressed opposition to a Department-required format and recommended that the Department permit covered entities to modify the language of the attestation.

Some commenters requested that the model attestation include a plain language explanation and a tip sheet or guidance for completion. They also requested that the model be an electronic, fillable form with a clear heading and that the editing capabilities be limited to the specific required fields. Some commenters recommended that the model attestation contain an outline of penalties for misuse of PHI.

A commenter requested that the Department guarantee that a health care provider's good faith reliance on a model attestation form would be objectively reasonable.

Response: We appreciate these recommendations and intend to publish model attestation language before the compliance date of this final rule. As discussed above, if an attestation, on its face, meets the requirements at 45 CFR 164.509(c), a regulated entity must consider the totality of the circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances.

Comment: In response to the Department's request for comment on how the proposed attestation would affect a regulated entity's process for responding to regular or routine requests from certain persons, a few commenters explained their current workflows and the resource requirements for managing these requests.

Some commenters suggested that an attestation requirement might require changes to workflows and discussed the changes that might be made.

Response: The Department appreciates these insights into how regulated entities currently respond to certain requests for the use or disclosure of PHI. We confirm that a person requesting the use or disclosure of PHI

[373] 45 CFR 164.514(d)(3)(iii)(A).

[374] 42 U.S.C. 1320d–5.

[375] 42 U.S.C. 1320d–6.

[376] 45 CFR 165.512(e)(1)(ii).

[377] 45 CFR 164.512(f)(1)(ii)(C).

[378] *See* 42 U.S.C. 1320d–6(a).

pursuant to 45 CFR 164.512(d), (e), (f), or (g)(1) must provide the regulated entity a signed and truthful attestation where the request is for PHI potentially related to reproductive health care before the regulated entity is permitted to use or disclose the requested PHI. The Department will consider developing guidance and technical assistance as needed on these topics in the future as necessary to ensure compliance with the Privacy Rule, including both the prohibition at 45 CFR 164.502(a)(5)(iii) and 164.509. It may benefit a regulated entity to require such documentation where the requested use or disclosure is for TPO or in response to a valid authorization or individual right of access request.

Comment: A few commenters recommended imposing obligations to limit redisclosures of PHI for certain purposes.

A few commenters stated that a person requesting the use or disclosure of PHI could seek a court order or provide a written attestation to permit the regulated entity to make the disclosure in question in the event they were unable to obtain an authorization.

Response: While we understand commenters' concerns regarding the uses and disclosures of health information by entities not covered by the Privacy Rule, the Department is limited to applying the HIPAA Rules to those entities covered by HIPAA (*i.e.,* health plans, health care clearinghouses, and health care providers that conduct covered transactions) and to business associates, as provided under the HITECH Act.

In the 2023 Privacy Rule NPRM, the Department considered permitting regulated entities to make uses or disclosures of PHI only after obtaining a valid authorization. However, the Department rejected the approach because requiring an authorization in all circumstances would not reflect the appropriate balance between individual privacy interests and other societal interests in disclosure. In particular, individuals may decline to authorize disclosure of PHI even in circumstances where their privacy interests are reduced and societal interests in disclosure are heightened, such as where the reproductive health care was unlawful under the circumstances in which it was provided.

Comment: Some commenters requested that the Department provide educational resources for regulated entities to implement the attestation. A commenter encouraged the Department to strongly enforce the attestation provision.

Response: We appreciate these recommendations and commit to providing additional resources to assist regulated entities with implementation of this rule.

Comment: In response to the Department's request for comment on alternative documentation that could assist regulated entities in complying with the proposed limitations on the use and disclosure of PHI, some commenters recommended that an attestation always be required, even if additional documentation is mandated, because the attestation would place the person requesting the use or disclosure of PHI on notice of the prohibition and to hold them accountable if they use the PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), in addition to helping a covered entity to determine whether the PHI is being requested for a legitimate or prohibited purpose. Others agreed because of the risk of coercion when authorizations are sought from individuals for certain purposes.

Some commenters suggested that the Department require that a court order, written attestation, or valid authorization accompany a request for the use or disclosure of any PHI for legal or administrative proceedings or law enforcement investigations because there are circumstances under which it would be unlikely for a person to obtain an authorization. Some commenters recommended that the Department not require an attestation when the disclosure of PHI is required by law, or when so ordered by a court of competent jurisdiction. A commenter proposed that the Department permit regulated entities to make the specified uses and disclosures with a written attestation, a HIPAA authorization, or alternative documentation described by the Department, including a court order, to minimize the administrative burden.

Response: The Department appreciates the approaches recommended by commenters to ensure that PHI requested is not for a prohibited purpose. We also believe that the attestation will place the person requesting the use or disclosure of PHI on notice of the prohibition and serve to hold them accountable if they use the PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii). However, we have limited the attestation requirement to requests for PHI that is potentially related to reproductive health care. In addition, as discussed above, because the Privacy Rule's authorization requirements empower individuals to make decisions about who has access to their PHI, we are not adopting the proposed exception to the permission to use or disclose PHI pursuant to a valid authorization, nor are we adopting the other recommendations made by commenters. The Department is not finalizing its proposal to prohibit the disclosure of PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) pursuant to an authorization. Accordingly, the final rule permits the disclosure of an individual's PHI to another person pursuant to a valid authorization, even if the disclosure would otherwise be prohibited under this rule. Therefore, a regulated entity may disclose PHI for a purpose that otherwise would be prohibited under 45 CFR 164.502(a)(5)(iii) by obtaining a valid authorization or pursuant to the individual right of access. We reiterate that in all cases, the conditions of the underlying permission must be met before a regulated entity is permitted to use or disclose the requested PHI.

D. Section 164.512—Uses and Disclosures for Which an Authorization or Opportunity To Agree or Object Is Not Required

1. Applying the Prohibition and Attestation Condition to Certain Permitted Uses and Disclosures

Section 164.512 of the Privacy Rule contains the standards for uses and disclosures for which an authorization or opportunity to agree or object is not required. Many of the uses and disclosures addressed by 45 CFR 164.512 relate to government or administrative functions and are described in the 2000 Privacy Rule preamble as ''national priority purposes.'' [379] These permissions for uses and disclosures were not required by HIPAA; instead they represented the Secretary's previous balancing of the privacy interests and expectations of individuals and the interests of communities in making certain information available for community purposes, such as for certain public health, health care oversight, and research purposes.[380] As discussed previously, the Department, in its implementation of HIPAA, has sought to ensure that individuals do not forgo health care when needed—or withhold important information from their health care providers that may affect the quality of health care they receive—out of a fear that their sensitive information would be revealed outside of their relationships with their health care providers.

To clarify that the proposal at 45 CFR 164.502(a)(5)(iii) would prohibit the use and disclosure of PHI in some

[379] 65 FR 82462, 82524 (Dec. 28, 2000).

[380] *See id.* at 82471.

circumstances where such uses or disclosures are currently permitted, the Department proposed to cite the proposed prohibition at the beginning of the introductory text of 45 CFR 164.512 and condition certain disclosures on the receipt of the attestation proposed at 45 CFR 164.509.[381] The proposed modification would add the clause, ''Except as provided by 45 CFR 164.502(a)(5)(iii), [. . .]'' and add ''and 45 CFR 164.509'' to ''subject to the applicable requirements of this section.'' This would create a new requirement to obtain an attestation from the person requesting the use and disclosure of PHI as a condition of making certain types of permitted uses and disclosures of PHI. Thus, under the proposal and subject to the Department finalizing the prohibition at paragraph (a)(5)(iii) of 45 CFR 164.502, uses and disclosures of PHI for certain purposes would be prohibited unless a regulated entity first obtained an attestation from the person requesting the use and disclosure under proposed 45 CFR 164.509.

The Department also proposed to replace ''orally'' with ''verbally'' at the end of the introductory paragraph for clarity.

Overview of Public Comments

While many commenters addressed the proposals to add a prohibition on the use and disclosure of PHI and to require an attestation in certain circumstances, few commenters addressed the proposal to modify the introductory paragraph to 45 CFR 164.512. Such commenters either expressed support for it or requested additional guidance on the Department's intention or the proposal's operation.

The Department is adopting its proposal without modification. As discussed above, this change creates a new requirement for a regulated entity to obtain an attestation from a person requesting the use or disclosure of PHI as a condition of making certain types of permitted uses and disclosures of PHI. For example, the Privacy Rule currently permits uses and disclosures for health care oversight,[382] judicial and administrative proceedings,[383] law enforcement purposes,[384] and about decedents to coroners and medical examiners,[385] provided specified conditions are met. When read in conjunction with the new prohibition at 45 CFR 164.502(a)(5)(iii), uses and disclosures of PHI for these purposes will be subject to an additional condition that the regulated entity first obtain an attestation from the person requesting the use and disclosure under the new attestation requirement at 45 CFR 164.509.

The Department assumes that there will be instances in which state or other law requires a regulated entity to use or disclose PHI for health care oversight, judicial and administrative proceedings, law enforcement purposes, or about decedents to coroners and medical examiners for a purpose not related to one of the prohibited purposes in 45 CFR 164.502(a)(5)(iii). The Department believes that a regulated entity will be able to comply with such laws and the attestation requirement. For example, a regulated entity may continue to disclose PHI without an individual's authorization to a state medical board, a prosecutor, or a coroner, in accordance with the Privacy Rule, when the request is accompanied by the required attestation. As a result, a regulated entity generally may continue to assist the state in carrying out its health care oversight, judicial and administrative functions, law enforcement, and coroner duties with the use or disclosure of PHI once a facially valid attestation has been provided to the regulated entity from whom PHI is sought. However, where an attestation is required but not obtained, a state seeking information about an individual's reproductive health or reproductive health care would need to obtain such information from an entity not regulated under the Privacy Rule [386] or demonstrate that the regulated entity has actual knowledge that the reproductive health care was not lawful under the circumstances in which such health care was provided, thereby reversing the presumption described at 45 CFR 164.502(a)(5)(iii)(C).

Additionally, we are replacing ''orally'' with ''verbally'' for clarity. No substantive change is intended.

Comment: One commenter expressed support for the Department's proposed revision to 45 CFR 164.512, while another commenter requested additional examples or detail in preamble about what the Department intends by this revision.

Response: The Department intends that the uses and disclosures of PHI made in accordance with 45 CFR 164.512 would be subject to both the 45 CFR 164.502(a)(5)(iii) prohibition and the 45 CFR 164.509 attestation, when applicable, specifically uses or disclosures made for health oversight activities,[387] judicial and administrative proceedings,[388] law enforcement purposes,[389] and about decedents to coroners and medical examiners.[390] For example, a regulated entity may disclose PHI for law enforcement purposes, subject to the conditions of the permission at 45 CFR 164.512(f), where the purpose of the request for the use or disclosure is to investigate a sexual assault and the person requesting the PHI provides the regulated entity with a valid attestation signifying that the purpose of the request is not for a prohibited purpose. Similarly, where a request meets the requirements of 45 CFR 164.502(a)(5)(iii), a regulated entity may disclose PHI for law enforcement purposes, subject to the conditions of the permission at 45 CFR 164.512(f), where the purpose of the request for the use or disclosure is to investigate the unlawful provision of reproductive health care with a valid attestation signifying that the purpose of the request is not one that is prohibited (*i.e.,* that the purpose of the use or disclosure is not to investigate or impose liability on any person for the lawful provision of reproductive health care). As another example, a regulated entity may disclose PHI to a state Medicaid agency in accordance with 45 CFR 164.512(d) where the purpose of the request is to ensure that the regulated entity is providing the reproductive health care for which the regulated entity has submitted claims for payment to Medicaid after obtaining an attestation that meets the requirements of 45 CFR 164.509 from the state Medicaid agency.

Comment: One commenter requested clarification regarding the intersection between the Department's proposed Rule of Construction at 45 CFR 164.502(a)(5)(iii)(D) and its proposal at 45 CFR 164.512.

Response: The Department is not adopting the proposed Rule of Construction. Rather, the language of the proposal has been integrated into the prohibition standard at 45 CFR 164.502(a)(5)(iii)(A). The finalized prohibition standard requires a

[381] 88 FR 23506, 23537–38 (Apr. 17, 2023).

[382] 45 CFR 164.512(d).

[383] 45 CFR 164.512(e).

[384] 45 CFR 164.512(f).

[385] 45 CFR 164.512(g)(1).

[386] The Privacy Rule only applies to PHI, which is IIHI that is maintained or transmitted by, for, or on behalf of a covered entity. Thus, it does not apply to individuals' health information when it is in the possession of a person that is not a regulated entity, such as a friend, family member, or is stored on a personal cellular telephone or tablet. *See* Off. for Civil Rights, ''Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet,'' U.S. Dep't of Health and Human Servs. (June 29, 2022), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.*

[387] 45 CFR 164.512(d).

[388] 45 CFR 164.512(e).

[389] 45 CFR 164.512(f).

[390] 45 CFR 164.512(g)(1).

regulated entity to ensure that they obtain a valid attestation from a person requesting the use or disclosure of PHI for health oversight activities, judicial and administrative proceedings, law enforcement purposes, or about decedents to coroners or medical examiners, assuring the regulated entity that the purpose of the request is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii).

2. Making a Technical Correction to the Heading of 45 CFR 164.512(c) and Clarifying That Providing or Facilitating Reproductive Health Care Is Not Abuse, Neglect, or Domestic Violence

Paragraph (c) of 45 CFR 164.512 permits a regulated entity to disclose PHI, under specified conditions, to an authorized government agency where the regulated entity reasonably believes the individual is a victim of abuse, neglect, or domestic violence. The regulatory text includes a serial comma, which clearly indicates that the provision addresses victims of three different types of crimes, but the heading of this standard does not include the serial comma.

For grammatical clarity, the Department proposed to add the serial comma after the word ''neglect'' in the heading of the standard contained at 45 CFR 164.512(c).[391]

The Department also proposed to add a new paragraph (c)(3) to 45 CFR 164.512(c), with the heading ''Rule of construction,'' to clarify that the permission to use or disclose PHI in reports of abuse, neglect, or domestic violence does not permit uses or disclosures based primarily on the provision or facilitation of reproductive health care to the individual.[392] The Department intended the proposed provision to safeguard the privacy of individuals' PHI against claims that uses and disclosures of that PHI are warranted because the provision or facilitation of reproductive health care, in and of itself, may constitute abuse, neglect, or domestic violence.

A few commenters supported the proposal because it would clarify that providing or facilitating access to health care is not itself abuse, neglect, or violence, while others expressed opposition to the proposal because they believed it would prevent health care providers from reporting abuse based on the provision of reproductive health care, including potentially coerced reproductive health care. Commenters both supported and opposed the inclusion of the phrase ''based primarily.''

The Department is finalizing the proposal to add the serial comma after the word ''neglect'' in the heading of the standard contained at 45 CFR 164.512(c).

As we explained in the 2023 Privacy Rule NPRM, the Department is concerned that recent state actions may lead regulated entities to believe that they are permitted to make disclosures of PHI when they believe that persons who provide or facilitate access to reproductive health care are perpetrators of a crime simply because they provide or facilitate access to reproductive health care. Thus, the Department is clarifying that providing or facilitating access to lawful reproductive health care itself is not abuse, neglect, or domestic violence for purposes of the Privacy Rule. This is consistent with the Department's understanding that the provision or facilitation of lawful health care is not itself abuse, neglect, or domestic violence. Such clarification has not previously been required, but recent developments in the legal landscape have made it necessary for us to codify this interpretation in the context of reproductive health care.

Accordingly, the Department is finalizing the proposed Rule of Construction at 45 CFR 164.512(c)(3), with modification as follows. The modification clarifies the circumstances under which regulated entities that are mandatory reporters of abuse, neglect, or domestic violence are permitted to make such reports. Specifically, we are replacing ''based primarily on'' with language specifying that the prohibition at 45 CFR 164.502(a)(5)(iii) cannot be circumvented by the permission to use or disclose PHI to report abuse, neglect, or domestic violence where the ''sole basis of'' the report is the provision or facilitation of reproductive health care. Thus, the Department makes clear that it may be reasonable for a covered entity that is a mandatory reporter to believe that an individual is the victim of abuse, neglect, or domestic violence and to make such report to the government authority authorized by law to receive such reports in circumstances where the provision of reproductive health care to the individual is but one factor prompting the suspicion. For example, it would not be reasonable for a covered entity to believe that an individual is the victim of domestic violence solely because the individual's spouse facilitated the covered entity's provision of reproductive health care to the individual.

Comment: A few commenters supported the Department's proposal. One commenter asserted that providing or facilitating access to any type of health care is not in and of itself abuse, neglect, or domestic violence and urged the Department to expand the scope of this language, particularly if the prohibition is similarly expanded in the final rule.

Response: The Department appreciates the comments about the modifications to 45 CFR 164.512(c). As discussed above, the scope of the prohibition is limited to reproductive health care. The proposed and final regulations are narrowly tailored and limited in scope to not increase regulatory burden beyond appropriate public policy objectives. Thus, we decline to expand the scope of this provision, as well.

Comment: A large coalition expressed concerns about mandatory domestic violence and sexual assault reporting laws. According to the coalition, mandatory reporting laws reduce the willingness of domestic violence survivors to seek help, including health care, and that the reports themselves worsen the situation for most survivors. The coalition asserted that permitting the disclosure of PHI to law enforcement and other agencies for reports of abuse, neglect, or domestic violence isolates survivors of such abuse and puts them at risk of losing their children. These commenters recommended that the Department prevent such disclosures.

Some commenters expressed opposition to the proposal because they believe it would put victims of domestic abuse at risk because it would prevent health care providers from reporting abuse, including child abuse, based on the provision or facilitation of reproductive health care. A commenter asserted that the proposal would circumvent the exception prohibiting disclosures to abusive persons at 45 CFR 164.512(b)(1)(ii). According to another commenter, the change would chill the willingness of covered entities to cooperate with investigations and judicial proceedings concerning individuals who may have used reproductive health care, regardless of the matter being adjudicated.

According to another commenter, the proposal is aimed at undermining state laws and shielding persons who provide or facilitate reproductive health care. Commenters expressed concern that the proposal would prohibit reports of abuse, neglect, or domestic violence because such reports are made for the purpose of investigating or prosecuting a person for providing or facilitating

[391] 88 FR 23506, 23538 (Apr. 17, 2023).

[392] *Id.*

unlawful reproductive health care, and for committing sexual assault.

Response: The Department appreciates the concerns raised by the commenters. Since publication of the final Privacy Rule in 2000, the Department has acknowledged that covered entities, including covered health care providers, may have legal obligations to report PHI in certain circumstances, including about suspected victims of abuse, neglect, or domestic violence. The Department did not propose to modify the Privacy Rule's permission to disclose PHI at 45 CFR 164.512(c). The Department declines to expand its proposal to eliminate the permission for covered entities to disclose PHI to public health authorities, law enforcement, and other government authority authorized by law to receive reports of abuse, neglect, or domestic violence.

Additionally, the Department does not agree that covered entities will be prevented from reporting PHI about victims of abuse, neglect, or domestic violence. The new language at 45 CFR 164.512(c)(3) is narrowly tailored to reduce the conflation between lawfully provided reproductive health care and the view that such lawful health care, on its own, is abuse. Readers are referred to the preamble discussion of 45 CFR 164.502(a)(5)(iii) that describes the scope of disclosure changes which are being made applicable to 45 CFR 164.512(c).

The Department does not agree that the modifications circumvent the exception prohibiting disclosures to abusive persons at 45 CFR 164.512(b)(1)(ii). The new language at 45 CFR 164.512(c)(3) does not modify or change the current Privacy Rule provision for disclosures to a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect. We believe the commenter is referring to 45 CFR 164.512(c)(2), which requires a covered entity to inform an individual that a report has been or will be made, and 45 CFR 164.512(c)(2)(ii), which removes the requirement to inform the individual when the covered entity would be informing a personal representative and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment. Because the new language at 45 CFR 164.512(c)(3) operates as a limitation on disclosure, it is not possible for the new provision to permit disclosures in more circumstances than previously permitted, and therefore does not circumvent the existing provision.

Comment: A commenter recommended that the Department clarify that the proposed Rule of Applicability would not prohibit disclosure and use of such records when they are sought for a defensive purpose by revising the proposed Rule of Construction at 45 CFR 164.512(c)(3) to more explicitly state that it permits such use or disclosure.

Response: The adopted Rule of Construction at 45 CFR 164.512(c)(3) applies to disclosures permitted by 45 CFR 164.512(c), which are explicitly to a government authority, including a social service or protective services agency, authorized by law to receive reports of abuse, neglect, or domestic violence. The Department is not aware of a disclosure that otherwise meets the requirements specified at 45 CFR 164.512(c)(1) that would constitute a disclosure for defensive purposes. Rather, disclosures of PHI for defensive purposes, such as a disclosure to defend against a prosecution for criminal prosecution for allegations of providing unlawful health care, are permitted by 45 CFR 164.512(f), as well as for health care operations when obtaining legal services. To the extent that a disclosure for a defensive purpose meets the applicable requirements and is permitted, the Department confirms that the final rule language generally would not prohibit a disclosure.

Comment: A few commenters requested clarification of the standard for determining what would constitute a report of abuse, neglect, or domestic violence that is based primarily on the provision of reproductive health care. Commenters also requested clarification about the interaction between the proposed prohibition and the permission at 45 CFR 164.512(c).

Response: The Privacy Rule permits but does not require the reporting of abuse, neglect, or domestic violence under certain conditions.[393] Under the final rule, the Department is clarifying that this permission does not apply where the sole basis of the report is the provision or facilitation of reproductive health care. With this modification, the Department makes clear that it may be reasonable for a covered entity that is a mandatory reporter to believe that an individual is the victim of abuse, neglect, or domestic violence and to make such report to the government authority authorized by law to receive such reports in circumstances where the provision or facilitation of reproductive health care is but one factor prompting the suspicion. We also note, as discussed above with respect to 45 CFR 164.512(b)(1)(i), this permission allows a covered entity to report known or suspected abuse, neglect, or domestic violence only for the purpose of making a report. The PHI disclosed must be limited to the minimum necessary information for the purpose of making a report.[394] These provisions do not permit the covered entity to disclose PHI in response to a request for the use or disclosure of PHI to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on a person based on suspected abuse, neglect, or domestic violence. Thus, any disclosure of PHI in response to a request from an investigator, whether in follow up to the report made by the covered entity (other than to clarify the PHI provided on the report) or as part of an investigation initiated based on an allegation or report made by a person other than the covered entity, must meet the conditions of disclosures for law enforcement purposes or judicial and administrative proceedings.[395]

3. Clarifying the Permission for Disclosures Based on Administrative Processes

Under 45 CFR 164.512(f)(1), a regulated entity may disclose PHI pursuant to an administrative request, provided that: (1) the information sought is relevant and material to a legitimate law enforcement inquiry; (2) the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and (3) de-identified information could not reasonably be used. Examples of administrative requests include administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law. The examples of administrative requests provided in the regulatory text include only requests that are enforceable in a court of law, and the catchall ''or similar process authorized by law'' similarly is intended to include only requests that, by law, require a response. This interpretation is consistent with the Privacy Rule's definition of ''required by law,'' which enumerates these and other examples of administrative requests that constitute ''a mandate contained in law that compels an entity to make a use or disclosure of protected health

[393] 45 CFR 164.512(c).

[394] *See* 45 CFR 164.502(b) and 164.514(d).

[395] *See* 45 CFR 164.512(e) and (f).

information and that is enforceable in a court of law.''

As we explained in the 2023 Privacy Rule NPRM, the Department has become aware that some regulated entities may be interpreting 45 CFR 164.512(f)(1) in a manner that is inconsistent with the Department's intent. Therefore, the Department proposed to clarify the types of administrative processes that this provision was intended to address.[396]

Specifically, the Department proposed to insert language to clarify that the administrative processes that give rise to a permitted disclosure include only requests that, by law, require a regulated entity to respond. Accordingly, the proposal would specify that PHI may be disclosed pursuant to an administrative request ''for which a response is required by law.'' The Department does not consider this to be a substantive change because the proposal was consistent with express language of the preamble discussion on this topic in the 2000 Privacy Rule.[397] The Department intends that the express inclusion of this language will ensure that regulated entities more fully appreciate the permitted uses and disclosures pursuant to 45 CFR 164.512(f)(1)(ii)(C).

The Department received few comments on the proposal to clarify the permission at 45 CFR 164.512(f)(1)(ii)(C). Comments were mixed, with some support, some opposition, and some requesting additional modifications or additional examples or guidance.

While the Department received few comments on this clarification, the Department is aware of reports that covered entities are misinterpreting the intention of the requirements of 45 CFR 164.512(f)(1)(ii)(C) that disclosures of PHI to law enforcement be necessary and limited in scope. For example, a congressional inquiry recently highlighted concerns about disclosures of PHI to law enforcement from retail pharmacy chains. The inquiry found that some pharmacy staff are providing PHI directly to law enforcement without advice from their legal departments in part because their staff ''face extreme pressure to immediately respond to law enforcement demands.'' [398] Based on this inquiry, these disclosures often are made without a warrant or subpoena issued by a court.[399]

The Department is adopting the clarification as proposed because regulated entities are misinterpreting the requirements of 45 CFR 164.512(f)(1)(ii)(C) that ensure that disclosures of PHI to law enforcement are necessary and limited in scope. Accordingly, the Department is adding to 45 CFR 164.512(f)(1)(ii)(C) language that specifies that PHI may be disclosed pursuant to an administrative request ''for which a response is required by law.'' Thus, the regulatory text now clearly states that the administrative processes for which a disclosure is permitted are limited to only requests that, by law, require a regulated entity to respond, consistent with preamble discussion on this topic in the 2000 Privacy Rule.[400]

Comment: A few commenters supported the Department's proposed clarification of 45 CFR 164.512(f)(1)(ii)(C). A commenter recommended that the Department revise the language to refer to an administrative subpoena or summons, a civil or other ''expressly'' authorized demand, or other similar process. The commenter recommended that, at a minimum, the Department prohibit disclosures in response to oral requests, require all informal administrative requests be in writing, and require qualifying administrative requests to obtain express supervisory approval.

A commenter asserted, without providing examples, that there are many disclosures currently made under Federal agencies' interpretations of the Privacy Act of 1974 [401] that would not be permitted under the NPRM proposal.

Response: The Department appreciates the comments on this clarification. The Department understands the commenter's request to add language identifying specific processes but declines to make the suggested modification at this time. The Department is concerned that references to specific items or actions could be understood to not apply to similarly situated administrative requests understood by different names. In guidance for law enforcement, the Department has provided its interpretation that administrative requests must be accompanied by a written statement.[402]

In addition, the Department does not control whether a verbal or other non-written request is sufficient to meet the standards of various jurisdictions for an administrative process that would require a responding covered entity to be legally required to respond. The Department understands that valid, justiciable reasons for responding to a verbal or other non-written request may exist, such as an emergent situation that requires an immediate response to avoid an adverse outcome. The Department believes the additional text sufficiently clarifies the misunderstandings of some regulated entities about what constitutes administrative process for the purposes of this permission.

4. Request for Information on Current Processes for Receiving and Addressing Requests Pursuant to 164.512(d) Through (g)(1)

The Department requested information and comments on certain considerations to help inform development of the final rule.[403] In particular, the Department asked how regulated entities currently receive and address requests for PHI when requested pursuant to the Privacy Rule permissions at 45 CFR 164.512(d), (e), (f), or (g)(1), and what effect expanding the scope of the proposed prohibition to include any health care would have on the proposed attestation requirement and the ability of regulated entities to implement it. Comments submitted in response to the question about the effects of expanding the scope of the proposed prohibition have been included in prior discussions of the specific policy issues elsewhere, as applicable.

Comment: Several commenters responded to this request for information concerning current processes for receiving certain requests pursuant to 45 CFR 164.512 by providing specific information about how they receive such requests. Some requests for PHI are received in hard copy, either by mail or hand delivery, while others are received via email. Still

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[396] 88 FR 23506, 23538–39 (Apr. 17, 2023).

[397] *See* 65 FR 82462, 82531 (Dec. 28, 2000).

[398] *See* U.S. Senate Committee on Finance News Release (Dec. 12, 2023), *https://www.finance.senate.gov/chairmans-news/wyden-jayapal-and-jacobs-inquiry-finds-pharmacies-fail-to-protect-the-privacy-of-americans-medical-records-hhs-must-update-health-privacy-rules* (describing legislative inquiry into pharmacy chains and release of health information in response to law enforcement). *See also* Letter from Sen. Wyden and Reps. Jayapal and Jacobs to HHS Sec'y Xavier Becerra (Dec. 12, 2023), *https://www.finance.senate.gov/imo/media/doc/hhs_pharmacy_surveillance_letter_signed.pdf* (describing findings from Congressional oversight, including survey of chain pharmacies about their processes for responding to law enforcement requests for PHI).

[399] *See* U.S. Senate Committee on Finance News Release, *supra* note 399 and Letter from Sen. Wyden and Reps. Jayapal and Jacobs, *supra* note 399; *see also* Remy Tumin, ''Pharmacies Shared Patient Records Without a Warrant, an Inquiry Finds,'' The New York Times (Dec. 13, 2023), *https://www.nytimes.com/2023/12/13/us/pharmacy-records-abortion-privacy.html.*

[400] *See* 65 FR 82462, 82531 (Dec. 28, 2000).

[401] Public Law 93–579, 88 Stat. 1896 (Dec. 31, 1974) (codified at 5 U.S.C. 552a).

[402] Off. for Civil Rights, ''Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: A Guide for Law Enforcement,'' *https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/final_hipaa_guide_law_enforcement.pdf.*

[403] 88 FR 23506, 23539 (Apr. 17, 2023).

others are received through the regulated entities online portal or facsimile. In emergency circumstances, such requests may be received verbally. Commenters generally receive assurances through hard copy, email, their patient portal, and fax. A few commenters seek assurances for every subsequent related request, while another commenter stated that it does not require or obtain assurances for every subsequent related request if the subsequent request is related to the initial request for which the initial assurance was received.

A commenter asserted that the privacy interests at stake outweigh potential administrative burdens and provided examples of state laws that are more privacy protective than the Privacy Rule. The commenter explained that the privacy landscape is constantly evolving, as do the HIPAA Rules, and as such, regulated entities must adapt in response.

Response: The Department appreciates the information provided by commenters explaining the processes by which regulated entities currently receive requests for the use or disclosure of PHI for certain purposes and the workflows of regulated entities to ensure that such requests comply with the conditions of the applicable Privacy Rule permissions. We reviewed and considered this information when evaluating the burden of the proposed modifications to the Privacy Rule during the development of this final rule.

E. Section 164.520—Notice of Privacy Practices for Protected Health Information

1. Current Provision

The Privacy Rule generally requires that a covered entity provide individuals with an NPP to ensure that they understand how a covered entity may use and disclose their PHI, as well as their rights and the covered entity's legal duties with respect to PHI.[404] Section 164.520(b)(1)(ii) of the Privacy Rule describes the required contents of the NPP, including descriptions of the types of permitted uses and disclosures of their PHI. More specifically, the NPP must describe the ways in which the covered entity may use and disclose PHI for TPO, as well as each of the other purposes for which the covered entity is permitted or required to use or disclose PHI without the individual's written authorization. Additionally, the NPP must state the covered entity's duties to protect privacy, provide a copy of the NPP, and abide by the terms of the current notice. The NPP must also describe individuals' rights, including the right to complain to HHS and to the covered entity if they believe their privacy rights have been violated, as well as other statements if the covered entity uses PHI for certain activities, such as fundraising. The Privacy Rule does not, however, currently require a covered entity to provide information about specific prohibited uses and disclosures of PHI.

2. CARES Act

Section 3221(i) of the CARES Act directs the Secretary to modify the NPP provisions at 45 CFR 164.520 to include new requirements for covered entities that create or maintain PHI that is also a record of SUD treatment provided by a Part 2 program (*i.e.,* covered entities that are Part 2 programs and covered entities that receive Part 2 records from a Part 2 program). The CARES Act amended 42 U.S.C. 290dd–2 to require the Department to revise Part 2 to more closely align with the Privacy Rule.

3. Proposals in 2022 Part 2 NPRM and 2023 Privacy Rule NPRM

The Department proposed in December 2022 to modify both the Patient Notice requirements at 42 CFR 2.22 and the NPP requirements at 45 CFR 164.520 to provide consistent notice requirements for all Part 2 records. Revisions to the Patient Notice requirements were addressed and finalized in the 2024 Part 2 Rule, while modifications to the NPP provisions proposed in the 2022 Part 2 NPRM were deferred to a future rulemaking. The Department also separately proposed to modify the NPP provisions to support reproductive health care privacy as part of the 2023 Privacy Rule NPRM.

As part of the 2022 Part 2 NPRM, the Department proposed several changes to the NPP provisions. We proposed in a new paragraph (2) to 45 CFR 164.520(a) that individuals with Part 2 records that are created or maintained by covered entities would have a right to adequate notice of uses and disclosures, their rights, and the responsibilities of covered entities with respect to such records. The Department also proposed to remove 45 CFR 164.520(a)(3), the exception for providing inmates a copy of the NPP, which would require covered entities that serve correctional facilities to provide inmates with a copy of the NPP. Additionally, the Department proposed revising 45 CFR 164.520(b)(1) to specifically clarify that covered entities that maintain or receive Part 2 records would need to provide an NPP that is written in plain language and contains the notice's required elements. We also proposed to modify 45 CFR 164.520(b)(1)(i) to replace ''medical'' with ''health'' information.

The Department also proposed in the 2022 Part 2 NPRM to incorporate changes proposed to the NPP requirements in the 2021 Privacy Rule NPRM,[405] such as adding a requirement to include the email address for a designated person who would be available to answer questions about the covered entity's privacy practices; adding a permission for a covered entity to provide information in its NPP concerning the individual access right to direct copies of PHI to third parties when the PHI is not in an EHR and the ability to request the transmission using an authorization; and removing the requirement for a covered entity to obtain a written acknowledgment of receipt of the NPP. The Department is finalizing certain changes proposed in the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM that directly support the two final rules.

In both the 2022 Part 2 NPRM and 2023 Privacy Rule NPRM, the Department proposed to modify 45 CFR 164.520(b)(1)(ii), which requires covered entities to describe for individuals the purposes for which a covered entity is permitted to use and disclose PHI. Consistent with the CARES Act, we proposed in the 2022 Part 2 NPRM to modify paragraph (C) to clarify that where uses and disclosures are prohibited or materially limited by other applicable law, ''other applicable law'' would include Part 2, while the Department proposed to clarify at paragraph (D) that the requirement for a covered entity to include in the NPP sufficient detail to place an individual on notice of the uses and disclosures that are permitted or required by the Privacy Rule and other applicable laws, including Part 2.

The Department further proposed to require in 45 CFR 164.520(b)(1)(iii), which requires covered entities to include descriptions of certain activities in which the covered entity intends to engage, in a new paragraph (D) the inclusion of a statement that Part 2 records created or maintained by the covered entity will not be used in certain proceedings against the individual without the individual's written consent or a court order consistent with 42 CFR part 2. Additionally, we proposed to require in a new paragraph (E) that covered entities that intend to use Part 2 records for fundraising include a statement that

[404] 45 CFR 164.520. Unlike many provisions of the Privacy Rule, 45 CFR 164.520 applies only to covered entities, as opposed to both covered entities and their business associates.

[405] 86 FR 6446 (Jan. 21, 2021).

such records may be used or disclosed for fundraising purposes only if the individual grants written consent as provided in 42 CFR 2.31.

In 45 CFR 164.520(b)(1)(v)(C), which addresses a covered entity's right to change the terms of its notice, we also proposed to simplify and modify the regulatory text to clarify that this right is limited to circumstances where such changes are not material or contrary to law. The Department also proposed to add a new paragraph (4) to 45 CFR 164.520(d) to prohibit construing permissions for covered entities participating in organized health care arrangements [406] (OHCAs) to disclose PHI between participants as negating obligations relating to Part 2 records.

The 2023 Privacy Rule NPRM also proposed modifications to the NPP requirements.[407] Specifically, the Department proposed to modify 45 CFR 164.520(b)(1)(ii) by adding a new paragraph (F) to require a covered entity to describe and provide an example of the types of uses or disclosures prohibited by 45 CFR 164.502(a)(5)(iii), and to do so in sufficient detail for an individual to understand the prohibition. We also proposed adding a new paragraph (G) to 45 CFR 164.502(b)(1)(ii) to describe each type of use and disclosure for which an attestation is required under 45 CFR 164.509, with an example. Additionally, the Department requested comment on whether it would benefit individuals for the Department to require that covered entities include a statement in the NPP that would explain that the recipient of the PHI would not be bound by the proposed prohibition because the Privacy Rule would no longer apply after PHI is disclosed for a permitted purpose to an entity other than a regulated entity (*e.g.,* disclosed to a non-covered health care provider for treatment purposes).

4. Overview of Public Comments

We received many comments on the proposed NPP changes in both the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM. Some of the comments on the 2022 Part 2 NPRM addressed both the NPP and the Patient Notice. Comments concerning the Patient Notice are discussed in the 2024 Part 2 Rule.[408] Commenters on the NPP proposals in the 2022 Part 2 NPRM urged the Department to coordinate revisions to the NPP provisions across its proposed and final rules. Commenters also requested guidance about their ability to use a single form to satisfy both the NPP and Patient Notice requirements. Commenters generally expressed support for the Department's proposals to modify 45 CFR 164.520(a) and 164.520(b)(1) to apply the NPP requirements to certain entities, in coordination with changes required by the CARES Act and consistent with Part 2.

Commenters to the 2022 Part 2 NPRM generally did not express opposition to the Department's proposed changes to paragraph (b)(iii) of 45 CFR 164.520, although some did request additional guidance. We received no comments on our proposed modifications to add a new paragraph concerning OHCAs to 45 CFR 164.520(d).

Most commenters expressed support for the Department's 2023 Privacy Rule NPRM proposals to revise the NPP requirements. Many also recommended additional modifications to the NPP requirements or clarifications to the requirements. Most also recommended that the Department add a requirement that NPPs include a statement that would explain that the recipient of PHI would not be bound by the proposed prohibition because the Privacy Rule would no longer apply after PHI is disclosed for a permitted purpose to an entity other than a regulated entity (*e.g.,* disclosed to a non-covered health care provider for treatment purposes).

5. Final Rule

The Department published the 2024 Part 2 Rule on February 16, 2024. It included modifications to the Patient Notice in 42 CFR 2.22 and reserved modifications to the HIPAA NPP for a forthcoming HIPAA rule. We address the modifications proposed in the 2022 Part 2 NPRM here, in concert with the modifications proposed in the 2023 Privacy Rule NPRM.

As required by the CARES Act and in alignment with the Privacy Rule, we are modifying the NPP provisions in multiple ways. First, we are requiring in 45 CFR 164.520(a)(2) that covered entities that create or maintain Part 2 records provide notice to individuals of the ways in which those covered entities may use and disclose such records, and of the individual's rights and the covered entities' responsibilities with respect to such records. Second, we are revising 45 CFR 164.520(b)(1) to clarify that a covered entity that receives or maintains records subject to Part 2 must provide an NPP that is written in plain language and that contains the elements required. For clarity, we have reordered wording within this paragraph to refer to ''receiving or maintaining'' records, rather than ''maintaining or receiving'' records as initially proposed.

Third, the Department is modifying 45 CFR 164.520(b)(1)(ii) to revise paragraphs (C) and (D), and to add paragraphs (F), (G), and (H) to clarify certain statements and add new statements that must be included in an NPP. Consistent with the CARES Act, we are modifying paragraph (C) to clarify that where NPP's descriptions of uses or disclosures that are permitted for TPO or without an authorization must reflect ''other applicable law'' that is more stringent than the Privacy Rule, other applicable law includes Part 2. Likewise, we are modifying paragraph (D) to clarify that Part 2 is specifically included in the ''other applicable law'' referenced in the requirement to describe uses and disclosures that are permitted for TPO or without an authorization sufficiently to place an individual on notice of the uses and disclosures that are permitted or required by the Privacy Rule and other applicable law.

New paragraphs (F) and (G) provide individuals with additional information about how their PHI may or may not be disclosed for purposes addressed in this rule, furthering trust in the relationship between regulated entities and individuals by ensuring that individuals are aware that certain uses and disclosures of PHI are prohibited. Specifically, paragraph (F) requires that the NPP contain a description, including at least one example, of the types of uses and disclosures prohibited under 45 CFR 164.502(a)(5)(iii) in sufficient detail for an individual to understand the prohibition, while paragraph (G) requires that the NPP contain a description, including at least one example, of the types of uses and disclosures for which an attestation is required under new 45 CFR 164.509.

Additionally, based on feedback from commenters, we are requiring in a new paragraph (H) that covered entities include a statement explaining to individuals that PHI disclosed pursuant to the Privacy Rule may be subject to redisclosure and no longer protected by the Privacy Rule.This will help individuals to make informed decisions about to whom they provide access to or authorize the disclosure of their PHI.

Under new paragraph (D) of 45 CFR 164.520(b)(1)(iii), the Department is requiring that covered entities provide notice to individuals that a Part 2 record, or testimony relaying the content of such record, may not be used or disclosed in a civil, criminal, administrative, or legislative proceeding against the individual absent written

[406] 45 CFR 160.103 (definition of ''Organized health care arrangement'').

[407] 88 FR 23506, 23539 (Apr. 17, 2023).

[408] 89 FR 12472 (Feb. 16, 2024).

consent from the individual or a court order, consistent with the requirements of 42 CFR part 2.

The Department is also finalizing a requirement at 45 CFR 164.520(b)(1)(iii)(E) that a covered entity must provide individuals with a clear and conspicuous opportunity to elect not to receive any fundraising communications before using Part 2 records for fundraising purposes for the benefit of the covered entity.

Lastly, we are finalizing our proposal to add a new paragraph (4) in 45 CFR 164.520(d) regarding joint notice by separate covered entities. This modification clarifies that Part 2 requirements continue to apply to Part 2 records maintained by covered entities that are part of OHCAs.

We are not finalizing in this rule the proposal to remove the exception to the NPP requirements for inmates of correctional facilities in this rule because it would be better addressed within the context of care coordination.

6. Responses to Public Comments

Comment: Commenters on both the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM urged the Department to coordinate any changes made to the NPP provisions based on proposals made in the separate rulemakings. According to the commenters, coordinating the changes to the NPP requirements would help to ensure consistency, reduce the administrative burden on covered entities, and ensure individual understanding of the permitted uses and disclosures of their PHI, including PHI that is also a Part 2 record. A few commenters on the 2022 Part 2 NPRM explained the different concerns that updates to the NPP pose to covered entities of differing sizes, based on resource constraints directly related to their size. Several commenters on the 2023 Privacy Rule NPRM requested that the Department provide sample language and examples or provide an updated model NPP.

Response: As part of this rulemaking, the Department is finalizing modifications to certain NPP requirements that were proposed in the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM. Thus, these changes serve to implement certain requirements of the CARES Act and to support reproductive health care privacy. The Department appreciates the recommendations and will consider them for future guidance.

Comment: A few commenters on the 2022 Part 2 NPRM requested that the Department clarify whether they would be permitted to use a single document or form when providing notice statements to individuals to ensure compliance by regulated entities and understanding of the notices by individuals. A few commenters agreed that a single NPP would reduce the administrative burden on regulated entities or be the most effective way to convey privacy information to individuals and asked for confirmation that this was permitted. A commenter requested that the Department update the Patient Notice in a manner such that the NPP header may be used in the combined notice if they are permitted to use a combined NPP/Patient Notice.

Response: As we have provided previously in guidance on the Privacy Rule and Part 2, notices issued by covered entities for different purposes may be separate or combined, as long as all of the required elements for both are included.[409] Thus, it is acceptable under both the Privacy Rule and Part 2 to meet the notice requirements of the Privacy Rule, Part 2, and state law by either providing separate notices or combining the required notices into a single notice, as long as all of the required elements are included.

Comment: A few commenters on the 2022 Part 2 NPRM and most of the commenters on the 2023 Privacy Rule NPRM suggested the proposed approach to modifying both the Patient Notice and NPP would bolster transparency and the public's understanding of how their health information is used or disclosed and collected. Many commenters on the 2023 Privacy Rule NPRM provided recommendations for ways in which the Department could improve the NPP, including requiring that the NPP be in plain language.

Response: The Department appreciates the comments on its proposal to modify the NPP to align with changes made in the Patient Notice and in support of reproductive health care privacy. The modifications will bolster transparency and public understanding of how information is used, disclosed, and protected. Covered entities have long been required under 45 CFR 164.520(b)(1) to provide an NPP that is written in plain language. Discussion of this requirement can be found in the preamble to the 2000 Privacy Rule.[410] The Department's model NPP forms, available in both English and Spanish, provide one example of how the plain language requirement may be met.[411] As discussed above, we are modifying 45 CFR 164.520 to clarify that this requirement applies to covered entities that use and disclose Part 2 records. Additional resources on writing in plain language can be found at *https://plainlanguage.gov.* Additionally, covered entities are required to comply with all Federal nondiscrimination laws, including laws that address language access requirements. Information about such requirements is available at *www.hhs.gov/hipaa.*

Comment: Commenters expressed concerns about the interplay of the Part 2 Patient Notice requirements with the NPP, the burden on covered entities to modify the NPP, and including the attestation requirement in the NPP.

Response: We have sought to align the requirements for the Patient Notice as closely as possible with the NPP requirements and to modify the NPP requirements to allow for a combined Patient Notice and NPP. The changes the Department is making to the NPP empower the individual and improve health outcomes by improving the likelihood that health care providers will make accurate diagnoses and informed treatment recommendations to individuals. These changes to the NPP provide the individual with clear information and reassurance about their privacy rights and their ability to discuss their reproductive health and related health care because they inform an individual that their PHI may not be used or disclosed for certain purposes prohibited by new 45 CFR 164.502(a)(5)(iii). As such, the qualitative benefits of providing individuals with information about how their PHI may be used and disclosed under the Privacy Rule outweigh the quantitative burdens for covered entities to revise their NPPs. Accordingly, we are finalizing the modifications proposed to the NPP as part of the 2023 Privacy Rule NPRM.

Comment: A majority of the commenters on the 2023 Privacy Rule NPRM who expressed support for revising the NPP also recommended that the Department require that the NPP include an explanation that the prohibition or Privacy Rule generally would no longer apply to PHI that has been disclosed for a permitted purpose to a person that is not a regulated entity. A few commenters opposed the addition as unnecessary or expressed concern about the potential length of the NPP. A

[409] *See also* 82 FR 6052, 6082–83 (Jan. 18, 2017); Off. for Civil Rights, ''Notice of Privacy Practices for Protected Health Information,'' U.S. Dep't of Health and Human Servs. (July 26, 2013), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/privacy-practices-for-protected-health-information/index.html.*

[410] 65 FR 82462, 82548–49 (Dec. 28, 2000).

[411] Off. for Civil Rights, ''Model Notices of Privacy Practices,'' U.S. Dep't of Health and Human Servs. (Apr. 8, 2013), *https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices/index.html.*

few of the commenters opposed adding such a statement because they believed it could deter individuals from seeking reproductive health care, increase individuals' mistrust of health care providers, or not add to individuals' understanding of their rights and protections under the Privacy Rule.

Response: In response to comments and in support of transparency for individuals, the Department is finalizing a new requirement to include in the NPP a statement adequate to put the individual on notice of the potential for information disclosed pursuant to the Privacy Rule to be subject to redisclosure by the recipient and no longer protected by the Privacy Rule. This change will provide additional clarity to individuals directly and assist covered entities in explaining the limitations of the Privacy Rule to individuals. We believe that any concerns about the negative effects of these modifications on length are outweighed by their benefits to the individual.

Comment: Several commenters to the 2023 Privacy Rule NPRM requested the Department provide additional time for compliance with the new NPP requirements and exercise enforcement discretion for a period of time after the compliance date.

Response: As noted above, we are finalizing certain modifications to the NPP provisions that were proposed in the 2022 Part 2 NPRM rule and other modifications to the same provisions that were proposed in the 2023 Privacy Rule NPRM. To ease the burden on covered entities and in compliance with 45 CFR 160.104, the Department is finalizing a compliance date of February 16, 2026, for the NPP provisions. The rationale for this compliance date is discussed in greater detail in the discussion of *Effective and Compliance Dates.*

F. Section 164.535—Severability

In the NPRM, the Department included a discussion of severability that explained how we believed the proposed rule should be interpreted if any provision was held to be invalid or facially unenforceable. We are finalizing a new 45 CFR 164.535 to codify this interpretation. The Department intends that, if a specific regulatory provision in this rule is found to be invalid or unenforceable, the remaining provisions of the rule will remain in effect because they would still function sensibly.

For example, the changes this final rule makes to the NPP requirements in 45 CFR 164.520 (including the changes finalizing proposals from the 2022 Part 2 NPRM) shall remain in full force and effect to the extent that they are not directly related to a provision in this rulemaking that is held to be invalid or unenforceable such that notice of that provision is no longer necessary. Conversely, if the NPP requirements are held to be invalid or unenforceable, the other modifications shall remain in full force and effect to the extent that they are not directly related to the NPP requirements.

As another example, we also intend that the revision in 45 CFR 160.103 to the definition of ''person'' shall remain in full force and effect if any other provision is held to be invalid or unenforceable because the new modified definition is not solely related to supporting reproductive health care privacy and is consistent with the Department's longstanding interpretation of the term and with regulated entities' current understanding and practices.

Similarly, we are finalizing technical corrections to the heading at 45 CFR 164.512(c) and a clarifying revision at 45 CFR 164.512(f) regarding the permission for disclosures based on administrative processes. Those changes are intended to remain in full force and effect even if other parts of this final rule are held to be invalid or unenforceable.

As another example, we also intend, if the addition in 45 CFR 160.103 of the definition of ''public health,'' as used in the terms ''public health surveillance,'' ''public health investigation,'' and ''public health intervention'' is held to be invalid and unenforceable, the other modifications to the rules shall remain in full force and effect to the extent that they are not directly related to the definition of public health.

We further intend that if the rule is held to be invalid and unenforceable with respect to its application to some types of health care, it should be upheld with respect to other types (*e.g.,* pregnancy or abortion-related care).

We also intend that any provisions of the Privacy Rule that are unchanged by this final rule shall remain in full force and effect if any provision of this final rule is held to be invalid or unenforceable.

These examples are illustrative and not exhaustive.

We received no comments on the language addressing severability in the 2023 Privacy Rule NPRM.

G. Comments on Other Provisions of the HIPAA Rules

Comment: A few commenters expressed concerns that the Department may grant exceptions to preemption and recommended that the Department clarify the standards for which exceptions to preemption would be made and consider strengthening these standards wherever possible or remove the potential for exceptions entirely.

One commenter expressed concern that the proposed rule could dissuade regulated entities from providing de-identified data for research, while another commenter recommended that the Department prohibit the sharing of de-identified reproductive health care data except in limited circumstances to prevent the re-identification of reproductive health data by third parties, such as law enforcement or data brokers

Response: The process for requesting exceptions to preemption and the standards for granting such requests are at 45 CFR 160.201 *et seq.* We did not propose any modifications to these provisions as part of the 2023 Privacy Rule NPRM, and as such, do not finalize modifications in this final rule.

The Department does not believe that this final rule will dissuade regulated entities from providing de-identified data for research or other purposes. Under the Privacy Rule, health information that meets the standard and implementation specifications for de-identification under 45 CFR 164.514 is considered not to be IIHI.[412] HIPAA confers on the Department the authority to set standards for the privacy of IIHI, including for de-identification. We did not propose to modify the de-identification standard as part of the 2023 Privacy Rule NPRM, and as such, do not finalize modifications in this final rule.

Comment: A commenter posited that the proposed rule's preemption of contrary state laws was not sufficiently clear and recommended that the Department reinforce the preemption provision in the final rule.

Response: The Department did not propose changes to the preemption provisions of the HIPAA Rules, which are based in statute,[413] and believes that the provisions, in combination with our discussion of preemption in the preamble, are sufficient.

VI. Regulatory Impact Analysis

A. Executive Order 12866 and Related Executive Orders on Regulatory Review

The Department of Health and Human Services (HHS or ''Department'') has examined the effects of this final rule under Executive Order (E.O.) 12866, Regulatory Planning and Review,[414] as

[412] 45 CFR 164.502(d)(2).

[413] *See* 45 CFR part 160, subpart B—Preemption of State Law.

[414] 58 FR 51735 (Oct. 4, 1993).

amended by E.O. 14094,[415] E.O. 13563, Improving Regulation and Regulatory Review,[416] the Regulatory Flexibility Act[417] (RFA), and the Unfunded Mandates Reform Act of 1995[418] (UMRA). E.O.s 12866 and 13563 direct the Department to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive effects; and equity). This final rule is significant under section 3(f)(1) of E.O. 12866, as amended.

The RFA requires us to analyze regulatory options that would minimize any significant effect of a rule on small entities. As discussed in greater detail below, this analysis concludes, and the Secretary certifies, that the rule will not result in a significant economic effect on a substantial number of small entities.

The UMRA (section 202(a)) generally requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' [419] The current threshold after adjustment for inflation is $177 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly Federal mandate costs resulting from imposing enforceable duties on state, local, or Tribal governments or the private sector; or increasing the stringency of conditions in, or decreasing the funding of, state, local, or Tribal governments under entitlement programs. This final rule imposes mandates that would result in the expenditure by state, local, and Tribal governments, in the aggregate, or by the private sector, of more than $177 million in any one year. The impact analysis in this final rule addresses such effects both qualitatively and quantitatively. In general, each regulated entity, including government entities that meet the definition of covered entity (*e.g.,* state Medicaid agencies), is required to adopt new policies and procedures for responding to requests for the use or disclosure of protected health information (PHI) for which an attestation is required and to train its workforce members on the new requirements. Additionally, although the Department has not quantified the costs, state, local, and Tribal law enforcement agencies must analyze requests that they initiate for the use or disclosure of PHI and provide regulated entities with an attestation that the request is not for a prohibited purpose in instances where the request is made for health oversight activities, judicial and administrative proceedings, law enforcement purposes, or about decedents to coroners and medical examiners, and is for PHI potentially related to reproductive health care. One-time costs for all regulated entities to change their policies will increase costs above the UMRA threshold in one year. The Department initially estimated that ongoing expenses for the new attestation condition would not increase significantly, but we sought additional data to inform our estimates. Although Medicaid makes Federal matching funds available for states for certain administrative costs, these are limited to costs specific to operating the Medicaid program. There are no Federal funds directed at Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance activities.

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996,[420] the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs has determined that this final rule meets the criteria set forth in 5 U.S.C. 804(2) because it is projected to have an annualized effect on the economy of more than $100,000,000. Because of the large number of covered entities that are subject to this final rule and the large number of individuals with health plan coverage, any rule modifying the HIPAA Privacy Rule that requires updating policies and procedures and the Notice of Privacy Practices (NPP) and distributing the NPP to a percentage of individuals is likely to meet the threshold in 5 U.S.C. 804(2).

The Justification for this Rulemaking and Summary of Final Rule Provisions section at the beginning of this preamble contain a summary of this rule and describe the reasons it is needed. The Department presents a detailed analysis below.

1. Summary of Costs and Benefits

The Department identified six general categories of quantifiable costs arising from these proposals: (1) responding to requests for the use or disclosure of PHI for which an attestation is required; (2) revising business associate agreements; (3) updating the NPP and posting it online; (4) developing new or modified policies and procedures; (5) revising training programs for workforce members; and (6) requesting an exception from HIPAA's general preemption authority. The first five categories apply primarily to covered entities, while the sixth category applies to states and other interested persons.

The Department estimates that the first-year costs attributable to this final rule total approximately $595.0 million. These costs are associated with covered entities responding to requests for the use or disclosure of PHI that are conditioned upon an attestation; revising business associate agreements; revising policies and procedures; updating, posting, and mailing the NPP; and revising training programs for workforce members, and with states or other persons requesting exceptions from preemption. These costs also include increased estimates for wages, postage, and the number of NPPs distributed by health plans as compared to the baseline of existing annual cost and burden estimates for these activities in the approved HIPAA information collection. For years two through five, estimated annual costs of approximately $20.9 million are attributable to ongoing costs related to the attestation requirement. Table 1 reports the present value and annualized estimates of the costs of this final rule covering a 5-year time horizon. Using a 7% discount rate, the Department estimates this final rule will result in annualized costs of $151.8 million; and using a 3% discount rate, these annualized costs are $142.6 million.

[415] 88 FR 21879 (Apr. 11, 2023).

[416] 76 FR 3821 (Jan. 21, 2011).

[417] Public Law 96–354, 94 Stat. 1164 (codified at 5 U.S.C. 601–612).

[418] Public Law 104–4, 109 Stat. 48 (codified at 2 U.S.C. 1501).

[419] *Id.* at sec. 202 (codified at 2 U.S.C. 1532(a)).

[420] Also referred to as the Congressional Review Act, 5 U.S.C. 801 *et seq.*

TABLE 1—ACCOUNTING TABLE, COSTS OF THE RULE

[$ Millions]

Costs	Primary estimate	Year dollars	Discount rate (%)	Period covered
Present Value	$678.6	2022	Undiscounted	2024–2028
Present Value	622.3	2022	7	2024–2028
Present Value	653.1	2022	3	2024–2028
Annualized	151.8	2022	7	2024–2028
Annualized	142.6	2022	3	2024–2028

The changes to the Privacy Rule will likely result in important benefits and some costs that the Department is unable to fully quantify at this time. As explained further below, unquantified benefits include improved trust and confidence between individuals and health care providers; enhanced privacy and improved access to reproductive health care and information, which may prevent increases in maternal mortality and morbidity; increased accuracy and completeness in patient medical records, which may prevent poor health outcomes; enhanced support for survivors of rape, incest, and sex trafficking; and maintenance of family economic stability by allowing families to determine the timing and spacing of whether or when to be pregnant. Additionally, allowing regulated entities to accept an attestation for requests for the use or disclosure of PHI potentially related to reproductive health care, and to presume that reproductive health care provided by another person was lawful under the circumstances it was provided, will reduce potential liability for regulated entities by providing some assurance with respect to whether the requested disclosure is prohibited.

TABLE 2—POTENTIAL NON-QUANTIFIED BENEFITS FOR COVERED ENTITIES AND INDIVIDUALS

Benefits
Improve access to complete information about lawful reproductive health care options, including for individuals who are pregnant or considering a pregnancy (*i.e.,* improve health literacy), by reducing concerns about disclosure of PHI.
Maintain or reduce levels of maternal mortality and morbidity by ensuring that individuals and their clinicians can freely communicate and have access to complete information needed for quality lawful health care, including coordination of care.
Decrease barriers to accessing prenatal health care by maintaining privacy for individuals who seek a complete range of lawful reproductive health care options.
Enhance mental health and emotional well-being of pregnant individuals by reducing fear of potential disclosures of their PHI to investigate or impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating lawful health care.
Improve or maintain trust between individuals and health care providers by reducing the potential for health care providers to report PHI in a manner that could harm the individuals' interests.
Prevent or reduce re-victimization of pregnant individuals who have survived rape or incest by protecting their PHI from undue scrutiny.
Improve or maintain families' economic well-being by not exposing individuals or their family members to costly investigations or activities to impose liability for seeking, obtaining or facilitating lawful reproductive health care.
Maintain the economic well-being of regulated entities by not exposing regulated entities or workforce members to costly investigations or activities to impose liability on them for engaging in lawful activities.
Ensure individuals' ability to obtain full and complete information and make lawful decisions concerning fertility- or infertility-related health care that may include selection or disposal of embryos without risk of PHI disclosure for criminal, civil, or administrative investigations or activities to impose liability for engaging in lawful activities.

The Department also recognizes that there may be some costs that are not readily quantifiable, notably, the potential burden on persons requesting PHI to investigate or impose liability on persons for seeking, obtaining, providing, or facilitating reproductive health care that is not lawful under the circumstances in which such health care is provided. As discussed elsewhere in this final rule, we acknowledge that, in certain limited circumstances, the final rule may, prevent persons from obtaining an individual's PHI, such as where the request is directed to the health care provider that provided the reproductive health care and that health care provider reasonably determines that such health care was provided lawfully. However, the existing permission for disclosures for law enforcement does not create a mandate for disclosure to law enforcement agencies. Rather, it establishes the conditions under which a regulated entity may disclose PHI if it so chooses. Accordingly, consistent with how the Privacy Rule has operated since its inception, persons whose requests for PHI are declined by regulated entities may incur additional costs if they choose to pursue their investigations through other methods and obtain evidence from non-covered entities. We have not previously quantified the costs to such persons for obtaining an individual's PHI, such as where a law enforcement official is required to prepare a formal administrative request or obtain a qualified protective order and we do not do so here. We do not view the attestation requirement as changing this calculus and have designed the attestation to impose a minimal burden on requests for PHI related to lawful conduct by health care providers by offering a model attestation form. Despite the minimal formality of providing a signed attestation, some state law enforcement agencies may experience the requirement as a burden, and we acknowledge that potential as a non-quantifiable cost.

2. Baseline Conditions

The Privacy Rule, in conjunction with the Security and Breach Notification Rules, protects the privacy and security of individuals' PHI, that is, individually identifiable health information (IIHI) transmitted by or maintained in electronic media or any other form or

medium, with certain exceptions. It limits the circumstances under which regulated entities are permitted or required to use or disclose PHI and requires covered entities to have safeguards in place to protect the privacy of PHI. The Privacy Rule also establishes certain rights for individuals with respect to their PHI and sets limits and conditions on the uses and disclosures that may be made of such information without an individual's authorization.

As explained in the preamble, the Department has the authority under HIPAA to modify the Privacy Rule to prohibit the use or disclosure of PHI for activities to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it was provided, as well as to identify any person for the purpose of initiating such activities. The Privacy Rule has been modified several times since it was first issued in 2000 to address statutory requirements, changed circumstances, and concerns and issues raised by stakeholders regarding the effects of the Privacy Rule on regulated entities, individuals, and others. Recently, as the preamble discusses, changed circumstances resulting from new inconsistencies in the regulation of reproductive health care nationwide and the negative effects on individuals' expectations for privacy and their relationships with their health care providers, as well as the additional burdens imposed on regulated entities, require the modifications made by this final rule.

For purposes of this Regulatory Impact Analysis (RIA), this final rule adopts the list of covered entities and cost assumptions identified in the Department's 2023 Information Collection Request (ICR).[421] The Department also relies on certain estimates and assumptions from the 1999 Privacy Rule NPRM[422] that remain relevant, and the 2013 Omnibus Rule,[423] as referenced in the analysis that follows.

The Department quantitatively analyzes and monetizes the effect that this final rule may have on regulated entities' actions to: revise business associate agreements between covered entities and their business associates, including release-of-information contractors; create new forms; respond to certain types of requests for PHI; update their NPPs; adopt policies and procedures to implement the requirements of this final rule; and train their employees on the updated policies and procedures. The Department analyzes the remaining benefits and burdens qualitatively because of the uncertainty inherent in predicting other concrete actions that such a diverse scope of regulated entities might take in response to this rule.

Analytic Assumptions

The Department bases its assumptions for calculating estimated costs and benefits on several publicly available datasets, including data from the U.S. Census, the U.S. Department of Labor, Bureau of Labor Statistics, Centers for Medicare & Medicaid Services, and the Agency for Healthcare Research and Quality. For the purposes of this analysis, the Department assumes that benefits plus indirect costs equal approximately 100 percent of pre-tax wages and adjusts the hourly wage rates by multiplying by two, for a fully loaded hourly wage rate. The Department adopts this as the estimate of the hourly value of time for changes in time use for on-the-job activities.

Implementing the regulatory changes likely will require covered entities to engage workforce members or consultants for certain activities. The Department assumes that a lawyer will draft or review the new attestation form, revisions to business associate agreements, revisions to the NPP, and required changes to HIPAA policies and procedures. The Department expects that a training specialist will revise the necessary HIPAA training and that a web designer will post the updated NPP. The Department further anticipates that a workforce member at the pay level of medical records specialist will confirm receipt of required attestations. To the extent that these assumptions affect the Department's estimate of costs, the Department solicited comment on its assumptions, particularly assumptions in which the Department identifies the level of workforce member (*e.g.,* clerical staff, professional) that will be engaged in activities and the amount of time that particular types of workforce members spend conducting activities related to this RIA as further described below. Table 3 also lists pay rates for occupations referenced in the explanation of estimated information collection burdens in Section F of this RIA and related tables.

The Department received several comments about the occupations engaged in certain activities and the time burden associated with them. We reviewed these submissions and used the provided information to revise the estimate for the cost of processing requests for the use or disclosure of PHI that require an attestation. For more details, please see the sections discussing the costs of the rule below.

The Department received no comment on the hourly value of time; therefore, we retain all relevant assumptions laid out in the 2023 Privacy Rule NPRM, as described above (see Table 3 for a list of occupations and corresponding wages).[424]

[421] 88 FR 3997 (Jan. 23, 2023).

[422] 64 FR 59918 (Nov. 3, 1999).

[423] 78 FR 5566 (Jan. 25, 2013).

[424] For each occupation performing activities as a result of the final rule, the Department identifies a pre-tax hourly wage using a database maintained by the Bureau of Labor Statistics. *See* U.S. Dep't of Labor, ''Occupational Employment and Wages'' (May 2022), *https://www.bls.gov/oes/current/oes_nat.htm.*

TABLE 3—OCCUPATIONAL PAY RATES

Occupation code and title		Mean hourly wage	Fully loaded hourly wage
00–0000	All Occupations	$29.76	$59.52
43–3021	Billing and Posting Clerks	21.54	43.08
29–0000	Healthcare Practitioners and Technical Occupations	46.52	93.04
29–9021	Health Information Technologists and Medical Registrars	31.38	62.76
29–9099	Healthcare Practitioners and Technical Workers, All Other	32.78	65.56
15–1212	Information Security Analysts	57.63	115.26
23–1011	Lawyers	78.74	157.48
13–1111	Management Analysts	50.32	100.64
11–9111	Medical and Health Services Manager	61.53	123.06
29–2072	Medical Records Specialist	24.56	49.12
43–0000	Office and Administrative Support Occupations	21.90	43.80
11–2030	Public Relations and Fundraising Managers	68.56	137.12
13–1151	Training and Development Specialist	33.59	67.18
43–4171	Receptionists and Information Clerks	16.64	33.28
15–1255	Web and Digital Interface Designers	48.91	97.82

The Department assumes that most covered entities will be able to incorporate changes to their workforce training into existing HIPAA training programs rather than conduct a separate training because the total time frame for compliance from date of finalization would be 240 days.[425]

Covered Entities Affected

The Department received no substantive comments on the number or type of HIPAA covered entities affected by this rule; therefore, we retain the methodology and entity estimates as described in the 2023 Privacy Rule NPRM and the baseline conditions section above.

To the extent that covered entities engage business associates to perform activities under the rule, the Department assumes that any additional costs will be borne by the covered entities through their contractual agreements with business associates. The Department's estimate that each revised business associate agreement will require no more than 1 hour of a lawyer's labor assumes that the hourly burden could be split between the covered entity and the business associate. Thus, the Department calculated estimated costs based on the potential number of business associate agreements that will be revised rather than the number of covered entities or business associates with revised business associate agreements.

The Department requested data on the number of business associates (which may include health care clearinghouses acting in their role as business associates of other covered entities) that would be affected by the rule and the extent to which they may experience costs or other burdens not already accounted for in the estimates of burdens for revising business associate agreements. The Department also requested comment on the number of business associate agreements that would need to be revised, if any. We did not receive any actionable comments on the number of affected business associates, the number of business associate agreements, or any specific costs that business associates might bear. For more details, see the section on business associate agreements below.

The Department requested public comment on these estimates, including estimates for third party administrators and pharmacies where the Department has provided additional explanation. The Department additionally requested detailed comment on any situations, other than those identified here, in which covered entities would be affected by this rulemaking. We did not receive any substantive comments related to these issues.

TABLE 4—ESTIMATED NUMBER AND TYPE OF COVERED ENTITIES

Covered entities			
NAICS code	Type of entity	Firms	Establishments
524114	Health and Medical Insurance Carriers	880	5,379
524292	Third Party Administrators	456	783
622	Hospitals	3,293	7,012
44611	Pharmacies	19,540	[a] 67,753
6211–6213	Office of Drs. & Other Professionals	433,267	505,863
6215	Medical Diagnostic & Imaging	7,863	17,265
6214	Outpatient Care	16,896	39,387
6219	Other Ambulatory Care	6,623	10,059
623	Skilled Nursing & Residential Facilities	38,455	86,653
6216	Home Health Agencies	21,829	30,980
532283	Home Health Equipment Rental	611	3,197
Total		549,713	774,331

[a] Number of pharmacy establishments is taken from industry statistics.

[425] This includes 60 days from publication of a final rule to the effective date and an additional 180 days until the compliance date.

Individuals Affected

The Department believes that the population of individuals potentially affected by the rule is approximately 76 million overall,[426] representing nearly one-fourth of the U.S. population, including approximately 6 million pregnant individuals annually and an unknown number of individuals facing a potential pregnancy or pregnancy risk due to sexual activity, contraceptive avoidance or failure, rape (including statutory rape), and incest. According to Federal data, 78 percent of sexually active females received reproductive health care in 2015–2017.[427]

The Department received comments related to the number of individuals affected by the rule, some of which are summarized below. One commenter asserted that the Department had overestimated the number of affected individuals and urged reducing the estimate to 78 percent of sexually active females (52.72 million). The same commenter also argued that even this revised number might be an overestimate, and that the number of individuals directly affected by the rule would be closer to 50,400 a year. Another commenter suggested that the number of individuals potentially affected by the proposed rule is much larger than the estimate and that the estimate should include any individual who was ever capable of bearing children and their family members.

Another commenter asserted that the Department was underestimating the number of individuals that would be affected by the proposed rule but did not include an estimate of their own.

After reviewing the comments, the Department is finalizing the estimates of the number of individuals that will be affected by this final rule as described above, which includes updates for 2022 data. The Department considers a key category of individuals affected by this final rule those who have the potential to become pregnant because pregnancies may occur and result in a need for reproductive health care nationwide. Pregnancy, concern about potential pregnancy, and the need for reproductive health care do not recognize state boundaries or regulatory timelines.

Commenters recommended data points above and below the Department's proposed estimate of 74 million affected individuals. We believe that the number of affected individuals is far greater than the total who are survivors of sexual assault or sex trafficking (as recommended by a commenter), yet less than the number of all individuals who have ever been of childbearing age and their family members (as recommended by another commenter). We recognize that the age range for the proposed estimate of females, 10–44, imperfectly reflects the number of females of childbearing age; however, the number of females over age 44 who could become pregnant may be offset by the number of females aged 10–13 who are not yet capable of childbearing. We use the number of females of potentially childbearing age as a proxy for the number of individuals affected by the final rule as shown in Table 5 below.

TABLE 5—ESTIMATED NUMBER OF INDIVIDUALS AFFECTED

Females of potentially childbearing age[428]	Population estimate
10 to 14 years	10,327,799
15 to 19 years	10,618,136
20 to 24 years	10,957,463
25 to 29 years	10,762,368
30 to 34 years	11,440,546
35 to 39 years	11,013,337
40 to 44 years	10,771,942
Total	75,891,591

3. Costs of the Rule

Below, the Department provides the basis for its estimated quantifiable costs resulting from the changes to specific provisions of the Privacy Rule. Many of the estimates are based on assumptions formed through the Office for Civil Rights' (OCR's) experience with its compliance and enforcement program and accounts from stakeholders received at outreach events. The Department has quantified recurring burdens for this final rule for obtaining an attestation from a person requesting the use or disclosure of PHI potentially related to reproductive health care for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners or medical examiners.

The Department requested information or data points from commenters to further refine its estimates and assumptions. We examine the most substantive comments received in the cost section below. Additionally, we received comments that are also discussed below on topics that are not directly addressed in the cost section.

A commenter asserted that the Department did not account for the additional costs associated with major depressive disorders that would arise from the increase in abortions due to the rule. The Department does not believe that is a valid benchmark for the effects of this final rule, in part because we reject the premise, which is not backed by medical evidence or data, that this final rule will result in an increase in pregnancy terminations or depression.[429] Further, researchers have raised numerous concerns about the methodology of the 2011 study cited in

[426] *See* U.S. Census Bureau, American Community Survey S0101, AGE AND SEX 2022: ACS 5-Year Estimates Subject Tables (females aged 10–44), *https://data.census.gov/table/ACSST1Y2022.S0101*. The U.S. Census Bureau uses the term ''sex'' to equate to an individual's biological sex. ''Sex—Definition,'' U.S. Census Bureau (accessed Mar. 20, 2024), *https://www.census.gov/glossary/?term=Sex.*

[427] *See* ''Reproductive and Sexual Health,'' Sexually active females who received reproductive health services (FP–7.1), *Healthypeople.gov, https://wayback.archive-it.org/5774/20220415172039/https:/www.healthypeople.gov/2020/leading-health-indicators/2020-lhi-topics/Reproductive-and-Sexual-Health/data.*

[428] *See* American Community Survey S0101, AGE AND SEX 2022: ACS 5-Year Estimates Subject Tables (females aged 10–44), *supra* note 427.

[429] *See* M. Antonia Biggs et al., ''Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study,'' 74(2) JAMA Psychiatry 169, 177 (2017), *https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2592320. See also* Julia R. Steinberg et al., ''The association between first abortion and first-time non-fatal suicide attempt: a longitudinal cohort study of Danish population registries,'' 6(12) The Lancet Psychiatry 1031–1038 (Dec. 2019).

the comment.[430] Accordingly, we are not including the costs associated with treatment of depression in the cost section.

a. Costs Associated With Requests for Exception From Preemption

The Department anticipates that states with laws that restrict access to reproductive health care are likely to seek an exception to the requirements of this final rule that preempt state law. Given the pace at which state laws governing access to reproductive health care are changing, the Department is finalizing its proposed estimate that a potential increase of 26 states[431] will incur costs to develop a request to except a provision of state law from HIPAA's general preemption authority to submit to the Secretary.[432] Based on existing burden estimates for this activity,[433] the Department is finalizing its estimate that each exception request will require approximately 16 hours of labor at the rate of a general health care practitioner and that approximately 26 states will make such requests. Thus, the Department estimates that states will spend a total of 416 hours requesting exception from preemption and monetize this as a one-time cost of $38,705 [= 16 × 26 × $93.04].

b. Estimated Costs From Adding a Requirement for an Attestation for Disclosures for Certain Purposes

Multiple commenters asserted that the projected attestation cost in the proposed rule was incorrect and underestimated the true cost of implementing the proposed requirement. One commenter asserted that the proposed rule underestimated the time to review medical records for PHI about reproductive health care and recommended that it be increased significantly. The same commenter also suggested that the Department adopt a requirement to obtain an individual's authorization, instead of an attestation, because it would reduce costs. Other commenters asserted that the proposed cost estimates for the attestation requirement did not account for associated administrative burdens, urged the Department to require an attestation for every request for PHI to decrease overall costs by establishing a procedural norm, or requested that the Department provide grants and trainings to regulated entities to offset the costs of the attestation provision. Finally, another commenter requested that the Department release a model attestation form to decrease the cost burden for covered entities.

A few commenters asserted that the Department mis-identified the types of staff that would performing specific components of the attestation requirement. One posited that both a lawyer and a medical professional would need to review medical records for the use or disclosure of PHI in response to the proposed revisions to the Privacy Rule. Another asserted that the person reviewing PHI in response to a request for the use or disclosure of PHI would be a medical records clerk.

The Department has modified the attestation requirement in response to public comments. As discussed above, this final rule requires regulated entities to obtain an attestation that the request for the use or disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) when the request is for certain purposes (health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners and medical examiners) and is for PHI potentially related to reproductive health care. Where the request is for a purpose that implicates 45 CFR 164.502(a)(5)(iii) and the reproductive health care was provided by someone other than the regulated entity that received the request, such health care is presumed lawful under the circumstances in which it was provided unless the conditions of 45 CFR 164.502(a)(5)(iii)(C) are met. We expect the presumption of lawfulness to lower the burden for regulated entities to process requests for the use or disclosure of PHI for which an attestation is required; however, we also acknowledge that the proposed estimate did not fully represent the number of likely requests for the use or disclosure of PHI. The Department declines to require a valid authorization for these requests, as opposed to an attestation, and no grants to offset costs will be needed because of the lower estimated burden per request. The revised cost estimates include review of each request for the use or disclosure of PHI for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners and medical examiners, to determine if an attestation has been provided and administrative burdens associated with obtaining the attestation.

This final rule necessitates that regulated entities establish a process for responding to requests for the use or disclosure of PHI for which an attestation is required, such as reviewing and screening requests that are not accompanied by a valid authorization and are not a right of access request. We anticipate that across all regulated entities, this final rule will result in approximately 2,794,201 requests that regulated entities need to review in connection with the permissions under 45 CFR 164.512(d)–(g)(1). The Department estimates 5 minutes of average processing time per attestation based on the average wage of a mix of several occupations: medical and health services managers, medical records specialists, and health practitioners.[434] For example, a medical records specialist may forward certain requests for the use or disclosure of PHI (for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners and medical examiners) to a manager to review whether the request pertains to the lawfulness of reproductive health care. A health practitioner may review a number of records subject to a request for whether they contain PHI potentially related to reproductive health care. We calculate the annual cost for initial processing of the estimated 2,794,201 requests requiring attestations to total $20,585,500 [2,794,201 × (5/60) × $88.41]. For almost all of these requests, we believe that a brief review will be sufficient for a regulated entity to make a final disclosure determination.

For a small number of these requests, approximately 1,300, we assume that the brief review will not be sufficient; we assume that these requests will require legal review. This figure is an estimate of the number of requests that are generated to investigate or impose liability on a person for the mere act of seeking or obtaining lawful reproductive health care, including from a health care

[430] *See* Julia R. Steinberg et al., ''Fatal flaws in a recent meta-analysis on abortion and mental health,'' 86(5) Contraception 430–7 (Nov. 2012), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3646711/* (discussing errors and significant shortcomings of the studies included in the 2011 meta-analysis that render its conclusions invalid).

[431] *See* Lawrence O. Gostin et al., ''One Year After *Dobbs*—Vast Changes to the Abortion Legal Landscape,'' 4(8) JAMA Health Forum (2023), *https://jamanetwork.com/journals/jama-health-forum/fullarticle/2808205* (counting 21 states with post-*Dobbs* limits that are more restrictive than *Roe* v. *Wade* allowed) and Laura Deal, ''State Laws Restricting or Prohibiting Abortion,'' Congressional Research Service (Jan. 22, 2024), *https://crsreports.congress.gov/product/pdf/R/R47595*. Because of the pace of change in this area, the Department relies on a higher number than JAMA's 2023 figure as a basis for its cost estimates.

[432] *See* 45 CFR 160.201 *et seq.* for information about exceptions to HIPAA's general preemption authority and the process for requesting such an exception and the criteria for granting it.

[433] ''Information Collection: Process for Requesting Exception Determinations (states or persons),'' U.S. Gen. Servs. Admin. & Off. of Mgmt. and Budget, *https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201909-0945-001&icID=10428.*

[434] *See supra,* Table 3 of this RIA.

provider in a state other than the state where the regulated entity is located. The Department's estimate assumes that approximately 26 states may seek to restrict access to out-of-state reproductive health care, including reproductive health care that is lawful under the circumstances in which it provided, and will initiate an average of 50 such requests annually. The Department estimates on average 1 hour of review for such requests based on the wage of a lawyer.[435] We calculate the annual legal review cost for the estimated 1,300 requests totals $204,724 [1,300 × 1 × $157.48]. This additional review increases the cost of processing attestations to $20,790,224.

We anticipate that approximately one-quarter of requests that result in legal reviews, approximately 325, will require additional managerial review by the regulated entity before making a disclosure decision. The Department estimates on average 3 hours of additional review for each of these requests based on the wage of medical and health insurance managers.[436] We calculate a total cost for additional actions for these requests of $119,984 [325 × 3 × $123.06]. The total annual estimated cost of processing attestations, including all additional legal and managerial reviews, is $20,910,207.

Upon consideration of the estimated cost for regulated entities to create a new attestation form, the Department is planning to develop a model form to be available prior to the compliance date of this final rule. This will save an estimated total of $60,970,823 [= 774,331 × (30/60) × $157.48], based on 30 minutes of labor by a lawyer.

c. Costs Arising From Revised Business Associate Agreements

The Department anticipates that a certain percentage of business associate agreements will likely need to be updated to reflect a determination made by parties about their respective responsibilities when either party receives requests for disclosures of PHI under 45 CFR 164.512(d), (e), (f), or (g)(1). For example, each of the parties to the business associate agreement may need to notify the other party when they have knowledge that a request is for an unlawful purpose and allocate their respective responsibilities for handling these less frequent requests. The Department is finalizing its proposed estimate that each new or significantly modified contract between a business associate and its subcontractors will require, on average, one hour of labor by a lawyer at the wage reported in Table 3. We believe that approximately 35 percent of 1 million business associates, or 350,000 entities, will decide to create or significantly modify subcontracts, resulting in total costs of $55,118,000 [= 350,000 × $157.48].

A few commenters asserted that the Department's estimates for business associates' costs were incorrect and that it should consider additional costs. A commenter recommended that the Department adopt a non-enforcement period to allow business associates to achieve compliance and limit legal costs. Another commenter stated that the Department did not adequately identify the costs that would be associated with increased legal scrutiny of business associates as a result of the proposed rule. And another commenter urged the Department to consider the additional costs for renegotiated contracts as a result of the proposed rule. Lastly, a commenter requested that the Department apply the attestation requirement to business associates because it would reduce the costs of the rule.

The Department has reviewed the comments and is adopting the 2023 Privacy Rule NPRM cost analysis in this final rule. Business associate costs are adequately captured by the estimate for revising agreements. Applying costs directly to business associates (as opposed to covered entities) is distributional and will not alter the total impact of the rule. The Department declines to create an additional non-enforcement period for this provision of the final rule beyond the 180 days from the date of publication for the final rule to the compliance date.[437] The estimated cost for responding to requests for PHI for which an attestation is required accounts for increased scrutiny of a small number of requests for PHI, and the estimated costs for updating business associate agreements accounts for renegotiation of an average of one release of information vendor contract for nearly half of all covered entities.

d. Costs Arising From Changes to the Notice of Privacy Practices

The final rule modifies the NPP to notify individuals that covered entities cannot use or disclose PHI for certain purposes and that in certain circumstances, covered entities must obtain an attestation from a person requesting the PHI that affirms that the use or disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). The final rule also modifies the NPP to align with changes proposed in the 2022 Part 2 NPRM. This includes requiring covered entities that create or maintain Part 2 records to provide a notice that: addresses such records; references Part 2 as ''other applicable law'' that is more stringent than the Privacy Rule; explains that covered entities may not use or disclose a Part 2 record in a civil, criminal, administrative, or legislative proceeding against the individual absent written consent from the individual or a court order; and clarifies the applicability of Part 2 for organized health care arrangements that hold Part 2 records. Additionally, the final rule further modifies language for fundraising by covered entities that use or disclose Part 2 records to require a clear and conspicuous opt-out opportunity for patients. Finally, the modifications require the NPP to explain that PHI disclosed to a person other than a regulated entity is no longer subject to the requirements of the Privacy Rule.

The Department believes the burden associated with revising the NPP consists of costs related to developing and drafting the revised NPP for covered entities. The Department estimates that the updating and revising the language in the NPP will require 50 minutes of professional legal services at the wage reported in Table 3. Across all covered entities, the Department estimates a cost of $101,618,038 [= 774,331 × (50/60) × $157.48]. The Department does not anticipate any new costs for health care providers associated with distribution of the revised notice other than posting it on the entity's website (if it has one) because health care providers have an ongoing obligation to provide the notice to first-time patients that is already accounted for in cost estimates for the HIPAA Rules. Health plans that post their NPP online will incur minimal costs by posting the updated notice and then including the updated NPP in the next annual mailing to subscribers.[438] Health plans that do not provide an annual mailing will potentially incur an additional $12,743,700 in capital expenses for mailing the revised NPP to an estimated 10 percent of the 150,000,000 health plan subscribers who receive a mailed, paper copy of the notice, as well as the labor expense for an administrative support staff member at the rate shown in Table 3 to complete the mailing, for approximately $2,737,500 [= 62,500 hours × $43.80]. The Department further estimates the cost of posting the revised NPP on the

[435] *Id.*

[436] *Id.*

[437] This includes 60 days from the date of publication to the effective date, plus 120 days from the effective date to the compliance date.

[438] 45 CFR 164.520(c)(1)(v)(A).

covered entity's website will be 15 minutes of a web designer's time at the wage reported in Table 3. Across all covered entities, the Department estimates a cost of online posting as $18,936,265 [= 774,331 × (15/60) × $97.82].

A commenter expressed concern that the Department was underestimating the cost of mailing updates associated with changes to NPP policies.

The Department is already accounting for the cost of mailing updated NPPs within the estimated capital costs, which include printing copies of NPPs that are provided in person and those that are mailed, and postage for health plans that will need to conduct a mailing that is off-cycle from its regular schedule. We estimate that half of NPPs will need to be mailed and that health plans may include the updated NPP with their next regular mailing to individuals.

e. Estimated Costs for Developing New or Modified Policies and Procedures

The Department anticipates that covered entities will need to develop new or modified policies and procedures for the new requirements for attestations, the new category of prohibited uses and disclosures, modifications to certain uses and disclosures permitted under 45 CFR 164.512, and clarification of personal representative qualifications. The Department is finalizing its proposed estimate that the costs associated with developing such policies and procedures will be the labor of a lawyer for 2.5 hours and that this expense represents the largest area of cost for compliance with this final rule, for a total of $304,854,115 [= 774,331 × 2.5 × $157.48].

A few commenters stated that the estimate for covered entities to draft new policies was incorrect and provided additional information or alternatives to reduce costs. A commenter stated that the time burden for drafting new policies was insufficient and did not accurately represent the amount of time it would take a covered entity to draft a policy that complied with the proposed rule. Another commenter urged the Department to include the costs for organizations to update their privacy policies because of the proposed rule. A few commenters requested that the Department provide organizations with additional time to develop new policies that comply with the final rule.

The Department considered the concerns raised by commenters about the burdens of the requirements to revise the Privacy Rule and made several additional modifications in this final rule to reduce burdens on regulated entities. For example, regulated entities are not required to develop policies to routinely evaluate whether reproductive health care that was provided by someone else was lawful. Instead, regulated entities will need to develop policies to ensure that regulated entities identify requests for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners or medical examiners and procedures for obtaining the required attestation if it is not provided with the request for the use or disclosure of PHI. Additional policies will be required to address requests for the above purposes that could result in a prohibited use or disclosure, such as requests from law enforcement for the use or disclosure of PHI that assert, without any other information, that reproductive health care was provided unlawfully. The updating of privacy policies is included in the overall cost of updating policies and the estimate for updating the NPP. Because of changes in the final rule that simplify compliance with the new requirements, the Department is not adjusting the time burden for revising or creating new policies and procedures.

f. Costs Associated With Training Workforce Members

The Department anticipates that covered entities will be able to incorporate new content into existing HIPAA training requirements and that the costs associated with doing so will be attributed to the labor of a training specialist for an estimated 90 minutes for a total of $78,029,335 [= 774,331 × (90/60) × $67.18].

A few commenters addressed training costs within the proposed rule, including one who asserted that such costs could be reduced by ensuring that the effective date for all of the provisions of the rule is the same. Another commenter stated that covered entities would incur both a one time and yearly training cost, with the yearly training cost accounting for most of the total training cost in year 1.

The Department is finalizing the cost estimate for training workforce members as proposed, which includes the cost of a training a specialist to update the covered entity's HIPAA training program with new content to include in training for workforce members within the first year. Any further recurring component is likely to be implemented into regularly scheduled employee training and will thus not be directly attributable to this rule.

g. Total Quantifiable Costs

The Department summarizes in Table 6 the estimated nonrecurring costs that covered entities and states will experience in the first year of implementing the regulatory changes. The Department anticipates that these costs will be for requesting exceptions from preemption of contrary state law, implementing the attestation requirement, revising business associate agreements, revising the NPP, mailing and posting it online, revising policies and procedures, and updating HIPAA training programs.

TABLE 6—NEW NONRECURRING COSTS OF COMPLIANCE WITH THE FINAL RULE

Nonrecurring costs	Burden hours/ action × hourly wage	Respondents	Total costs (millions)
Exception Requests	16 × $93.04	26 States	$0.04
BA Agreements, Revising	1 × $157.48	350,000 BAAs	55
NPP, Updating	50/60 × $157.48	774,331 Covered entities	102
NPP, Mailing	0.25/60 × $43.80	15,000,000 Subscribers	3
NPP, Posting Online	15/60 × $97.82	774,331 Covered entities	19
Policies & Procedures	150/60 × $157.48	774,331 Covered entities	305
Training	90/60 × $67.18	774,331 Covered entities	78
Capital Expenses, Mailing NPPs—Health Plans	$.85/NPP	15,000,000 Subscribers	13
Total Nonrecurring Burden			[a] 574

[a] Totals may not add up due to rounding.

Table 7 summarizes the recurring costs that the Department anticipates covered entities will incur annually as a result of the regulatory changes. These new costs are based on responding to requests for uses and disclosures of PHI that are conditioned upon an attestation.

TABLE 7—RECURRING ANNUAL COSTS OF COMPLIANCE WITH THE FINAL RULE [a]

Recurring costs	Burden hours × wage	Respondents	Total annual cost (millions)
Disclosures for which an attestation is required	232,850 × $88.41	2,794,201	$20,585,500
Attestation investigation review	1,300 × $157.48	1,300	204,724
Attestation additional actions	975 × 123.06	325	119,984
Total Recurring Annual Burden			20,910,207

[a] Totals may not add up due to rounding.

Costs Borne by the Department

The covered entities that are operated by the Department will be affected by the changes in a similar manner to other covered entities, and such costs have been factored into the estimates above.

The Department expects that it will incur costs related to drafting and disseminating a model attestation form and information about the regulatory changes to covered entities, including health care providers and health plans. In addition, the Department anticipates that it may incur a 26-fold increase in the number of requests for exceptions from preemption of contrary state law in the first year after a final rule becomes effective, at an estimated total cost of approximately $146,319 to analyze and develop responses for an average cost of $7,410 per request. This increase is based on the number of states that have enacted or are likely to enact laws restricting access to reproductive health care [439] and may seek to obtain individuals' PHI to enforce those laws. This estimate assumes that the Department receives and reviews exception requests from the 26 states, that half require a more complex analysis, and that all requests result in a written response within one year of the final rule's publication.

Benefits of the Final Rule

The benefits of this final rule to individuals and families are likely substantial, and yet are not fully quantifiable because the area of health care this final rule addresses is among the most sensitive and life-altering if privacy is violated. Additionally, the value of privacy, which cannot be recovered once lost, and trust that privacy will be protected by others, is difficult to quantify fully. Health privacy has many significant benefits, such as promoting effective communication between individuals and health care providers, preventing discrimination, enhancing autonomy, supporting medical research, and protecting the individual from unwanted exposure of sensitive health information.[440]

Notably, reproductive health care may include circumstances resulting in a pregnancy, considerations concerning maternal and fetal health, family genetic conditions, information concerning sexually transmitted infections, and the relationship between prospective parents (including victimization due to rape, incest, or sex trafficking). Involuntary or poorly-timed disclosures can irreparably harm relationships and reputations, and even result in job loss or other negative consequences in the workplace,[441] as well as investigation, civil litigation or proceedings, and prosecution for lawful activities.[442] Additionally, fear of potential penalties or liability that may result from disclosing information to a health care provider about accessing reproductive health care may cast a long shadow, decreasing trust between individuals and health care providers, discouraging and deterring access to other valuable and necessary health care, or compromising ongoing or subsequent care if an individual's medical records are not accurate or complete.[443] This final rule will prevent or reduce the harms discussed here, resulting in non-quantifiable benefits to individuals and their families, friends, and health care providers. In particular, the role of trust in the health care system and its importance to the provision of high-quality health care is discussed extensively in Section III of this preamble.

The Department anticipates that this final rule will increase health literacy by improving access to complete information about health care options for individuals.[444] For example, the prohibition on the use and disclosure of PHI for purposes of investigating or imposing liability on an individual, a person assisting them, or their health care provider for lawful health care will increase individuals' access to complete information about their health care options because they will have increased confidence to share information about their life, including their health, with health care providers. In turn, the receipt of more complete information from patients will enable

[439] *See* ''One Year After *Dobbs*—Vast Changes to the Abortion Legal Landscape,'' *supra* note 432 (counting 21 states with post-*Dobbs* limits that are more restrictive than *Roe* v. *Wade* allowed) and ''State Laws Restricting or Prohibiting Abortion,'' *supra* note 432. Because of the pace of change in this area, the Department relies on a higher number than JAMA's 2023 figure as a basis for its cost estimates.

[440] *See* ''Trust and Privacy: How Patient Trust in Providers is Related to Privacy Behaviors and Attitudes,'' *supra* note 120; Paige Nong et al., ''Discrimination, trust, and withholding information from providers: Implications for missing data and inequity,'' SSM—Population Health (Apr. 7, 2022), *https://www.sciencedirect.com/science/article/pii/S2352827322000714; See also* S.J. Nass et al., ''Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research,'' Institute of Medicine (US) Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule (2009), *https://www.ncbi.nlm.nih.gov/books/NBK9579/.*

[441] *See* Danielle Keats Citron & Daniel J. Solove, ''Privacy Harms,'' GWU Legal Studies Research Paper No. 2021–11, GWU Law School Public Law Research Paper No. 2021–11, 102 B.U. L. Rev. 793, 830–861 (Feb. 9, 2021), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3782222.*

[442] *See* ''Reclaiming Tort Law to Protect Reproductive Rights,'' *supra* note 152.

[443] See Div. of Reproductive Health, Nat'l Ctr. for Chronic Disease Prevention and Health Promotion, ''Women With Chronic Conditions Struggle to Find Medications After Abortion Laws Limit Access,'' Ctrs. for Disease Control and Prevention (Jan. 4, 2023), *https://www.cdc.gov/teenpregnancy/health-care-providers/index.htm;* see also Brittni Frederiksen et al., ''Abortion Bans May Limit Essential Medications for Women with Chronic Conditions,'' Kaiser Family Foundation (Nov. 17, 2022), *https://www.kff.org/womens-health-policy/issue-brief/abortion-bans-may-limit-essential-medications-for-women-with-chronic-conditions/.*

[444] *See* Lynn M. Yee et al., ''Association of Health Literacy Among Nulliparous Individuals and Maternal and Neonatal Outcomes,'' JAMA Network Open (Sept. 1, 2021), *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783674.*

health care providers to provide more accurate and relevant medical information about lawful reproductive health care, and the new prohibition will enable them to do so without fear of serious and costly professional repercussions.

This final rule will also contribute to increased access to prenatal health care at the critical early stages of pregnancy by affording individuals the assurance that they may obtain lawful reproductive health care without fearing that records related to that care would be subject to disclosure. For example, if a sexually active individual fears they or their health care providers could be subject to prosecution as a result of disclosure of their PHI, the individual may avoid informing health care providers about symptoms or asking questions of medical experts and may consequently fail to receive necessary support and health care for a pregnancy diagnosis.[445] Similarly, this final rule will likely contribute to a decreased rate of maternal mortality and morbidity by improving access to information about health services.[446]

Additionally, this final rule will enhance the mental health and emotional well-being of individuals seeking or obtaining lawful reproductive health care by reducing fear that their PHI will be disclosed to investigate or impose liability on the individual, their health care provider, or any persons facilitating the individual's access to lawful reproductive health care. This is especially important for individuals who need access to reproductive health care because they are survivors of rape, incest, or sex trafficking. For at least some such individuals, certain types of reproductive health care, including abortion, often remain legal even if pregnancy termination is not available to the broader population under state law. The Department expects that this final rule will help to prevent or reduce re-victimization of pregnant individuals who have been subject to rape, incest, or sex trafficking by protecting their PHI from disclosure.

Activities conducted to investigate and impose liability that rely on that information may be costly to defend against and thus are financially draining for the target of those activities and for persons who are not the target of the activity but whose information may be used as evidence against others. Witnesses or targets of such activities may lose time from work and incur steep legal bills that create unmanageable debt or otherwise harm the economic stability of the individual, their family, and their health care provider. In the absence of this final rule, much of the costs may be for defending against the unwanted use or disclosure of PHI. Thus, the Department expects that this final rule will contribute to families' economic well-being by reducing the risk of exposure to costly activities to investigate or impose liability on persons for lawful activities as a result of disclosures of PHI.

This final rule will also contribute to improved continuity of care and ongoing and subsequent health care for individuals, thereby improving health outcomes. If a health care provider believes that PHI is likely to be disclosed without the individual's or the health care provider's knowledge or consent, possibly to initiate or be used in criminal or civil proceedings against the individual, their health care provider, or others, the health care provider is more likely to omit information about an individual's medical history or condition, leave gaps, or include inaccuracies when preparing the individual's medical records. And if an individual's medical records lack complete information about the individual's health history, a subsequent health care provider may not be able to conduct an appropriate health assessment to reach a sound diagnosis and recommend the best course of action for the individual. Alternatively, health care providers may withhold from the individual full and complete information about their treatment options because of liability concerns stemming from fears about the privacy of an individual's PHI.[447] Heightened confidentiality and privacy protections enable a health care provider to feel confident maintaining full and complete patient records. Without complete patient records, an individual is less likely to receive appropriate ongoing or future health care, including correct diagnoses, and will be impeded in making informed treatment decisions.

Comparison of Benefits and Costs

A few commenters stated that the 2023 Privacy Rule NPRM reflected the staffing costs of covered entities in full. One posited that covered entities will receive more requests for PHI because of changes in the legal environment after *Dobbs,* which will require some regulated entities that may not typically get such requests to adjust according to the changes in the law and how it is enforced. Another commenter stated that the proposed rule did not account for higher staffing costs from more highly qualified employees. The commenters did not provide any relevant data or discussion of methodology for how these costs should be quantified. Therefore, the Department did not include any additional labor costs in the economic analysis based on this comment.

A few additional commenters expressed general concerns related to electronic health record (EHR) systems and data storage. One urged the Department to include costs associated with updating EHR systems to ensure compliance and to allow for data segmentation. Another asserted that the current classifications for different types of PHI are not clear enough for effective data segmentation, contributing to increased costs. As a result, they recommended that the Department provide clearer guidelines on the different types of PHI. The Department did not attempt to estimate additional data maintenance or EHR-related costs because any adjustments will be part of the regular cost of business for regulated entities.

A commenter stated that the Department did not quantify the costs associated with violations of the rule by regulated entities, such as incurring a monetary penalty after impermissibly responding to a court order. The Department does not quantify the costs of noncompliance as part of its analysis. Whether a violation will result in a monetary penalty is dependent on numerous factors and the aim of the Department's enforcement is to bring regulated entities into compliance.

A few commenters asserted that the proposed rule would make it more difficult for law enforcement to investigate criminals for crimes related to sex and recommended that the Department quantify this cost. The Department acknowledges that the final rule may result in some changes to procedures for handling law enforcement requests for PHI; however, the burden on regulated entities is calculated in its cost estimates. The Department is unable to quantify the burdens to law enforcement resulting from this final rule. However, to address concerns about victims' ability to disclose their PHI related to reproductive health care, the final rule

[445] *See* ''Texas Maternal Mortality and Morbidity Review Committee and Department of State Health Services Joint Biennial Report 2022,'' *supra* note 123.

[446] *See* Helen Levy & Alex Janke, ''Health Literacy and Access to Care,'' J. of Health Commc'n (2016), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4924568/; see also* Brief for Zurawski, *Zurawski* v. *State of Texas* (No. D–1–GN–23–000968) (W.D. Tex. 2023), *https://reproductiverights.org/wp-content/uploads/2023/03/Zurawski-v-State-of-Texas-Complaint.pdf.*

[447] *See* Brief for Zurawski, at 10, *supra* note 447.

permits individuals to authorize disclosures for any purpose, including law enforcement investigations. Therefore, the Department is not including costs to law enforcement in the quantified costs and benefits analysis. The Department expects the totality of the benefits of this final rule to outweigh the costs, particularly in light of the privacy benefits for individuals who could become pregnant (nearly one-fourth of the U.S. population in any given year) and seek access to lawful health care without the risk of their PHI being used or disclosed in furtherance of activities to conduct criminal, civil, or administrative investigations or impose liability without their authorization. The Department expects covered entities and individuals to benefit from covered entities' increased confidence to be able to provide lawful health care according to professional standards.

The Department's qualitative benefit-cost analysis asserts that the regulatory changes in this final rule will support an individual's privacy with respect to lawful health care, enhance the relationship between health care providers and individuals, strengthen maternal well-being and family stability, and support victims of rape, incest, and sex trafficking. The regulatory changes will also aid health care providers in developing and maintaining a high level of trust with individuals and maintaining complete and accurate medical records to aid ongoing and subsequent health care. Greater levels of trust will further enable individuals to develop and maintain relationships with health care providers, which would enhance continuity of health care for all individuals receiving care from the health care provider, not only individuals in need of reproductive health care.

The financial costs of this final rule will accrue primarily to covered entities, particularly health care providers and health plans in the first year after implementation of a final rule, with recurring costs accruing annually at a lower rate.

B. Regulatory Alternatives to the Final Rule

In addition to regulatory proposals in the 2023 Privacy Rule NPRM that are not adopted here, the Department considered several alternatives to the policies finalized in this rule.

Define Public Health in the Context of Public Health Surveillance, Intervention, or Investigation

The Department considered alternatives to the proposed definition of ''public health'' in the context of public health surveillance, investigation, and intervention, particularly the reference to population-level activities. Specifically, the Department considered whether to add ''individual-level'' to further distinguish public health surveillance, investigation, and intervention from other activities but did not adopt this approach because it would add a new undefined term that would generate more complexity without adding clarity. The Department also considered removing ''population-level'' from the definition in this final rule, but we are not adopting that approach because it might lead people to believe that the focus of public health is not on activities benefiting the population as a whole. Additionally, the Department considered defining ''public health'' surveillance, investigation, or intervention only in the negative—that is, by listing activities that are excluded—but decided not to adopt this approach to ensure that stakeholders understand what public health surveillance, investigation, or intervention means.

Modify Prohibition To Presume That Reproductive Health Care Is Lawful Absent Actual Knowledge

The Department considered adding a provision that would allow regulated entities to presume that certain requests for PHI are about reproductive health care that was lawful under the circumstances in which such health care was provided where it was provided by someone other than the regulated entity receiving the PHI request, unless the regulated entity had actual knowledge that such health care was not lawful under the circumstances in which it was provided. However, in consultation with Federal partners, the Department decided to finalize a second exception to the presumption to permit uses or disclosures of PHI where privacy interests are reduced, as compared to the societal interest in the PHI for certain non-health care purposes. This exception is available where factual information supplied by the person requesting the use or disclosure of PHI demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

Administrative Requests by Law Enforcement

The Department received reports that not all regulated entities are interpreting the administrative request provision correctly and proposed a clarification to 45 CFR 164.512(f)(1)(ii)(C). To address concerns that disclosures currently made under Federal agencies' interpretations of the Privacy Act of 1974[448] would not be permitted under the NPRM proposal, the Department considered adding qualifying language to paragraph 45 CFR 164.512(f)(1)(ii)(C) to state that PHI may be disclosed by a Federal agency in response to an administrative request from law enforcement where the Federal agency is authorized, but not required, to disclose under applicable law (*see, e.g.,* the Privacy Act and OMB 1975 Guidelines[449]). However, the Department determined that the contemplated change was not necessary because the intent of the Privacy Rule was adequately captured in the clarification proposed in the NPRM and finalized in this rule at 45 CFR 164.512(f)(1)(ii)(C). As finalized, this provision permits disclosures to law enforcement in response to ''an administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law.''

Scope of Prohibited Conduct

In response to public comments on the 2023 Privacy Rule NPRM, the Department considered several approaches to outlining prohibited conduct. One approach was creating a category of ''highly sensitive PHI'' and prohibiting its use and disclosure in certain proceedings based on the mere act of, for example, obtaining, providing, or aiding that category of health care. The Department did not adopt this category based on many concerns expressed in public comments. For example, distinguishing between the sensitivity of different types of PHI would require complicated subjective determinations, and prohibiting or limiting uses or disclosures of highly sensitive PHI for certain purposes could negatively affect efforts to eliminate data segmentation and further stigmatize the types of health care included in the ''highly sensitive'' category.

Another approach the Department considered was to require an attestation for all requested uses and discloses of PHI under 45 CFR 164.512(d)–(g)(1), rather than limiting the requirement to only requested uses and disclosures of PHI potentially related to reproductive health care under such provisions. This would have reduced the burden on

[448] Public Law 93–579, 88 Stat. 1896 (Dec. 31, 1974) (codified at 5 U.S.C. 552a).

[449] 40 FR 28948, 28955 (July 9, 1975).

regulated entities to screen requested PHI for whether it contained information potentially related to reproductive health care and increased the burden on persons requesting PHI to evaluate and attest to all requests for use and disclosure of PHI under 45 CFR 164.512(d)–(g)(1). However, in recognition of the importance of oversight and law enforcement entities' ability to obtain PHI for legitimate inquiries, the Department decided not to require an attestation for all requests under these provisions.

Requiring an Attestation Under Penalty of Perjury

The Department requested comments about the possibility of adding a required penalty of perjury statement to strengthen the attestation requirement but did not propose this statement in the 2023 Privacy Rule NPRM. After reviewing public comments on this topic, the Department considered adding a requirement that the attestation be signed by the person requesting the use or disclosure of PHI under penalty of perjury but did not adopt such a requirement in the final rule. As discussed in greater detail above, a person who knowingly and in violation of the Administrative Simplification provisions of HIPAA obtains or discloses IIHI relating to another individual or discloses IIHI to another person is subject to criminal liability.[450] Thus, a person who knowingly and in violation of HIPAA [451] falsifies an attestation (*e.g.,* makes material misrepresentations about the intended uses of the PHI requested) to obtain (or cause to be disclosed) an individual's IIHI could be subject to criminal penalties as outlined in the statute. The Department believes such penalties are sufficient to hold persons who knowingly submit false attestations accountable for their actions and deter such submissions entirely.

Right To Request Restrictions

In the 2023 Privacy Rule NPRM, the Department requested comments regarding the right of individuals to request restrictions of uses and disclosures of their PHI. We did not propose any changes to this provision in the 2023 Privacy Rule NPRM, nor are we proposing or finalizing any modifications to it at this time. We appreciate the comments we received regarding expanding the rights to request disclosures and will take them under advisement when we consider future modifications to the Privacy Rule.

C. Regulatory Flexibility Act—Small Entity Analysis

The Department has examined the economic implications of this final rule as required by the RFA. If a rule has a significant economic impact on a substantial number of small entities, the RFA requires agencies to analyze regulatory options that would reduce the economic effect of the rule on small entities.

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The Act defines ''small entities'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, and (3) a small government jurisdiction of less than 50,000 population. A few commenters raised concerns about the effects of the proposed rule on small or rural providers and requested additional analysis, guidance, or technical assistance from the Department to aid these entities. The Department did not receive any public comments on the small business analysis assumptions used in the NPRM. Accordingly, we are not changing the baseline assumptions for this final rule. We have updated our analysis of small entities for consistency with revisions to the RIA for the costs and savings for covered entities. The Department has determined that roughly 90 percent or more of all health care providers meet the SBA size standard for a small business or are a nonprofit organization. Therefore, the Department estimates that there are 696,898 small entities affected by the final rule.[452] The SBA size standard for health care providers ranges between a maximum of $16 million and $47 million in annual receipts, depending upon the type of entity.[453]

With respect to health insurers, the SBA size standard is a maximum of $47 million in annual receipts, and for third party administrators it is $45.5 million.[454] While some insurers are classified as nonprofit, it is possible they are dominant in their market. For example, a number of Blue Cross/Blue Shield insurers are organized as nonprofit entities; yet they dominate the health insurance market in the states where they are licensed.[455]

For the reasons stated below, we do not expect that the cost of compliance will be significant for small entities. Nor do we expect that the cost of compliance will fall disproportionately on small entities. Although many of the covered entities affected by this final rule are small entities, they will not bear a disproportionate cost burden compared to the other entities subject to the rule. The projected total costs are discussed in detail in the RIA. The Department does not view this as a substantial burden because the result of the changes will be annualized costs per covered entity of approximately $184 [= $142.6 million [456]/774,331 covered entities]. In the context of the RFA, HHS generally considers an economic impact exceeding 3 percent of annual revenue to be significant, and 5 percent or more of the affected small entities within an identified industry to represent a substantial number. The quantified impact of $184 per covered entity would only apply to covered entities whose annual revenue is $6,133 or less. We believe almost all, if not all covered entities have annual revenues that exceed this amount. Accordingly, the Department has determined that this final rule is unlikely to affect a substantial number of small entities that meet the RFA threshold. Thus, this analysis concludes, and the Secretary certifies, that the rule will not result in a significant economic effect on a substantial number of small entities.

D. Executive Order 13132—Federalism

As required by E.O. 13132 on Federalism, the Department has examined the provisions in both the proposed and final regulation for their effects on the relationship between the Federal Government and the states. In the Department's view, the final regulation may have federalism implications because it may have direct effects on the states, the relationship between the Federal Government and states, and on the distribution of power and responsibilities among various

[450] 42 U.S.C. 1320d–6(a).

[451] A person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d–9(b)(3) of this title) and the individual obtained or disclosed such information without authorization. *Id.*

[452] 696,898 = 774,331 × .90.

[453] *See* U.S. Small Business Administration, Table of Small Business Size Standards (Mar. 17, 2023), *https://www.sba.gov/sites/sbagov/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf.*

[454] *Id.*

[455] Kaiser Family Foundation, ''Market Share and Enrollment of Largest Three Insurers—Large Group Market'' (2019), *https://www.kff.org/other/state-indicator/market-share-and-enrollment-of-largest-three-insurers-large-group-market/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[456] This figure represents annualized costs discounted at a 3% rate.

levels of government relating to the disclosure of PHI.

The changes from this final rule flow from and are consistent with the underlying statute, which authorizes the Secretary to issue regulations that govern the privacy of PHI. The statute provides that, with limited exceptions, such regulations supersede contrary provisions of state law unless the provision of state law imposes more stringent privacy protections than the Federal law.[457]

Section 3(b) of E.O. 13132 recognizes that national action limiting the policymaking discretion of states will be imposed only where there is constitutional and statutory authority for the action and the national activity is appropriate when considering a problem of national significance. The privacy of PHI is of national concern by virtue of the scope of interstate health commerce. As described in the preamble to the proposed rule and this final rule, recent state actions affecting reproductive health care have undermined the longstanding expectation among individuals in all states that their highly sensitive reproductive health information will remain private and not be used against them for seeking or obtaining legal health care. These state actions thus directly threaten the trust that is essential to ensuring access to, and quality of, lawful health care. HIPAA's provisions reflect this position by authorizing the Secretary to promulgate regulations to implement the Privacy Rule.

Section 4(a) of E.O. 13132 expressly contemplates preemption when there is a conflict between exercising state and Federal authority under a Federal statute. Section 4(b) of the E.O. authorizes preemption of state law in the Federal rulemaking context when ''the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.'' The approach in this regulation is consistent with the standards in the E.O. because it supersedes state authority only when such authority is inconsistent with standards established pursuant to the grant of Federal authority under the statute.

State and local laws that impinge on the privacy protections for PHI of individuals who obtain lawful reproductive health care undermine Congress' directive to develop a health information system for the purpose of improving the effectiveness of the health care system, which requires that all individuals who receive health care legally are assured a minimum level of privacy for their PHI. Congress established specific, narrow exceptions to preemption that did not include the use or disclosure of an individual's medical records for law enforcement purposes generally. Nor did Congress include a specific exception to preemption that would permit states to use PHI against that individual, health care providers, or third parties merely for seeking, obtaining, providing, or facilitating lawful health care.[458] Both the personal and public interest is served by protecting PHI so as not to undermine an individual's access to and quality of lawful health care services and their trust in the health care system.

The Department anticipates that the most significant direct costs on state and local governments would be the cost for state and local government-operated covered entities to revise business associate agreements, revise policies and procedures, update the NPP, update training programs, and process requests for disclosures for which an attestation is required. These costs would be similar in kind to those borne by non-government operated covered entities. In addition, the Department anticipates that approximately half of the states may choose to file a request for an exception to preemption. The longstanding regulatory provisions that govern preemption exception requests under the HIPAA Rules would remain undisturbed by this rule.[459] However, based on the legal developments in some states that are described elsewhere in this preamble, the Department anticipates that in the first year of implementation of a final rule, more states will submit requests for exceptions from preemption than have done so in the past. The RIA above addresses these costs in detail.

Pursuant to the requirements set forth in section 8(a) of E.O. 13132, and by the signature affixed to the final rule, the Department certifies that it has complied with the requirements of E.O. 13132, including review and consideration of comments from state and local government officials and the public about the interaction of this rule with state activity, for the final rule in a meaningful and timely manner.

E. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999[460] requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. This final rule is expected to strengthen the stability of the family and marital commitment because it protects individual privacy in the context of sensitive decisions about family planning. The rule may be carried out only by the Federal Government because it would modify Federal health privacy law, ensuring that American families have confidence in the privacy of their information about lawful reproductive health care, regardless of the state where they are located when health care is provided. Such health care privacy is vital for individuals who may become pregnant or who are capable of becoming pregnant.

F. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995[461] (PRA), agencies are required to submit to OMB for review and approval any reporting or record-keeping requirements inherent in a proposed or final rule and are required to publish such proposed requirements for public comment. To fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;

2. The accuracy of the agency's estimate of the information collection burden;

3. The quality, utility, and clarity of the information to be collected; and

4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department considered public comments on its assumptions and burden estimates in the 2023 Privacy Rule NPRM and addresses those comments above in the discussion of benefits and costs of this final rule.

In this RIA, the Department is revising certain information collection requirements associated with this final rule and, as such, is revising the information collection last prepared in

[457] 42 U.S.C. 1320d–7(a)(1).

[458] 42 U.S.C. 1320d–7(a)(2)(A).

[459] 45 CFR 160.201 through 160.205.

[460] Public Law 105–277, 112 Stat. 2681 (Oct. 21, 1998).

[461] Public Law 104–13, 109 Stat. 163 (May 22, 1995).

2023 and approved under OMB control #0945–0003. The revised information collection describes all new and adjusted information collection requirements for covered entities pursuant to the implementing regulation for HIPAA at 45 CFR parts 160 and 164, the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules (''HIPAA Rules'').

The estimated annual labor burden presented by the regulatory modifications in the first year of implementation, including nonrecurring and recurring burdens, is 4,584,224 burden hours at a cost of $582,242,165 [462] and $20,910,207 of estimated annual labor costs in years two through five. The overall total burden for respondents to comply with the information collection requirements of all of the HIPAA Privacy, Security, and Breach Notification Rules, including nonrecurring and recurring burdens presented by program changes, is 953,982,236 burden hours at a cost of $107,336,705,941, plus $197,364,010 in capital costs for a total estimated annual burden of $107,534,069,951 in the first year following the effective date of the final rule. Details describing the burden analysis for the proposals associated with this RIA are presented below and explained further in the ICR associated with this final rule.

Explanation of Estimated Annualized Burden Hours

Below is a summary of the significant program changes and adjustments made since the approved 2023 ICR; because the ICR addresses regulatory burdens associated with the full suite of HIPAA Rules, the changes and adjustments include updated data and estimates for some provisions of the HIPAA Rules that are not affected by this final rule. These program changes and adjustments form the bases for the burden estimates presented in the ICR associated with this RIA.

Adjusted Estimated Annual Burdens of Compliance

(1) Increasing the number of covered entities from 700,000 to 774,331 based on program change.

(2) Increasing the number of respondents requesting exceptions to state law preemption from 1 to 27 based on an expected reaction by states that have enacted restrictions on reproductive health care access.

(3) Increasing the burden hours by a factor of two for responding to individuals' requests for restrictions on disclosures of their PHI under 45 CFR 164.522 to represent a doubling of the expected requests.

(4) Updating the number of breaches for which notification is required to reflect data in OCR's 2022 Report to Congress [463] and related burdens.

(5) Increasing the number of estimated uses and disclosures for research purposes.

(6) Increasing the total number of NPPs distributed by health plans by 50% to total 300,000,000 due to the increase in number of Americans with health coverage.

New Burdens Resulting from Program Changes

In addition to these changes, the Department added new annual burdens as a result of program changes in the final rule:

(1) A nonrecurring burden of 1 hour for each of 350,000 business associate agreements that is likely to be revised as a result of the changes to handling requests for PHI under 45 CFR 164.512(d), (e), (f), and (g)(1), to allocate responsibilities between covered entities and their release-of-information contractors.

(2) A recurring burden of 5 minutes per request for staff to determine whether an attestation is required for disclosure under 45 CFR 164.509.

(3) A recurring burden of 1 hour per request for legal review of whether certain requests identified by staff as potentially requiring an attestation pertain to the lawfulness of reproductive health care.

(4) A recurring burden of 3 hours per request for a percentage of requests requiring legal review that might require additional manager review to determine whether the requirements at 45 CFR 164.509 are met.

(5) A nonrecurring burden of 50 minutes per covered entity to update the required content of its NPP.

(6) A nonrecurring burden of 15 minutes per covered entity for posting an updated NPP online.

(7) A nonrecurring burden of 2.5 hours for each covered entity to update its policies and procedures.

(8) A nonrecurring burden of 90 minutes for each covered entity to update the content of its HIPAA training program.

[462] This includes an increase of 416 burden hours and $36,442 in costs added to the existing information collection for requesting exemption determinations under 45 CFR 160.204.

[463] *See* Off. for Civil Rights, ''Annual Report to Congress on Breaches of Unsecured Protected Health Information,'' U.S. Dep't of Health and Human Servs. (2022), *https://www.hhs.gov/hipaa/for-professionals/breach-notification/reports-congress/index.html.*

List of Subjects

45 CFR Part 160

Health care, Health records, Preemption, Privacy, Public health, Reproductive health care.

45 CFR Part 164

Health care, Health records, Privacy, Public health, Reporting and recordkeeping requirements, Reproductive health care.

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter C, parts 160 and 164 as set forth below:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 160 continues to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); 5 U.S.C. 552; secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279; and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

■ 2. Amend § 160.103 by:
■ a. Revising the definition of ''Person''; and
■ b. Adding in alphabetical order the definitions of ''Public health'' and ''Reproductive health care''.

The revision and additions read as follows:

§ 160.103 Definitions.

* * * * *

Person means a natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

* * * * *

Public health, as used in the terms ''public health surveillance,'' ''public health investigation,'' and ''public health intervention,'' means population-level activities to prevent disease in and promote the health of populations. Such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information. But such activities do not include those with any of the following purposes:

(1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(3) To identify any person for any of the activities described at paragraphs (1) or (2) of this definition.

Reproductive health care means health care, as defined in this section, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

* * * * *

PART 164—SECURITY AND PRIVACY

■ 3. The authority citation for part 164 continues to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)); and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279.

■ 4. Amend § 164.502 by
■ a. Revising paragraph (a)(1)(vi);
■ b. Adding paragraph (a)(5)(iii); and
■ c. Revising paragraph (g)(5).

The addition and revisions read as follows:

§ 164.502 Uses and disclosures of protected health information: General rules.

(a) * * *

(1) * * *

(vi) As permitted by and in compliance with any of the following:

(A) This section.

(B) Section 164.512 and, where applicable, § 164.509.

(C) Section 164.514(e), (f), or (g).

* * * * *

(5) * * *

(iii) *Reproductive health care*—(A) *Prohibition.* Subject to paragraphs (a)(5)(iii)(B) and (C) of this section, a covered entity or business associate may not use or disclose protected health information for any of the following activities:

(*1*) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(*2*) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(*3*) To identify any person for any purpose described in paragraphs (a)(5)(iii)(A)(*1*) or (*2*) of this section.

(B) *Rule of applicability.* The prohibition at paragraph (a)(5)(iii)(A) of this section applies only where the relevant activity is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care, and the covered entity or business associate that received the request for protected health information has reasonably determined that one or more of the following conditions exists:

(*1*) The reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided.

(*2*) The reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided.

(*3*) The presumption at paragraph (a)(5)(iii)(C) of this section applies.

(C) *Presumption.* The reproductive health care provided by another person is presumed lawful under paragraph (a)(5)(iii)(B)(*1*) or (*2*) of this section unless the covered entity or business associate has any of the following:

(*1*) Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided.

(*2*) Factual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.

(D) *Scope.* For the purposes of this subpart, seeking, obtaining, providing, or facilitating reproductive health care includes, but is not limited to, any of the following: expressing interest in, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, administering, authorizing, providing coverage for, approving, counseling about, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same.

* * * * *

(g) * * *

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative, provided that the conditions at paragraphs (g)(5)(i) and (ii) of this section are met:

(i) Paragraphs (g)(5)(i)(A) and (B) of this section both apply.

(A) The covered entity has a reasonable belief that any of the following is true:

(*1*) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person.

(*2*) Treating such person as the personal representative could endanger the individual.

(B) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(ii) The covered entity does not have a reasonable belief under paragraph (g)(5)(i)(A) of this section if the basis for their belief is the provision or facilitation of reproductive health care by such person for and at the request of the individual.

* * * * *

■ 5. Add § 164.509 to read as follows:

§ 164.509 Uses and disclosures for which an attestation is required.

(a) *Standard: Attestations for certain uses and disclosures of protected health information to persons other than covered entities or business associates.* (1) A covered entity or business associate may not use or disclose protected health information potentially related to reproductive health care for purposes specified in § 164.512(d), (e), (f), or (g)(1), without obtaining an attestation that is valid under paragraph (b)(1) of this section from the person requesting the use or disclosure and complying with all applicable conditions of this part.

(2) A covered entity or business associate that uses or discloses protected health information potentially related to reproductive health care for purposes specified in § 164.512(d), (e), (f), or (g)(1), in reliance on an attestation that is defective under paragraph (b)(2) of this section, is not in compliance with this section.

(b) *Implementation specifications: General requirements*—(1) *Valid attestations.* (i) A valid attestation is a document that meets the requirements of paragraph (c)(1) of this section.

(ii) A valid attestation verifies that the use or disclosure is not otherwise prohibited by § 164.502(a)(5)(iii).

(iii) A valid attestation may be electronic, provided that it meets the requirements in paragraph (c)(1) of this section, as applicable.

(2) *Defective attestations.* An attestation is not valid if the document submitted has any of the following defects:

(i) The attestation lacks an element or statement required by paragraph (c) of this section.

(ii) The attestation contains an element or statement not required by paragraph (c) of this section

(iii) The attestation violates paragraph (b)(3) of this section.

(iv) The covered entity or business associate has actual knowledge that material information in the attestation is false.

(v) A reasonable covered entity or business associate in the same position would not believe that the attestation is true with respect to the requirement at paragraph (c)(1)(iv) of this section.

(3) *Compound attestation.* An attestation may not be combined with any other document except where such other document is needed to satisfy the requirements at paragraph (c)(iv) of this section or at § 164.502(a)(5)(iii)(C), as applicable.

(c) *Implementation specifications: Content requirements and other obligations*—(1) *Required elements.* A valid attestation under this section must contain the following elements:

(i) A description of the information requested that identifies the information in a specific fashion, including one of the following:

(A) The name of any individual(s) whose protected health information is sought, if practicable.

(B) If including the name(s) of any individual(s) whose protected health information is sought is not practicable, a description of the class of individuals whose protected health information is sought.

(ii) The name or other specific identification of the person(s), or class of persons, who are requested to make the use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity is to make the requested use or disclosure.

(iv) A clear statement that the use or disclosure is not for a purpose prohibited under § 164.502(a)(5)(iii).

(v) A statement that a person may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if that person knowingly and in violation of HIPAA obtains individually identifiable health information relating to an individual or discloses individually identifiable health information to another person.

(vi) Signature of the person requesting the protected health information, which may be an electronic signature, and date. If the attestation is signed by a representative of the person requesting the information, a description of such representative's authority to act for the person must also be provided.

(2) *Plain language requirement.* The attestation must be written in plain language.

(d) *Material misrepresentations.* If, during the course of using or disclosing protected health information in reasonable reliance on a facially valid attestation, a covered entity or business associate discovers information reasonably showing that any representation made in the attestation was materially false, leading to a use or disclosure for a purpose prohibited under § 164.502(a)(5)(iii), the covered entity or business associate must cease such use or disclosure.

* * * * *

■ 6. Amend § 164.512 by:

■ a. Revising the introductory text and the paragraph (c) paragraph heading;

■ b. Adding paragraph (c)(3); and

■ c. Revising paragraph (f)(1)(ii)(C) introductory text.

The revisions and addition read as follows:

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

Except as provided by § 164.502(a)(5)(iii), a covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section and § 164.509. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given verbally.

* * * * *

(c) *Standard: Disclosures about victims of abuse, neglect, or domestic violence*—* * *

(3) *Rule of construction.* Nothing in this section shall be construed to permit disclosures prohibited by § 164.502(a)(5)(iii) when the sole basis of the report of abuse, neglect, or domestic violence is the provision or facilitation of reproductive health care.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(C) An administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

* * * * *

■ 7. Amend § 164.520 by:

■ a. Revising and republish paragraphs (a) and (b); and

■ b. Adding paragraph (d)(4).

The revisions and additions read as follows:

§ 164.520 Notice of privacy practices for protected health information.

* * * * *

(a) *Standard: Notice of privacy practices*—(1) *Right to notice.* Except as provided by paragraph (a)(3) or (4) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) *Notice requirements for covered entities creating or maintaining records subject to 42 U.S.C. 290dd-2.* As provided in 42 CFR 2.22, an individual who is the subject of records protected under 42 CFR part 2 has a right to adequate notice of the uses and disclosures of such records, and of the individual's rights and the covered entity's legal duties with respect to such records.

(3) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO

offered by the plan, is not required to maintain or provide a notice under this section.

(4) *Exception for inmates.* An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.

(b) *Implementation specifications: Content of notice*—(1) *Required elements.* The covered entity, including any covered entity receiving or maintaining records subject to 42 U.S.C. 290dd-2, must provide a notice that is written in plain language and that contains the elements required by this paragraph.

(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed:

''THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.''

(ii) *Uses and disclosures.* The notice must contain:

(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.

(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, such as 42 CFR part 2, the description of such use or disclosure must reflect the more stringent law as defined in § 160.202 of this subchapter.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law, such as 42 CFR part 2.

(E) A description of the types of uses and disclosures that require an authorization under § 164.508(a)(2)–(a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by § 164.508(b)(5).

(F) A description, including at least one example, of the types of uses and disclosures prohibited under § 164.502(a)(5)(iii) in sufficient detail for an individual to understand the prohibition.

(G) A description, including at least one example, of the types of uses and disclosures for which an attestation is required under § 164.509.

(H) A statement adequate to put the individual on notice of the potential for information disclosed pursuant to this subpart to be subject to redisclosure by the recipient and no longer protected by this subpart

(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) or (B) of this section must include a separate statement informing the individual of such activities, as applicable:

(A) In accordance with § 164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications;

(B) In accordance with § 164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan;

(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan,* intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes;

(D) Substance use disorder treatment records received from programs subject to 42 CFR part 2, or testimony relaying the content of such records, shall not be used or disclosed in civil, criminal, administrative, or legislative proceedings against the individual unless based on written consent, or a court order after notice and an opportunity to be heard is provided to the individual or the holder of the record, as provided in 42 CFR part 2. A court order authorizing use or disclosure must be accompanied by a subpoena or other legal requirement compelling disclosure before the requested record is used or disclosed; or

(E) If a covered entity that creates or maintains records subject to 42 CFR part 2 intends to use or disclose such records for fundraising for the benefit of the covered entity, the individual must first be provided with a clear and conspicuous opportunity to elect not to receive any fundraising communications.

(iv) *Individual rights.* The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under § 164.522(a)(1)(vi);

(B) The right to receive confidential communications of protected health information as provided by § 164.522(b), as applicable;

(C) The right to inspect and copy protected health information as provided by § 164.524;

(D) The right to amend protected health information as provided by § 164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by § 164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

(v) *Covered entity's duties.* The notice must contain:

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices, and to notify affected individuals following a breach of unsecured protected health information;

(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and

(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.

(vi) *Complaints.* The notice must contain a statement that individuals may complain to the covered entity and

to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.

(vii) *Contact.* The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by § 164.530(a)(1)(ii).

(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) *Optional elements.* (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i).

(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) *Revisions to the notice.* The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

* * * * *

(d) * * *

* * * * *

(4) The permission in paragraph (d) of this section for covered entities that participate in an organized health care arrangement to issue a joint notice may not be construed to remove any obligations or duties of entities creating or maintaining records subject to 42 U.S.C. 290dd-2, or to remove any rights of patients who are the subjects of such records.

* * * * *

■ 8. Add § 164.535 to read as follows:

§ 164.535 Severability.

If any provision of the HIPAA Privacy Rule to Support Reproductive Health Care Privacy is held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–08503 Filed 4–22–24; 4:15 pm]

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Part VI

Department of Transportation

Federal Aviation Administration

14 CFR Parts 5, 21, 91, et al.
Safety Management Systems; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 5, 21, 91, and 119

[Docket No.: FAA–2021–0419; Amdt. Nos. 119–21, 21–108, 5–2, 91–374]

RIN 2120–AL60

Safety Management Systems

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

ACTION: Final rule.

SUMMARY: The FAA is updating requirements for safety management systems and requiring certain certificate holders and commercial air tour operators to develop and implement a safety management system (SMS). This rule extends the requirement for an SMS to all certificate holders operating under the rules for commuter and on-demand operations, commercial air tour operators, production certificate holders that are holders or licensees of a type certificate for the same product, and holders of a type certificate that license out that type certificate for production. The FAA is publishing this rule in part to address a Congressional mandate as well as recommendations from the National Transportation Safety Board and two aviation rulemaking committees. Additionally, the rule more closely aligns the United States with Annex 19 to the Convention on International Civil Aviation. This rule will improve aviation safety by requiring organizations to implement a proactive approach to managing safety.

DATES: Effective May 28, 2024.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see ''How to Obtain Additional Information'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Scott Van Buren, Office of Accident Investigation and Prevention, AVP–4, Federal Aviation Administration, 800 Independence Avenue SW, Room 300 East, Washington, DC 20591, telephone (202) 494–8417; email *Scott.VanBuren@faa.gov.*

SUPPLEMENTARY INFORMATION:

List of Abbreviations and Acronyms Frequently Used In This Document

AC—Advisory Circular
ACSAA—Aircraft Certification, Safety, and Accountability Act of 2020
ANPRM—Advance notice of proposed rulemaking
ARC—Aviation Rulemaking Committee
ASAP—Aviation Safety Action Program
CAA—Civil Aviation Authority
CFR—Code of Federal Regulations
EASA—European Union Aviation Safety Agency
FAA—Federal Aviation Administration
FOIA—Freedom of Information Act
FRFA—Final Regulatory Flexibility Analysis
HTAWS—Helicopter Terrain Awareness and Warning System
ICAO—International Civil Aviation Organization
IRFA—Initial Regulatory Flexibility Analysis
LOA—Letter of Authorization
NAICS—North American Industry Classification System
NPRM—Notice of Proposed Rulemaking
NTSB—National Transportation Safety Board
OMB—Office of Management and Budget
OpSpec—Operations Specifications
PC—Production Certificate
PMA—Parts Manufacturer Approval
RFA—Regulatory Flexibility Act
RIA—Regulatory Impact Analysis
SBA—Small Business Administration
SMS—Safety Management System
STC—Supplemental Type Certificate
TC—Type Certificate
TSOA—Technical Standard Order Authorization
U.S.C.—United States Code
WBAT—Web-Based Analytical Technology

Table of Contents

I. Executive Summary

A. Purpose of the Regulatory Action

A safety management system (SMS) provides an organization-wide approach to identifying safety hazards, assessing and managing safety risk, and assuring the effectiveness of safety risk controls. An SMS provides a set of decision-making processes and procedures that can improve safety by assisting an organization in planning, organizing, directing, and controlling its aviation-related business activities. Currently, the SMS requirements of part 5 of title 14 of the Code of Federal Regulations (CFR) apply only to air carriers certificated under part 119 and conducting operations in accordance with part 121 (part 121 operators). This final rule extends the applicability of the SMS requirements in part 5 to include additional entities to enhance safety, respond to a Congressional mandate, and more closely align the FAA's SMS requirements with International Civil Aviation Organization (ICAO) Annex 19.

Historically, the approach to aviation safety was based on the reactive analysis of past accidents and the introduction of corrective actions to prevent the recurrence of those events. An SMS, in contrast, helps organizations proactively identify potential hazards in the operating environment, analyze the risks of those hazards, and mitigate those risks to prevent an accident or incident. In 2015, the FAA promulgated

14 CFR part 5, which required part 121 operators to develop and implement SMS and set out the basic requirements for those systems. The next step in improving aviation safety is to extend the SMS requirements in part 5 to additional organizations that play a critical role in the design, manufacturing, and operation of aircraft (*i.e.,* part 119 certificate holders operating under part 135, Letter of Authorization (LOA) holders operating commercial air tours under § 91.147, and certain certificate holders under part 21). These aviation organizations are in the best position to prevent future incidents and accidents because they are closest to the hazards, and they know the most about their operations and products.

An SMS provides a structured, repeatable, systematic approach to proactively identify hazards and manage safety risk. With implementation of an SMS, these aviation organizations will be better able to develop and implement mitigations that are appropriate to their environment and operational structure. SMS can be used to avoid or mitigate future aviation accidents. This final rule is based on the recommendations of two previous Aviation Rulemaking Committees (ARCs),[1] the National Transportation Safety Board (NTSB),[2] and the Joint Authorities Technical Review of the Boeing 737 MAX Flight Control System,[3] and consideration of public comments received during the comment period.

Further, the Aircraft Certification, Safety, and Accountability Act of 2020 (Pub. L. 116–260, 134 Stat. 2309, hereafter referred to as ACSAA), enacted on December 27, 2020, mandated the application of SMS regulatory requirements to holders of both a Type Certificate (TC) and a Production Certificate (PC) issued under part 21.[4] Congress further mandated that the FAA include certain requirements in its implementing regulations. The amendments to part 5 are in accordance with this legislation.

Lastly, requiring SMS for certain commercial operators and design and manufacturing organizations more closely aligns the FAA's SMS requirements with ICAO Annex 19; therefore, this final rule increases U.S. alignment with other civil aviation authorities (CAAs) that are also implementing SMS requirements in accordance with ICAO Standards and Recommended Practices.[5]

The FAA emphasizes that the requirements of this rule are limited to those activities that directly affect aviation safety. Therefore, to the extent the organizations covered by this rule also engage in activities that do not directly affect aviation safety (*e.g.,* processing consumer payments, mitigating slip-and-fall accidents on company property, administering employee payroll), those activities need not be covered by an SMS required by this rule (but an organization is not prohibited from covering such activities by its SMS, if it chooses to do so).

B. Changes Made in This Final Rule

After considering the information provided by commenters, the FAA is making several changes in this final rule from what was proposed in the notice of proposed rulemaking (NPRM).[6] Table 1 below summarizes the changes. The changes are discussed in more detail in Section IV.

TABLE 1—SUMMARY OF REGULATORY TEXT CHANGES

Proposed 14 CFR section affected	Description	Summary of final rule changes from NPRM
5.1(e) and 5.1(f)	Applicability of part 5 to part 21 certificate holders.	"For the same product" (aircraft, aircraft engine, or propeller) is added to § 5.1(e) and § 5.1(f) to clarify that part 5 does not apply to either a supplemental type certificate (STC) holder or a PC holder for an STC, or PC holders that only produce parts or articles.
5.1(g) and 5.15(a)	Applicability of part 5 to foreign manufacturers.	Foreign holders of a validated TC issued under § 21.29 are now excluded.
5.3	Definition of "Hazard."	The proposed revision to the definition of "hazard" is partially adopted. The terms "incidents" and "objects" are incorporated as proposed, but the proposal to replace the term "foreseeably" with "potential to" is not adopted. The new definition is: "Hazard means a condition or an object that could foreseeably cause or contribute to an incident or aircraft accident, as defined in 49 CFR 830.2."
5.5	Scalability	The proposal to remove the scalability language in original § 5.3 is not adopted. The language is retained and placed in § 5.5(a) to provide a better understanding related to scalability.
5.5(b), 5.95(c)	Organizational system description	The "system description" proposed in § 5.5(b) is renamed to "organizational system description." The requirement is moved to § 5.17 and is now applicable only to covered part 21 entities (§§ 5.11(a), 5.13(b)(1), 5.15(b)(1), and 5.15(c)(1)). The proposed regulatory language is revised to make explicit that only a summary of information in the organizational system description is required. Also, the proposal to require SMS documentation of the system description in § 5.95(c) is not adopted.

[1] The SMS ARCs are discussed in Section III.D.

[2] NTSB recommendations are discussed in Section III.C.

[3] Joint Authorities Technical Review (JATR), *Boeing 737 MAX Flight Control System: Observations, Findings, and Recommendations,* Washington, October 11, 2019.

[4] Section 102(a)(1) of ACSAA.

[5] Several major civil aviation authorities have established or are in the process of establishing SMS requirements for air operators, air traffic management, airports, and maintenance organizations, including the European Union Aviation Safety Agency (EASA), Brazil, Canada, Japan, New Zealand, and Australia. Fewer countries have design and manufacturing organizations and, therefore, they have not established SMS requirements for those entities. However, New Zealand, Japan, and EASA have established SMS requirements for design and manufacturing organizations.

[6] 88 FR 1932.

TABLE 1—SUMMARY OF REGULATORY TEXT CHANGES—Continued

Proposed 14 CFR section affected	Description	Summary of final rule changes from NPRM
5.7(a)	Part 121 submission requirements	The FAA proposed in § 5.7(a) that existing part 121 operators would be required to submit to the FAA for acceptance revisions to their SMS necessary to meet the new requirements in part 5. In the final rule, existing part 121 operators with acceptable SMS are required to make revisions to their SMS. However, in alignment with the requirements for new part 121 applicants, part 135 operators, and LOA holders under § 91.147, FAA acceptance of the SMS and revisions made by existing part 121 operators will not be required.
5.7(b), 5.9(a) and (b), and 91.147(c)(8).	Statement of Compliance	The FAA proposed that existing part 135 operators and LOA holders under § 91.147 submit a statement of compliance. In the final rule, the name is changed from a statement of compliance to a declaration of compliance. The requirement to submit a statement of compliance was also proposed for applicants for part 121 or 135 operations and LOAs under § 91.147. This requirement is not adopted in the final rule.
5.9(a)(1) and (a)(2)	Part 135 operators and § 91.147 air tour operators compliance timeline.	The compliance timeline for existing operators is extended from 24 months to 36 months.
5.9	Single-pilot operators	Part 135 operators and part 91 commercial air tour operators are required to have an SMS, as proposed; but some SMS requirements have been determined not to be applicable to certain single-pilot operators. New § 5.9(e) enumerates the exceptions for certain single-pilot operators.
5.11; 5.13; 5.15	Requirements for part 21 certificate holders.	For existing part 21 certificate holders, the deadline for submission of SMS implementation plans is changed from December 27, 2024, to no later than 6 months after the final rule's effective date. SMS must be implemented by these entities no later than 36 months after the effective date. For PC applicants or TC holders entering into a licensing agreement, the deadline to implement SMS is changed to no later than 36 months after submission of the implementation plan. Finally, the sequence of the requirements is changed to move development of the implementation plan before development of the SMS.
5.17	Implementation plan	The implementation plan requirements in proposed § 5.17 are moved to § 5.19 to more logically follow the ''organizational system description'' requirements (now § 5.17). Language is added to require that the implementation plan be based on the organizational system description.
5.71	Safety performance monitoring and measurement.	In the NPRM, the FAA proposed removing the word ''operations'' from § 5.71(a) and (b) to clarify the requirement and avoid confusion with the term ''operator.'' The FAA does not adopt that change in the final rule.
5.94 and 5.97(d)	Notification of hazards to interfacing persons.	The proposed § 5.94(a) requirement for notification of hazards is moved to subpart C—Safety Risk Management, in new § 5.57. The term ''interfacing persons'' is now clarified to be ''those who contribute to the safety'' of a covered organization's ''aviation-related products and services.'' In addition, a requirement is included in subpart D—Safety Assurance (new § 5.71(a)(8)) to have a process for investigating hazard notifications that have been received. Thus, the requirement in proposed § 5.94(b) to develop procedures for reporting and receiving hazard information is removed. Section 5.97(d) is updated to replace the reference to ''§ 5.94'' with ''§ 5.57.''
119.8	Requirement to meet part 5 for part 121 and 135 operators.	Section 119.8 is changed to: ''Certificate holders authorized to conduct operations under part 121 or 135 of this chapter must have a safety management system that meets the requirements of part 5 of this chapter.'' This change corrects an inadvertent error in the NPRM.

C. Summary of the Costs and Benefits

As presented in the NPRM, the FAA estimated quantified annualized costs of $47.4 million using a 7 percent discount rate over a 5-year period of analysis. The costs represent resources to develop and implement an SMS. Mitigation costs to reduce or eliminate any hazards identified by an SMS, which are yet to be identified and thus unknown, are not quantified in the analysis. The FAA evaluated benefits qualitatively. The benefits are the value that would result from avoided fatalities, injuries, aircraft damage, and investigation costs. The analysis of costs and benefits reflects changes in the final rule from the NPRM. See Section V.A. for more information.

II. Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in title 49 of the United States Code (U.S.C.). Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII,

Aviation Programs, describes in more detail the scope of the Agency's authority. This rulemaking is promulgated under the authority described in 49 U.S.C. 106(f), which establishes the authority of the Administrator to promulgate regulations and rules.

In 2010, Congress mandated that the FAA conduct rulemaking to require part 121 operators to implement an SMS in the Airline Safety and Federal Aviation Administration Extension Act of 2010 (Pub. L. 111–216, 124 Stat. 2366).

Subsequently, Congress enacted ACSAA, on December 27, 2020. Section 102, titled ''Safety Management Systems,'' requires the FAA to initiate a rulemaking to require manufacturers that hold both a TC and a PC issued pursuant to 49 U.S.C. 44704 have an SMS consistent with the Standards and Recommended Practices established by ICAO and contained in Annex 19 to the Convention on International Civil Aviation (61 Stat. 1180) for such systems, and ensure their SMSs are consistent with, and complementary to, existing SMSs. Section 102 of ACSAA requires the implementing regulations to include a confidential employee reporting system through which employees can report hazards, issues, concerns, occurrences, and incidents without concern for reprisal for reporting, and a code of ethics. The regulations in the final rule are in accordance with those requirements.

Additionally, the FAA is using its discretion under the following authorities to proactively extend SMS requirements to part 119 certificate holders authorized to operate under part 135, LOA holders operating under § 91.147, and certain TC or PC holders not covered under section 102 of the ACSAA.

This rulemaking is promulgated under 49 U.S.C. 44701(a)(5) (''The Administrator of the Federal Aviation Administration shall promote safe flight of civil aircraft in air commerce by prescribing regulations and minimum standards for other practices, methods, and procedure the Administrator finds necessary for safety in air commerce and national security''); 44701(a)(2)(A) (''The Administrator of the Federal Aviation Administration shall promote safe flight of civil aircraft in air commerce by prescribing regulations and minimum standards in the interest of safety for inspecting, servicing, and overhauling aircraft, aircraft engines, propellers, and appliances''); 44702(a) (''The Administrator of the Federal Aviation Administration may issue airman certificates, design organization certificates, type certificates, production certificates, airworthiness certificates, air carrier operating certificates, airport operating certificates, air agency certificates, and air navigation facility certificates''); and 44704(a)(1) (''The Administrator of the Federal Aviation Administration shall issue a type certificate for an aircraft, aircraft engine, or propeller, or for an appliance specified under paragraph (2)(A) of this subsection when the Administrator finds that the aircraft, aircraft engine, propeller, or appliance is properly designed and manufactured, performs properly, and meets the regulations and minimum standards''). Additionally, this rulemaking is consistent with the requirements of 49 U.S.C. 44701(d)(1)(A) (''When prescribing a regulation or standard under [49 U.S.C. chapter 447], the Administrator shall consider the duty of an air carrier to provide service with the highest possible degree of safety in the public interest'').

Finally, 49 U.S.C. 44701(c) directs the Administrator to ''carry out this chapter in a way that best tends to reduce or eliminate the possibility or recurrence of accidents in air transportation.'' Among other things, this rulemaking requires certain entities whose activities affect safety in air transportation to develop and maintain an SMS to improve the safety of their operations. SMS enables persons to proactively identify and mitigate safety risk, thereby reducing the possibility or recurrence of accidents in air transportation consistent with the mandate in section 44701(c). For these reasons, the regulations identified in the final rule are within the scope of the FAA's authority and are consistent with Congress's mandate that the FAA exercise its authority proactively—not just reactively—to promote safe flight of civil aircraft and to reduce or eliminate hazards that could result in accidents in air transportation.

III. Background

A. Statement of the Problem

As described in the NPRM, over the last few decades, accidents involving commercial aviation operators have decreased.[7] Despite an overall reduction in accidents, the FAA determined that many of the accidents involving part 135 and § 91.147 operators could have been effectively mitigated by the presence of an SMS. These accidents highlight the systemic improvement opportunities to safety, which are described in the Regulatory Impact Analysis (RIA) for this rulemaking. According to NTSB data, from 2015 to 2019, there were 215 accidents involving part 135 operators, with a total of 121 fatalities,[8] as well as 33 accidents involving air tour operators operating under § 91.147, with a total of 16 fatalities.[9] Of these accidents, the FAA identified 35 involving part 135 operators and four involving § 91.147 operators that resulted in fatalities and serious injuries that could have been mitigated had those operators implemented an SMS. Additional accidents not involving fatalities or serious injuries may also have been avoided. The FAA also identified several accidents across part 91, 121, and 135 operations involving design and production issues that resulted in fatalities and serious injuries that could have been mitigated or prevented if the design and manufacturing organizations involved had implemented an SMS. A full listing of each accident used to inform the analysis of this rulemaking is included in Appendix A to the RIA.

Given the rapid development, growth, and increasing complexities of the airspace, the FAA is extending SMS requirements to parties that play critical roles in the design, manufacturing, and operation of aircraft. ACSAA requires the FAA to include holders of both a TC and a PC among those organizations that should be required to implement an SMS. Applying SMS to commuter and on-demand air carriers, air tours, and the manufacturers responsible for design and production of products will continue to reduce incidents, accidents, and fatalities. This extended application will improve safety in aviation by requiring these organizations to proactively identify hazards, assess risk of those hazards, and develop and implement mitigations, as necessary. ICAO, other CAAs, industry advisory groups, and the NTSB all agree that the use of an SMS improves safety. An SMS has been implemented by each part 121 operator, and many other aviation organizations have implemented an SMS within the context of the FAA's voluntary SMS programs.

B. Safety Management System Overview

An SMS is a formal, top-down, organization-wide approach to managing safety risk and ensuring the effectiveness of safety risk controls. It includes systematic procedures, practices, and policies for the management of safety risk. An SMS is

[7] U.S. Air Carrier Safety Data, *https://www.bts.gov/content/us-air-carrier-safety-data.* Accessed March 22, 2022.

[8] National Transportation Safety Board. US Civil Aviation Accident Rates. 2022. Available at: *https://www.ntsb.gov/safety/Pages/research.aspx.*

[9] Data file of sightseeing accidents provided by the NTSB April 2020.

a management system integrated into an organization's operations that enforces the concept that safety should be managed with as much emphasis, commitment, and focus as any other critical area of an organization.

An SMS is a formalized approach to managing safety by developing an organization-wide safety policy, developing formal methods of identifying hazards, analyzing and mitigating risk, developing methods for ensuring continuous safety improvement, and creating organization-wide safety promotion strategies. An SMS must include the following four components: Safety Policy, Safety Risk Management, Safety Assurance, and Safety Promotion. For additional information on these components and other elements of SMS see the ''Safety Management Systems for Domestic, Flag, and Supplemental Operations Certificate Holders'' final rule (80 FR 1309).

The purpose of an SMS is to reduce incidents, accidents, and fatalities by aiding aviation organizations in identifying hazards and mitigating the risk of those hazards before they lead to an incident or accident. An SMS can work to reduce incidents, accidents, and fatalities in many different ways. For example, an SMS may:

- Increase safety of products or services by identifying and addressing problems before they result in an incident, accident, or fatality.
- Improve data-informed decision making to prioritize resource allocation.
- Enhance communication regarding safety by using common, consistent terminology within the organization and throughout the industry.
- Strengthen the organization's safety culture.

SMS increases safety by requiring an organization with a part 5 SMS to ''connect the dots'' in a way that it may not do without an SMS. An SMS integrates discrete processes and procedures, such as organizational safety promotion, designation of safety roles and responsibilities, hazard identification, risk assessment and control, and performance assessment, into a comprehensive system to address aviation hazards. For example, consider an air carrier whose pilots suddenly start noticing that landings at a specific airport have recently become more difficult. Under SMS, those pilots are encouraged to communicate their individual observations to their management. Their management, upon noticing several reports have been received, would assess the situation and trigger their Safety Risk Management processes. These processes would then trigger a notification of the hazard to the airport. If the carrier does not have an SMS program, the carrier's pilots may not communicate their individual observations, the management may not have known of the hazard, and the systemic airport problem would not have been identified or addressed.

As another example, consider the scenario of an aircraft production line where a tool is calibrated improperly. The aircraft assembly technician was unaware of the improperly calibrated tool and completed the assembly process. During operation, an air carrier's pilots identified minor and repeated flight control issues and reported these issues to their management. Under an SMS, the air carrier's management would report the hazard to the aircraft manufacturer. The aircraft manufacturer, upon receipt of the hazard report, would assess the situation and trigger its Safety Risk Management processes. This analysis would identify that the flight control problems were caused by an improperly calibrated tool. The manufacturer would then implement safety risk mitigations to correct the tool calibration process and increase tool inspection. In addition, the manufacturer would identify all delivered aircraft that may have been assembled with the improperly calibrated tool and issue maintenance instructions to all operators. Without SMS, the potential hazard may go unrecognized, unreported, and unmitigated, presenting a safety issue for each aircraft in service.

Anecdotal evidence from FAA voluntary SMS program participants indicates that SMS improves the safety of aviation organizations.[10] The FAA's Voluntary Program started as a pilot project in 2007 with a primary focus on part 121 operators, and it was based on the ICAO's SMS framework in Annex 19. In 2015, with the publication of part 5, the pilot project was transitioned to what is now called the FAA's SMS Voluntary Program, and it is based on part 5.[11] As of October 31, 2023, the SMS Voluntary Program had 72 participants, which included 45 part 135 operators, two part 141 pilot schools, one part 142 training center, and 24 part 145 repair stations. As of October 31, 2023, there were 30 part 21 certificate holders participating in the associated voluntary program for design and production organizations, which includes 5 part 21 certificate holders with accepted SMSs. Recognizing this, the FAA has implemented SMS within many of its own organizations.

Further, expansion of the SMS requirements increases U.S. alignment with other CAAs that are also implementing SMS requirements in accordance with ICAO Standards and Recommended Practices. With an SMS, a U.S. company may have an enhanced ability to operate internationally due to improved alignment with ICAO Standards and Recommended Practices.

To date, SMS requirements have mainly focused on internal identification and mitigation of risk within an aviation organization. However, the FAA augmented these requirements in this rule to encourage a collaborative approach in which persons required to have an SMS share hazard information with each other and work together to identify and address hazards and safety issues. To enable collaboration, this rule requires persons to share hazard information with other aviation organizations to ensure that relevant information reaches the person in the best position to address the hazard. The expanded applicability and hazard information sharing among interfacing organizations will enable a network of aviation organizations working collaboratively to manage risk, thereby enhancing the safety benefits of SMS by assuring that hazards are communicated and mitigated effectively.

Accordingly, expanding the implementation of SMS in the aviation industry, as well as requiring the notification of identified hazards to those best positioned to address them, will increase safety throughout the industry.

C. Related Regulatory Actions

1. Safety Management Systems for Domestic, Flag, and Supplemental Operations

On July 23, 2009, the FAA published an advance notice of proposed rulemaking (ANPRM) to solicit public comments on whether certain 14 CFR parts 21, 119, 121, 125, 135, 141, 142, and 145 certificate holders, product manufacturers, applicants, and employers (product/service providers) should be required to develop an SMS.[12] On August 1, 2010, Congress subsequently enacted the Airline Safety

[10] As described in the RIA, for example, one participant noted that the compressed executive awareness time of new safety related issues resulted in formal management actions occurring in less than 90 days for low-risk issues and within hours for high-risk issues. Another participant noted that they have a seen a substantial drop in the major risk categories that they track.

[11] 80 FR 1308. The FAA published technical amendments on January 13, 2015 (80 FR 1584) and May 25, 2017 (82 FR 24009) to correct a date and a reference in the rule, respectively.

[12] ANPRM, ''Safety Management Systems,'' 74 FR 36414. July 23, 2009.

and Federal Aviation Administration Extension Act of 2010 (Pub. L. 111–216, 124 Stat. 2366), which directed the FAA to conduct rulemaking to ''require all part 121 air carriers to implement a safety management system.'' [13] To meet the rulemaking deadlines mandated by the Act, the FAA decided not to immediately address SMS for product/service providers other than part 121 air carriers.[14] Accordingly, the FAA limited the SMS rulemaking project to part 121 air carriers, issued an NPRM on November 5, 2010,[15] and subsequently withdrew the ANPRM.[16]

On January 8, 2015, the FAA published the ''Safety Management Systems for Domestic, Flag, and Supplemental Operations Certificate Holders'' final rule (SMS for part 121 final rule) requiring operators authorized to conduct operations under part 121 to develop and implement an SMS to improve the safety of their aviation related activities.[17] The final rule added part 5 to title 14 of the CFR, creating the SMS requirements for part 121 certificate holders, modeled on the ICAO SMS framework in ICAO Annex 19 and consistent with the 2009 ARC recommendations (as discussed in Section III.E.1.). The FAA crafted the requirements in part 5 to be applicable to aviation organizations of various sizes and complexities, as well as to be adaptable to fit the different types of organizations in the air transportation system and operations within an individual company. By 2018, all part 121 operators had met the requirement to have an SMS acceptable to the FAA.

2. Safety Management Systems for Part 139 Airports

On February 23, 2023, the FAA published a final rule [18] updating 14 CFR part 139 that requires certain airport certificate holders to develop, implement, maintain, and adhere to an airport SMS. Certificated airports that qualify under one or more of the following criteria are required to develop an SMS under this final rule: are classified as large, medium, or small hubs based on passenger data extracted from the FAA Air Carrier Activity Information System; have a 3-year rolling average of 100,000 or more total annual operations, meaning the sum of all arrivals and departures; or serve any international operation other than general aviation. This rule expanded SMS requirements to certain certificated airports and furthered the FAA's aviation-wide approach to SMS implementation to address safety at an organizational level. This rule became effective on April 24, 2023.

D. NTSB Recommendations

The NTSB first recommended in 1997 that transportation organizations implement an SMS, and early recommendations were aimed at improving safety in the maritime industry. Since then, a number of NTSB investigations related to various modes of transportation, including aviation, have cited organizational factors contributing to accidents and resulted in recommendations that SMS be used as a way to prevent future accidents and improve safety. The NTSB issued 18 recommendations regarding SMS for aviation organizations over a 15-year period, spanning 2007 through 2021.[19] These recommendations covered commercial operations under 14 CFR parts 121 and 135, revenue passenger carrying business operations under part 91, and certificate holders under part 21. Eight of the 18 NTSB recommendations were issued to the FAA.[20]

The NTSB publishes a Most Wanted List that ''highlights transportation safety improvements needed now to prevent accidents, reduce injuries, and save lives.'' [21] The NTSB 2021–2023 Most Wanted List recommended that the FAA ''Require and Verify the Effectiveness of Safety Management Systems in all Revenue Passenger-Carrying Aviation Operations.'' [22]

E. SMS ARCs

Prior to publishing the 2015 SMS rule, the FAA chartered two ARCs to provide advice on implementing SMS in aviation regulations. The industry stakeholders on these ARCs included individual companies and associations representing operators, design and manufacturing organizations, repair stations, and training organizations. These ARCs expressed industry support for SMS and recommended that the FAA publish rules requiring the use of SMS.

The FAA chartered the first ARC in 2009, after publishing an ANPRM seeking public input on requiring certain part 21, 119, 121, 125, 135, 141, 142, and 145 certificate holders to develop an SMS.[23] The ARC recommended the FAA issue regulations on SMS and that those regulations apply to certificate holders under 14 CFR parts 21, 119, 121, 125, 135, 141, 142, and 145, as well as operators under 14 CFR part 91 subpart K.[24] The ARC also recommended phased promulgation of SMS regulations and that the FAA prioritize new SMS regulations based on the potential safety benefit, as well as industry experience and regulatory oversight readiness. The rulemakings implementing SMS for part 121 operators and airports certificated under part 139 are addressed in more detail in Section III.C. of this preamble.

The FAA chartered a second ARC in 2012 [25] to evaluate improvements to the effectiveness and efficiency of existing ''certification procedures for products and parts,'' and the benefits of incorporating SMS in the design and manufacturing environment. The FAA received the ARC's final report in October 2014.[26] The ARC recommended establishing regulatory requirements for implementing SMS for design and production approval organizations that would be consistent with the part 5 requirements.

For more information about both ARCs' recommendations and the FAA's responses, see Section IV.A of the NPRM preceding this final rule.

[13] *See* Sec. 215(a).

[14] *See* ''Safety Management System; Withdrawal,'' 76 FR 14592. March 17, 2011.

[15] 75 FR 68224.

[16] *See id.*

[17] 80 FR 1308. The FAA published technical amendments on January 13, 2015 (80 FR 1584) and May 25, 2017 (82 FR 24009) to correct a date and a reference in the rule, respectively.

[18] 88 FR 11642.

[19] NTSB Safety recommendations: A–07–010 (2007), A–09–016 (2009), A–09–089 (2009), A–09–098 (2009), A–09–106 (2009), A–12–062 (2012), A–12–063 (2012), A–14–105 (2014), A–14–106 (2014), A–16–036 (2016), A–19–028 (2020), A–19–036 (2019), A–19–038 (2019), A–20–025 (2020), A–21–007 (2021), A–21–013 (2021), A–21–014 (2021), and A–21–048 (2021).

[20] NTSB Safety recommendations: A–07–010 (2007), A–09–089 (2009), A–09–016 (2009), A–16–036 (2016), A–19–028 (2020), A–21–013 (2021), A–21–014 (2021), and A–21–048 (2021).

[21] 2021–2023 NTSB Most Wanted List of Transportation Safety Improvements, *www.ntsb.gov/mwl.*

[22] 2021–2023, NTSB Most Wanted List of Transportation Safety Improvements, Require and Verify the Effectiveness of Safety Management Systems in all Revenue Passenger-Carrying Aviation Operations, *https://www.ntsb.gov/Advocacy/mwl/Pages/mwl-21-22/mwl-as-01.aspx.*

[23] 74 FR 36414, July 23, 2009.

[24] Safety Management System (SMS) Aviation Rulemaking Committee; Order 1110.152, Washington, DC. Available at: *https://www.faa.gov/regulations_policies/rulemaking/committees/documents/media/SMSARC-2122009.pdf* (as of March 15, 2022).

[25] 14 CFR 21/Safety Management Systems Aviation Rulemaking Committee Charter. Available at: *https://www.faa.gov/regulations_policies/rulemaking/committees/documents/media/Part21ARC-10052012.pdf* (visited March 15, 2022).

[26] Part 21/Safety Management Systems (SMS) Aviation Rulemaking Committee to the Federal Aviation Administration: Recommendations on Certification Procedures for Products and Parts. October 5, 2014.

F. Aircraft Certification, Safety, and Accountability Act

The Lion Air and Ethiopian Airlines accidents involving the Boeing 737 MAX resulted in several investigations, not only of the accidents, but also of the FAA's oversight and certification processes. One such investigation, convened by the FAA in April of 2019, was the Boeing 737 MAX Flight Control System Joint Authorities Technical Review. The Joint Authorities Technical Review included representatives from the National Aeronautics and Space Administration, the FAA, and several foreign CAAs. One of the Joint Authorities Technical Review recommendations was that the FAA encourage applicants to have a system safety function, such as an SMS, that is independent from their design organization.[27]

Subsequently, on December 27, 2020, Congress enacted ACSAA, which set forth a variety of reforms intended to address certain safety standards relating to the aircraft certification process. Section 102 of ACSAA required the FAA to promulgate rules that require holders of both a TC and a PC issued under 14 CFR part 21 to implement an SMS. ACSAA also established a timeline for those certificate holders to adopt an SMS (*i.e.,* no later than 4 years after the date of enactment, December 27, 2020), and it established certain requirements for the rulemaking, including a confidential employee reporting system through which employees can report hazards, issues, concerns, occurrences, and incidents without concern for reprisal for reporting, and a code of ethics.

G. International Movement Toward SMS

ICAO Annex 19, Safety Management, establishes a framework for member States to develop and implement SMS requirements within their respective State's rules. Several member States, including the United States, started developing and implementing SMS requirements within their countries after Annex 19 First Edition was published in July 2013 and became applicable in November 2013.[28] Annex 19 currently requires States to establish requirements for SMS for international commercial air transportation, design and manufacturing, maintenance, air traffic services, training organizations, and certified aerodromes, as well as SMS criteria for international general aviation operators of large or turbojet airplanes.

Member States continue to make progress in developing, implementing, and maintaining requirements for SMS that are aligned with ICAO's SMS Standards and Recommended Practices, including certificating authorities in Canada, Brazil, the United Kingdom, Japan, Australia, and Europe (EASA). For example, in the EASA regulatory framework, SMS is mandatory for certificated operators of airplanes and helicopters authorized to conduct commercial air transportation. Additionally, EASA also adopted rules for EU-part 145 organizations, which became applicable on December 2, 2022, and for design and production organizations (EU part 21), which became applicable on March 7, 2023.

H. Summary of the NPRM

On January 11, 2023, the FAA published the NPRM for Safety Management Systems.[29] The FAA proposed to update the SMS requirements in part 5 and extend the requirement to have an SMS to all certificate holders operating under the rules for commuter and on-demand operations (part 135), LOA holders operating commercial air tours under § 91.147, PC holders that are holders or licensees of a TC for the same product (part 21), and holders of a TC who license out that TC for production (part 21). The FAA proposed several amendments and new requirements to part 5 intended to increase the effectiveness of SMS. The FAA also proposed amendments to certain regulations in parts 21, 91, and 119 to conform with, and enable the implementation of, the proposed requirements in part 5.[30] The comment period was originally 60 days and was scheduled to close on March 13, 2023. In response to commenters' requests for extensions, the comment period was extended by 30 days and ultimately closed on April 11, 2023.[31]

I. General Overview of Comments

The FAA received 186 comment submissions in response to the NPRM from a variety of commenters, including air carriers, aircraft designers and manufacturers, trade associations, emergency medical transport services, a non-profit safety organization, a university, and private citizens. The FAA received comments from the following: Aerospace Industries Association (AIA), Air Charter Safety Foundation, Air Line Pilots Association (ALPA), Air Medical Operators Association (AMOA), Airbus Commercial Aircraft (Airbus), Aircraft Electronics Association (AEA), Aeronautical Repair Station Association (ARSA), Aircraft Owners and Pilots Association (AOPA), Alaska Air Carriers Association (AACA), Ameristar, Association for Uncrewed Vehicle Systems International (AUVSI), Association of Air Medical Services, Cargo Airline Association, Commercial Drone Alliance, Commission on Accreditation of Medical Transport Systems (CAMTS), Delta Air Lines, Embraer S.A., European Union Aviation Safety Agency (EASA), Experimental Aircraft Association (EAA), GE Aerospace, General Aviation Manufacturers Association (GAMA), Gulfstream Aerospace Corporation (Gulfstream), Helicopter Association International (HAI), Lockheed Martin, Minnesota Business Aviation Association, Modification and Replacement Parts Association (MARPA), National Business Aviation Association (NBAA), National Transportation Safety Board (NTSB), NetJets Association of Shared Aircraft Pilots, Piper Aircraft, Pratt & Whitney, Regional Air Cargo Carriers Association (RACCA), Transport Canada Civil Aviation (TCCA), Rolls-Royce, Regional Airline Association (RAA), Small UAV Coalition, Transport Workers Union of America, Transportation Trades Department—AFL–CIO, WYVERN, Zipline, as well as multiple individuals and smaller operators.

The FAA received comments on multiple aspects of the proposal. The comments and the FAA's responses are discussed in Section IV.

IV. Discussion of Comments and the Final Rule

A. Applicability to Part 135 and LOA Holders Under § 91.147

In the NPRM, the FAA proposed to apply part 5 to all operators under part 135 and air tour operators under § 91.147. Specifically, proposed § 5.1(b) stated that part 5 would apply to certificate holders or applicants authorized to conduct operations under part 135. Proposed § 5.1(c) provided that part 5 would apply to applicants and LOA holders under § 91.147.

1. Discussion of the Final Rule

The FAA is applying part 5 to all part 135 operators and air tour operators with a LOA issued under § 91.147, as well as to applicants for these operations. This amendment is designed

[27] Joint Authorities Technical Review (JATR), *Boeing 737 MAX Flight Control System: Observations, Findings, and Recommendations.* October 11, 2019.

[28] The Second Edition of Annex 19 was published in July 2016 and became applicable in November 2019.

[29] 88 FR 1932.

[30] 88 FR 1933.

[31] 88 FR 5812.

to further improve aviation safety for passenger-carrying and cargo operations conducted for compensation or hire. As detailed more thoroughly in the NPRM, the FAA identified a number of accidents involving part 135 operators and § 91.147 LOA air tour operators that resulted in fatalities and serious injuries that could have been mitigated through SMS.

After considering comments, the FAA adopts this applicability as proposed. However, for the reason discussed in the FAA Response section, the FAA decided not to require certain requirements within part 5 for those operators where a single pilot is the sole individual performing all necessary functions for the safe operation of the aircraft. Section 5.9 is revised from the NPRM to add paragraph (e), which identifies the requirements in part 5 that are not applicable to certain single-pilot organizations. These requirements generally focus on identification of designated management personnel, employee reporting, and communication across the aviation organization and are explained in more detail in section IV.A.3.

2. Summary of the Comments

Several commenters indicated that requiring part 135 operators and § 91.147 LOA holders to comply with the part 5 SMS requirements would impose a significant burden resulting in little safety benefit. Commenters, including the CAMTS, NATA, NBAA, and RACCA suggested part 5 was designed for large air carriers, not for smaller operators, nor for the diversity of operations conducted under part 135. The commenters also argued part 5 is too prescriptive to accommodate the variation of size and scope of part 135 operations. For these reasons, commenters recommended that the FAA develop separate SMS requirements for part 135 operators that are less complex than part 5 and are truly scalable for organizations with limited resources. As an alternative, NBAA recommended the FAA apply specific regulations to entities based on size or complexity, using criteria similar to the complexity criteria identified by the Safety Management International Collaboration Group.

Commenters also expressed concern about the difficulty for small businesses to implement SMS. NBAA indicated that the FAA should consider EASA and TCCA SMS models, and the feedback both entities received, highlighting the difficulties that small organizations face when implementing SMS. NBAA further noted that its experience with other regulatory frameworks has illustrated the need for additional full-time personnel or external contractors to manage the system.

NATA stated the FAA needs to recognize the challenges for small business and ensure that guidance and training address this issue. NATA noted that SMS solutions for small businesses must not be cost-prohibitive or so burdensome as to drive businesses to close, further stating that the FAA has the responsibility to impose SMS regulations on small operators only if it can be done in a way that enhances safety and minimizes burdens. NATA also stated that there have been no pilot programs or specialized analysis conducted to support the concept of SMS for smaller operators.

Some commenters asserted that air tour operations already have stringent requirements in place, and that imposing the part 5 requirements would negatively harm these small businesses and cause inadvertent negative safety effects by diverting resources. Other commenters suggested that certain air tour operators should be excluded from the requirement, such as § 91.147 LOA holders operating fewer than 100 flights per year or air tour operators with fewer than five employees.

Several commenters recommended excluding single-pilot operators from the SMS requirements. These commenters argued the requirements are impractical, unnecessary, and overly burdensome, citing the confidential reporting system as an example. Commenters noted SMS may be beneficial for larger organizations because a team is involved, but it does not make sense for a single pilot operator because that individual is already conducting all the functions that would be required under part 5. According to one commenter, requiring single-pilot operators to document their decisions, for example, is counter-productive and may distract them from important duties.

An individual commenter questioned the FAA's justification for requiring single-person operators to implement SMS. The commenter argued that the real-world accident descriptions in the NPRM did not provide evidence that an SMS would have prevented any of the accidents involving single-person operators. The commenter also noted the FAA did not present statistical evidence to justify making this regulatory change for single-person operators.

Other commenters, however, supported the proposed rule, stating companies requiring payment for service should have an SMS. For instance, the NTSB stated that it supports the proposed expansion of SMS to include all part 135 operators and all operators conducting air tours under § 91.147. The NTSB noted that if the proposed requirements were adopted, the rule could possibly satisfy the intent of Safety Recommendations A–16–36 and A–19–28. The NTSB also stated that the particular methods an operator uses to implement an SMS are not prescribed in the proposed rule; therefore, the current SMS framework provides sufficient flexibility to small operators under both part 135 and § 91.147, and no alternatives exist that would achieve the same safety objectives as SMS.

3. FAA Response

The FAA understands the concerns expressed by the commenters regarding the impact to small operators. Part 5 was designed to be scalable and flexible so aviation organizations could design and implement an SMS that fits their operations. Scalability was discussed at length in the preamble to the NPRM, discussed further in Section IV.J. of this preamble, and is addressed in Advisory Circular (AC) 120–92 and AC 21–58.[32] Appendix G in AC 120–92 includes implementation strategies and examples regarding how small operators could comply with part 5 requirements.

The public expects safe carriage from operators offering flight services for hire irrespective of whether an operator employs one pilot or many. Regardless of size, all companies have the responsibility to conduct safe operations. Accordingly, the FAA has determined SMS will be applicable to all part 135 operators as well as commercial air tours conducting their operations with a LOA under § 91.147 because they are all engaged in the transportation of passengers or cargo for compensation or hire. This expanded applicability also meets, in part, the NTSB's recommendations for commercial aircraft operations to have an SMS.

There is risk in aviation operations regardless of the size or complexity of the organization. A fundamental element of SMS is the identification of hazards and mitigating the risk of those hazards. Therefore, SMS is intended to be used to mitigate the risk in these operations, including the risk not currently addressed by existing regulations. Even though aviation organizations must ensure compliance with the relevant regulatory standards,

[32] Guidance, including ACs, to support this rule will be available at the FAA's Dynamic Regulatory System (*https://drs.faa.gov*) approximately 30 days after publication in the **Federal Register**.

they should use their SMS to identify and address the underlying causes of regulatory or procedural noncompliance and invest resources and efforts to preclude their recurrence.[33]

The FAA concludes that all commercial operators authorized under part 135 or § 91.147 can benefit from implementing an SMS because it increases safety by supporting a proactive, predictive method of managing safety to identify and address problems before they result in an incident or accident. SMS is not a comprehensive solution but serves as an additional preventive measure in the evolution of aviation safety.

In addition, the FAA recognizes that there is a spectrum of organizational sizes and complexities across the aviation industry. There are relatively low-cost implementation resources available to assist persons to meet part 5 requirements, including online platforms such as the Web-Based Analytical Technology (WBAT) platform. This platform is a federally funded software system that was originally created to support data collection and information technology for FAA voluntary safety programs. WBAT has since evolved, and it can now be used to assist organizations in meeting SMS requirements. The platform has modules to support all aspects of an SMS and it includes the following tools: SMS implementation manager, safety risk management, safety assurance, employee reporting, and data sharing. Basic access to the WBAT platform is free. Additional support is fee-based, and the platform has multiple tiers of service enabling organizations to decide which tier best fits their operations.

In response to NBAA's suggestion that the FAA use criteria similar to the Safety Management International Collaboration Group for small organizations, the FAA decided not to adopt these criteria because part 5 is already designed to be scalable based on the size and complexity of the aviation organization. Safety Management International Collaboration Group criteria are discussed further in AC 120–92 and may provide useful guidance for aviation organizations to use when implementing their SMS. However, the FAA is not codifying these specific criteria in this rule because the rule should allow for various ways to scale SMS implementation.

The FAA agrees with commenters that certain part 5 requirements may be impractical or illogical for many single-pilot organizations. As a result, the FAA adds a new paragraph (e) to § 5.9 to enumerate those SMS provisions that the FAA has determined shall not apply to certain single-pilot operations conducted under part 135 or an LOA issued under § 91.147 (specifically, §§ 5.21(a)(4), 5.21(a)(5), 5.21(c), 5.23(a)(2), 5.23(a)(3), 5.23(b), 5.25(b)(3), 5.25(c), 5.27(a), 5.27(b), 5.71(a)(7), 5.93, and 5.97(d)). These exceptions are limited to entities with a single pilot who is the sole individual performing all necessary functions in the conduct and execution related to, or in direct support of, the safe operation of the aircraft. All necessary functions would generally include: operational control, refueling, ground handling of the aircraft, flight planning, weight and balance calculations, performance of preventive maintenance, coordination of maintenance activities, pre-flight and post-flight activities, and financial decisions related to operating the aircraft safely, in addition to operating the aircraft. The FAA is removing requirements relating to employee reporting for these aviation organizations because the person reporting would be the same person receiving the reports. In addition, the requirements for communication within the aviation organization are also not necessary for these organizations; nor do they need to identify and designate various management personnel because the same person would be fulfilling those roles.

The FAA provides additional guidance in AC 120–92 to help these single-pilot organizations navigate the exceptions. The FAA is also providing additional time for compliance, as discussed in Section IV.D. Commenters' concerns regarding the cost and the perceived lack of benefits are discussed further in Section IV.V.

B. Applicability to Part 21 Foreign Entities

In the NPRM, the FAA proposed to apply the SMS requirements in part 5 to any TC holder that allows another person to use the TC to manufacture the product under a PC. The proposal did not distinguish between TC holders where the United States is the State of Design [34] and TC holders where a foreign country is the State of Design. Under 14 CFR 21.29, the FAA may issue a U.S. TC to a foreign manufacturer for an import product by ''validating'' the original TC issued to the manufacturer by the relevant foreign CAA. For the holder of a validated TC issued by the FAA, the foreign country (or jurisdiction) remains the State of Design because that country has regulatory authority over the original TC and TC holder. As proposed in the NPRM, part 5 would be applicable to a foreign holder of a TC issued under § 21.29 that licenses its TC to another person to manufacture the product in the United States. This applicability would therefore impose part 5 requirements on a holder of a TC issued under § 21.29, even though the United States is not the State of Design. The FAA did not intend for this provision to apply to these TC holders.

1. Discussion of the Final Rule

The FAA intends for this rule to require SMS for TC and PC holders where the United States is the State of Design or State of Manufacture.[35] In the final rule, the FAA makes changes to § 5.1(g) to address any ambiguity regarding to which entities the rule applies. Specifically, the FAA is revising § 5.1(g) and § 5.15(a) to exclude foreign holders of a validated TC issued under § 21.29 that allow another person to use the TC to obtain a PC to manufacture the product in the United States.[36]

2. Summary of the Comments

Embraer S.A. commented that the requirement as proposed in § 5.1(g) did not distinguish between a U.S. TC holder and a foreign TC holder with a validated TC issued under § 21.29. As a result, Embraer noted that one could interpret the provision to mean that the FAA would regulate a design organization for which the United States is not the State of Design. Embraer noted that this seems to be an unintended effect, based on information in the NPRM and the FAA's stated intention of seeking alignment with ICAO Annex 19, including section 4.1.5 of Chapter 4 of the Annex, which states ''the SMS of an organization responsible for the type design of aircraft, in accordance with Annex 8, shall be made acceptable to the State of Design.''

3. FAA Response

The FAA agrees that it did not intend for this rule to apply to a design

[33] An SMS does not excuse noncompliance with existing regulations.

[34] As defined in § 21.1(b)(8) of 14 CFR, the term ''State of Design'' means ''the country or jurisdiction having regulatory authority over the organization responsible for the design and continued airworthiness of a civil aeronautical product or article.''

[35] As defined in § 21.1(b)(9) of 14 CFR, the term ''State of Manufacture'' means ''the country or jurisdiction having regulatory authority over the organization responsible for the production and airworthiness of a civil aeronautical product or article.''

[36] Note that if the validated TC holder obtains a PC to manufacture the product itself, then it is subject to the rule.

organization for which the United States is not the State of Design. Rather, the FAA intended to require SMS for TC and PC holders where the United States is the State of Design or State of Manufacture. In the final rule, § 5.1(g) is revised to exclude foreign holders of a TC issued under § 21.29 that allow another person to use the TC to obtain a PC to manufacture the product in the United States. For purposes of this rule, the term ''production certificate'' in § 5.1(g) and in § 5.15 continues to refer to a production certificate issued by the FAA under part 21 or a production certificate or equivalent authorization issued by a foreign aviation authority.

C. Expansion of Proposed Applicability

The NPRM proposed to apply part 5 to part 135 operators, air tour operators operating under § 91.147 LOAs, and certain certificate holders under part 21. Several commenters suggested expanding applicability beyond the proposal. In addition, the FAA specifically asked the public for input regarding a possible future rule to apply part 5 to part 145 repair stations, as well as input regarding whether part 5 should apply to all design and production approval holders (*i.e.,* all holders of a TC, PC, technical standard order authorization (TSOA), supplemental type certificate (STC), or parts manufacturer approval (PMA)). The FAA also asked the public for input on whether part 5 applicability should be limited for certain subsets of the part 145 or part 21 entities.

1. Discussion of the Final Rule

The FAA has decided not to expand the applicability of this rule beyond the original proposal. The current applicability was chosen because the FAA believes this scope will capture segments of the aerospace system that have a large impact on safety without unduly delaying the effective date of the rule. Rather than expanding the scope of this rule, the FAA will continue to encourage voluntary implementation of SMS in segments of the aerospace system not covered by part 5.

2. Summary of the Comments

Commenters suggested expanding the applicability of the proposal in various ways. Some commenters pointed out areas in the aerospace system where they thought risk existed and could benefit from SMS. Other commenters focused on covering entities that charged a fee for service or covering all entities that ICAO Annex 19 requires have an SMS.

For the air transportation industry, the NTSB noted that FAA only proposed to apply the SMS requirements to air tour operations conducted under § 91.147 rather than applying the requirements to all revenue passenger-carrying operations conducted under part 91 as the NTSB recommended. The NTSB stated the proposed rule does not go far enough to meet the intent of Safety Recommendations A–21–13 and –14, reiterated its position that SMS is necessary to improve the safety of all part 91 revenue passenger-carrying operations, and urged FAA to include all revenue passenger-carrying operations conducted under part 91 in the final rule.

NATA commented that including fractional ownership programs would be consistent with the reasons the FAA decided to regulate part 91 subpart K operations.

TCCA and EASA expressed their support for expanding SMS to other areas within part 21.

For the aviation maintenance industry, the FAA asked in the NPRM whether it should consider a future rulemaking project to expand the applicability of part 5 to include repair stations certificated under part 145. Commenters that supported extending the application of part 5 to repair stations, included the NTSB, EASA, Air Charter Safety Foundation, ALPA, Transportation Trades Department—AFL–CIO, Transport Workers Union of America, and Airbus Commercial Aircraft, as well as individuals and operators. The NTSB indicated that SMS should be applied to part 145 repair stations to address Safety Recommendation A–21–48. EASA, Airbus Commercial Aircraft, GE Aerospace, and others cited the importance of harmonizing with ICAO and other CAAs as a reason to require part 145 repair stations to have an SMS.

Other commenters, including AEA, ARSA, and Pratt & Whitney, did not support extending the application of part 5 to part 145 repair stations. AEA and ARSA stated that the addition of part 5 to existing safety standards for repair stations is redundant, expensive, and unnecessary. Pratt & Whitney recommended that part 145 repair stations remain in the voluntary program.

A few commenters recommended applying SMS to part 145 repair stations to facilitate certificate acceptance by a foreign CAA.

For the aviation design and manufacturing industry, the FAA sought comment in the NPRM as to whether part 5 should apply to all holders of a TC, PC, STC, TSOA, or PMA. The FAA also requested input on whether any exceptions should be made to these holders and for commenters to provide supporting information and data on the safety benefits or impact of the broadened applicability. Some commenters noted that limiting part 5 applicability (for design and manufacturing entities) to holders of a TC or a PC leaves gaps in safety and requested that SMS be extended to certain design and manufacturing entities that produce safety-critical components. The commenters, however, did not provide any data or information supporting the benefit of extending applicability to STC, TSOA, and PMA holders.

3. FAA Response

Although the FAA agrees with many commenters that other areas of the aerospace system could benefit from SMS, the Agency is not expanding the applicability of this rule beyond the original proposal.

With regard to expanding the rule to include STC, TSOA, and PMA holders under part 21, the FAA's decision not to expand this final rule simply maintains the existing level of safety in part 21 applicable to those entities. Before making changes, the FAA would first establish that a safety justification (the safety ''gap'' as characterized by one commenter) exists. At this time the FAA does not have sufficient information to support a safety justification for expanding this rule to STC, TSOA, and PMA holders. The FAA would also need to take these steps to expand the applicability of part 5 to additional part 91 revenue passenger-carrying operations.

With respect to part 145 repair stations, the FAA acknowledges the comments received on whether the Agency should consider future rulemaking to cover these organizations under part 5. The FAA recognizes the significant impact repair stations have on aviation safety; the recommendations of the NTSB for the FAA to require organizations that maintain aircraft to establish SMS; and the applicability of ICAO Annex 19 to maintenance organizations. The comments received from the NPRM offer a diverse set of viewpoints across the aviation sector, all of which must be taken into account should the FAA consider a future rulemaking to require part 145 repair stations to develop and maintain an SMS. The FAA continues to collect and evaluate data to determine whether the benefits would justify the costs and will continue to pursue and promote part 145 repair station involvement in the FAA's SMS Voluntary Program.

In summary, applying SMS requirements to part 145 repair stations, additional part 21 design and production approval holders, and other entities as recommended in the comments requires careful and deliberative consideration by the FAA of many factors, including safety benefits, costs, and other priorities. The time needed to fully evaluate these considerations and to develop and apply the most appropriate SMS requirements for additional entities would inhibit the FAA's ability to finalize this rulemaking expeditiously. The FAA will continue to encourage voluntary implementation of SMS by aviation organizations not covered by part 5. The FAA acknowledges and appreciates the input provided by commenters in response to the questions posed on SMS applicability and may explore expansion of part 5 applicability in future initiatives, which could include future NPRMs for which the FAA would solicit additional public input.

D. Compliance Timelines and Submission Requirements

In the NPRM, the FAA proposed to require existing part 135 operators and § 91.147 air tour operators to develop and implement an SMS in accordance with part 5 and to submit a statement of compliance no later than 24 months after the effective date of a final rule. The FAA also proposed to require any new applicant for authorization to conduct operations under part 135 or for a LOA under § 91.147 to submit a statement of compliance as part of the certification or LOA process. In the NPRM, existing part 121 operators were required to revise their SMS to meet the new proposed requirements in part 5 and submit those revisions for acceptance by the FAA no later than 12 months from the effective date of the rule. The FAA also proposed to require any new applicant for authorization to conduct operations under part 121 to submit a statement of compliance as part of the certification process.

In addition, the FAA proposed that existing part 21 certificate holders be required to submit an implementation plan no later than December 27, 2024, and implement their SMS by December 27, 2025. For companies that apply for a PC, have a pending application for a PC, or have a TC and enter into a licensing agreement in accordance with § 21.55, the FAA proposed similar compliance timelines to maintain parity with the compliance timelines proposed for existing certificate holders. More specifically, the FAA proposed to require TC holders who enter into a licensing agreement to submit an implementation plan for FAA approval when providing a written licensing agreement to the FAA. The FAA also proposed to require PC applicants to submit an implementation plan for FAA approval during the certification process. In the proposal, PC applicants, as well as TC holders who enter into a licensing agreement, were required to implement their SMS no later than 1 year after the FAA's approval of the implementation plan.

1. Discussion of the Final Rule

i. Existing Part 135 Operators and LOA Holders Under § 91.147

In the final rule, the FAA has increased the compliance timeframe from the proposed 24 months to 36 months for part 135 operators and LOA holders under § 91.147 in response to comments received.

In addition, the FAA is changing the title of the document to be submitted for existing part 135 certificate holders as well as existing LOA holders under § 91.147 from ''statement of compliance'' to ''declaration of compliance.'' Submitting a declaration of compliance to the FAA serves to document that the aviation organization has developed and implemented an SMS meeting the applicable requirements of part 5. The FAA will assess the aviation organization's compliance with SMS requirements during routine surveillance. Aviation organizations are required to make their SMS processes and procedures available in accordance with §§ 5.9(d) and 5.95 to FAA personnel for review. Upon implementation of an SMS, if revisions to manuals are necessary, the aviation organization will submit those changes in accordance with applicable regulatory requirements.

ii. Existing Part 121 Operators

After further consideration, the FAA decided to remove the proposed requirement for existing part 121 operators to submit the changes to their SMS to meet the new requirements in part 5 to the FAA for acceptance. Specifically, part 121 operators are required to revise their SMS to meet the new requirements proposed in §§ 5.21(a)(7) (Safety Policy Code of Ethics), 5.53(b)(5) (Safety Risk Management Interfaces), 5.57 (Hazard Notification), 5.71(a)(7) (Employee Confidential Reporting System), 5.71(a)(8) (Investigating Hazard Notifications), and 5.97(d) (SMS Records). The FAA will validate compliance with these new requirements using existing oversight methods and tools.

Part 121 operators are still required to make available all necessary information and data that demonstrates that they have an SMS that meets the requirements in part 5, in accordance with § 5.7(d). Therefore, the proposed requirement (§ 5.7(a)(2)) is unnecessary, and the FAA has removed it.

iii. Applicants for Part 121 or 135 Operations or for an LOA Under § 91.147

The FAA makes minor changes to the submission requirements for anyone who applies to operate under part 121 or 135 or for an LOA under § 91.147 after the effective date of this rule. In the NPRM, the FAA proposed that these applicants submit a ''statement of compliance'' with their certificate or LOA application. After further consideration, the FAA concluded that it was not necessary to make this submission a regulatory requirement as a part of this rule. To be clear, the FAA will require part 121 and 135 and § 91.147 LOA applicants to implement SMS. However, instead of requiring these applicants to submit a ''statement of compliance,'' the FAA will include its assessment of the applicant's SMS using the same processes and procedures it uses to assess the applicant's compliance with other FAA requirements. Removing the requirement is consistent with how the FAA evaluates compliance with other regulatory requirements and aligns with terminology used in traditional air carrier and air operator certification, thereby reducing the potential for confusion.

Specifically, the general certification requirements in § 119.35 direct the air carrier or operator certificate applicant to submit an application with the necessary information and in a form and manner prescribed by the Administrator. The FAA provides guidance (AC 120–49) describing how to prepare and submit application materials and document compliance with regulatory requirements. This guidance includes information on how to document compliance with regulations that the applicants must comply with, including part 5. Similarly, for applicants requesting issuance of an LOA under § 91.147, the FAA will verify part 5 compliance during the application process. New § 91.147(b)(3) adds compliance with part 5 as a requirement for obtaining an LOA. This additional requirement, supported with requirements in § 5.9(c) and (d), provides sufficient assurance

that § 91.147 LOA applicants implement and maintain an SMS.

iv. Part 21 Certificate Holders

In response to comments, the FAA revises the compliance deadlines for covered part 21 entities to be based upon the effective date of the final rule. Existing certificate holders will have 6 months from the final rule effective date to develop and submit an implementation plan to the FAA and 36 months from the effective date to implement their SMS. PC applicants are required to submit an implementation plan for FAA approval during the certification process, and to implement the SMS no later than 36 months after submission of their implementation plan. Holders of a TC entering into a licensing agreement in accordance with § 21.55 are required to submit an implementation plan to the FAA when providing written licensing agreements, and to implement the SMS no later than 36 months after submission of their implementation plan.

2. Summary of the Comments and FAA Response

i. Part 135 Operators and LOA Holders Under § 91.147

a. Summary of the Comments

Industry associations, regulated entities, and several individuals submitted comments regarding implementation timeframes. Most of these commenters felt the 24-month timeframe was inconsistent with ICAO and other SMS implementation and maturity models, and that 24 months is insufficient to develop and implement SMS.

Commenters, including HAI, NBAA, and Jet Linx Aviation, recommended extensions ranging from 36 months to 5 years for development and implementation of the SMS. Individual commenters cited the 36-month timeframes for existing part 121 SMS and SMS for airports, which permits up to 5 years in some circumstances.

EAA, AMOA, NATA, AOPA, and LifeFlight of Maine recommended a phased (staged) approach to the timeline of SMS implementation instead of a rigid 24-month requirement. In particular, they cited no opportunity for operators to consult with the FAA before SMS acceptance and oversight, which could lead to noncompliance. These commenters noted the phased approach would also allow FAA inspectors to become familiar with SMS processes, procedures, and oversight. An individual commenter said that a more measured timeline would reduce the burden on business aviation operators.

b. FAA Response

The FAA agrees with the commenters that extending the compliance timeframe would be beneficial and in the final rule extends the timeframe by 12 months for part 135 operators and LOA holders under § 91.147, as well as provides pending applicants 36 months to meet part 5. This extension will allow more time for operators to obtain a comprehensive understanding of SMS. In addition, the 36-month timeline is more consistent with the timeframes provided to part 121 operators and airports, as well as the part 21 certificate holders covered by this rule (as discussed in Section IV.D.2.ii.).

Although the FAA has chosen not to follow a phased approach as suggested by the commenters, the extended compliance timelines adopted in this final rule will help address their concerns over the lack of FAA consultation. The FAA and many industry stakeholders have gained significant experience with SMS principles in the years since part 5 was originally published. The FAA, industry associations, and third-party service providers have resources to help stakeholders with implementation, which are further discussed in Section IV.L.2. Stakeholders will continue to have the opportunity to contact the FAA for compliance assistance, as appropriate. The change from 24 months to 36 months for compliance provides operators with the necessary time to implement SMS effectively.

ii. Part 21 Certificate Holders

a. Summary of the Comments

Commenters, such as Pratt & Whitney, Piper Aircraft, Aviation Safety Solutions, Gulfstream, and GAMA/AIA noted that the timeframes proposed in the NPRM would provide insufficient time to implement an SMS and emphasized that the compliance deadlines should not be based on pre-established calendar dates. Commenters referenced timeframes recommended by the 2012 part 21 SMS ARC and the compliance deadlines established for part 121 operators under the part 5 rule issued in 2015. Pratt & Whitney, Piper Aircraft, Aviation Safety Solutions, Gulfstream, and GAMA/AIA requested additional time for submitting an implementation plan and fully implementing SMS, ranging from 6–12 months for submitting the implementation plan, and 24–48 months for fully implementing SMS.

Airbus asked why the timeframes are different across different sections of the NPRM for part 21 entities.

Individual commenters remarked on the requirement for PC applicants to submit an SMS implementation plan as a prerequisite to obtaining or amending a PC. Some commenters asked for the FAA to clarify that the submission of the implementation plan is the only part 5 prerequisite to obtaining or amending the PC and that companies are not expected to have the SMS fully implemented to obtain or amend a PC. GAMA/AIA requested an exception for TC holders that apply for a PC less than 1 year after the final rule becomes effective, recommending that these applicants should be given 1 year after PC approval to submit their implementation plan.

TCCA asked if 1 year to implement SMS is reasonable and indicated that the provision does not seem to consider the size and complexity of organizations, suggesting that large organizations may need more time to fully implement their SMS due to organizational structuring or re-structuring. TCCA suggested that the FAA consider an implementation schedule based on the size of the organization, factoring in any existing voluntary programs. EASA noted that the proposed compliance timelines for part 21 are close to the compliance timeline for full implementation of SMS in the European regulatory framework (March 7, 2025) and that extending timelines beyond those as proposed may delay FAA's SMS compliance with ICAO Annex 19 and may delay harmonization with other CAAs.

b. FAA Response

The FAA acknowledges the need to provide design and manufacturing companies adequate time to plan and implement their SMSs. Further, the FAA recognizes the challenges posed by establishing compliance deadlines for existing holders based upon fixed calendar dates that may be impacted by delays in the publication of the final rule. Based on the feedback the FAA received, the FAA is extending the time for design and manufacturing companies to implement SMS. Under the final rule, existing part 21 certificate holders that come under this final rule will be afforded 6 months after the rule's effective date to develop and submit an implementation plan and 36 months after the rule's effective date to implement their SMS in accordance with the FAA-approved implementation plan. This approach is consistent with the approach in the original part 5 for part 121 operators, as well as EASA's

SMS rule and the recommendations from the 2012 part 21 SMS ARC.

New and pending applicants for a PC will be required to submit implementation plans as part of the production certification process (as was proposed in the NPRM). The FAA will not issue a PC until the Agency has received the required implementation plan. Submission of the implementation plan is the only prerequisite under part 5 before an applicant may be issued a PC. Once an implementation plan has been submitted to the FAA, applicants will have 36 months to implement their SMSs rather than the 12 months previously proposed.

As a result of these changes, the timeframes for existing certificate holders and future and pending applicants will be consistent. Regarding GAMA/AIA's request to extend the requirement for TC holders that apply for a PC less than 1 year after the final rule becomes effective, the FAA does not agree that an extension is warranted because development of the implementation plan itself need not be complex. In addition, the FAA has provided information and materials in AC 21–58 to aid in the development of the plan.

E. Use of the Term ''Person''

In the NPRM, the FAA proposed to amend various sections in part 5 to change the term ''certificate holder'' to ''person.'' The FAA proposed this revision as a non-substantive conforming change. Prior to this rule, part 5 had only applied to part 121 certificate holders, and the reference to ''certificate holder'' in part 5 was appropriate. The FAA proposed to expand applicability beyond certificate holders to include § 91.147 LOA holders. With that change, ''certificate holder'' would no longer be accurate and the FAA proposed replacing it with ''person.''

1. Discussion of the Final Rule

This rule adopts the proposal to use the term ''person'' in place of ''certificate holder.''

2. Summary of the Comments

Commenters, including Airbus, Alaska Seaplanes, Ameristar Air Cargo, Cargo Airline Association, Delta Air Lines, RAA, NBAA, U.S.C. Aviation Safety Management, U.S.C., and three individuals objected to or sought clarification regarding the change to use the term ''person'' instead of ''certificate holder.''

3. FAA Response

The term ''person'' is defined in 14 CFR 1.1 as: ''an individual, firm, partnership, corporation, company, association, joint-stock association, or governmental entity. It includes a trustee, receiver, assignee, or similar representative of any of them.'' This definition includes certificate holders, service providers, or other types of individuals or business entities and is used throughout 14 CFR. As a result, the term ''person'' is not only appropriate, but also consistent with existing FAA use. Accordingly, the FAA replaces ''certificate holder'' with the term ''person,'' as proposed.

F. System Description

In the NPRM, the FAA proposed in § 5.5 that any person that is required to have an SMS must develop a system description. The proposed description included, at minimum, the person's aviation-related processes, procedures, and activities; the function and purpose of the aviation products or services provided; the operating environment; and the personnel, equipment, and facilities; as well as identifies the interfacing persons that contribute to the aviation-related products and services provided.

1. Discussion of the Final Rule

In the final rule, the FAA adopts a system description requirement with a number of notable changes from the NPRM. First, the requirement to develop a system description applies only to part 21 certificate holders. Second, the FAA removes the system description requirement from § 5.5. Instead, the FAA is moving most of these requirements to § 5.17. Section 5.17 now expressly states that only summary information must be included in the system description. The FAA is not adopting the proposed requirement for the system description to include information concerning the aviation organization's interfacing persons. Finally, the term ''system description'' is renamed to ''organizational system description'' to clearly denote that this requirement applies to the aviation organization and to avoid any confusion with the ''system analysis'' in § 5.53.

As a result of these changes, the requirements for developing and maintaining an organizational system description are now in the sections specific to the part 21 entities (§§ 5.11(a), 5.13(b)(1), 5.15(b)(1) and 5.15(c)(1)) and the documentation requirement in proposed § 5.95(c) is removed.

2. Summary of the Comments

Several commenters expressed concern that the proposed requirements in § 5.5(b) to develop and maintain a system description creates an administrative burden without a corresponding safety benefit. Commenters, including Pratt & Whitney, GE Aerospace, and University of Southern California Aviation Safety and Security, said it would be a significant administrative burden to maintain a system description that lists all interfacing entities because the list is continuously changing given the fluidity of aviation operations. In addition, an individual indicated the requirement was unnecessary and Delta Air Lines requested clarification regarding the FAA's expectations.

Baldwin Safety and Compliance noted that system descriptions are not required by most other CAAs and suggested the requirement be removed from the final rule to better align with the ICAO Annex 19 Appendix 2 framework and other CAAs. TCCA suggested a system description may be better as a recommendation within guidance, rather than a required document, because it may be burdensome for small operators without enhancing their safety.

Some commenters expressed concern about how the system description requirement would affect part 121 operators. Delta Air Lines said the system description could create significant administrative work. RAA and Cargo Airline Association acknowledged system descriptions may be helpful for new adopters of SMS, but strongly recommended the FAA remove the requirement for part 121 operators or limit it to new applicants.

3. FAA Response

The FAA acknowledges the concerns by some commenters on the potential impacts to operators, large and small. Upon further evaluation, the FAA has determined that developing a system description should not be a requirement for operators (§ 91.147, part 135, and part 121) because the information required by the proposed provision is already documented by part 121 and 135 operators in their Operations Specifications and in the LOA application for § 91.147 operators.

Production organizations holding or applying for a production certificate have certain organizational description requirements in § 21.135 (requiring the PC holder or applicant to provide a document describing how its organization will ensure regulatory compliance and describing assigned

responsibilities, delegated authorities, and organizational relationships for quality). However, there are no organizational requirements associated only with a type certificate. This difference may cause some aviation organizations to believe that SMS is applicable only to production activities and not to other activities such as design. As a result, the FAA retains the organizational system description requirement for part 21 organizations to ensure that SMS is applied to design, certification, production, and continued airworthiness activities.

In response to commenters' concern that developing a system description would be overly burdensome and difficult to maintain, the FAA is requiring in the final rule that only a ''summary'' of these processes, procedures, and activities need to be included in the organizational system description. Therefore, a part 21 design and manufacturing organization should include a summary of the following processes in their organizational system description: design, certification, production, and continued operational safety; however, it does not have to list every process individually. AC 21–58 includes guidance regarding developing the organizational system description.

The FAA acknowledges the concerns over the potential burden related to the proposed requirement in § 5.5(b) for an aviation organization to include in its system description information on ''interfacing persons that contribute to the safety of the aviation-related products and services provided.'' The list of interfacing persons for a large company could number in the thousands, but most of those persons may never actually be involved with a safety hazard. As a result, in the final rule, the FAA is removing the requirement to include information about interfacing persons from the organizational system description. The design or production organization will engage with the proper interfacing persons during safety risk management through the requirement that the organization ''consider interfaces'' in § 5.53(b)(5) and the ''hazard notification to interfacing persons'' requirement in the new § 5.57 (discussed in the following section). This change will allow the covered aviation organization to identify the proper interfacing persons on an as-needed basis rather than developing and maintaining a listing of all interfacing persons that could theoretically be involved in safety risk management.

G. Notification of Hazards and Protection of Information

In the NPRM, the FAA proposed to add a new section (§ 5.94) to require the person who identifies a hazard to notify the interfacing person in the best position to address that hazard or mitigate the risk, and also to develop and maintain procedures for reporting and receiving such hazard information.

1. Discussion of the Final Rule

The FAA is retaining the intent of proposed § 5.94 but is making regulatory text changes to better integrate sending and receiving hazard information with other functions in the SMS. To that end, the FAA has decided to remove proposed § 5.94, instead placing these requirements in subparts C—Safety Risk Management and D—Safety Assurance. Specifically, the requirement to provide notification of hazards is added to § 5.57, which is also amended to include language clarifying that ''interfacing persons'' are those who contribute to the safety of the aviation-related product or service.

In addition, the FAA has added to § 5.71(a)(8) a requirement to investigate hazards received from external sources to clarify that the aviation organization must investigate any hazard information received and process the investigation results through its safety assurance and safety risk management processes. Proposed § 5.94(b) required a process to receive the hazard notification but did not require the aviation organization to do anything upon receipt of a hazard notification. While the proposed regulation implied that the aviation organization should investigate, it did not explicitly require such action. The final rule makes it clear that an aviation organization must investigate and address through its safety assurance and safety risk management processes all hazard notifications it receives. Finally, § 5.97(d) is updated to replace the reference to ''§ 5.94'' with ''§ 5.57'' to ensure aviation organizations retain records regarding the hazard communications.

2. Summary of the Comments

Several commenters requested clarification regarding the proposed notification of hazards to interfacing persons requirement. Some commenters asked for clarification regarding who the ''interfacing person'' would be and the actions the interfacing person would be required to take.

Pratt & Whitney recommended the FAA clarify ''interfacing persons'' be limited to those stakeholders outside the organization's quality management system having airworthiness decision-making responsibilities because this would result in a manageable list of stakeholders while realizing the hazard notification benefits. GE Aerospace noted a person who identifies a hazard may not have the requisite knowledge or information available to identify which persons are best able to address or mitigate the hazard. It recommended that the FAA either delete this requirement or revise it to require the person to notify the appropriate holders of FAA design, production, or maintenance approvals.

Other commenters requested that the FAA clarify what hazards must be reported under the notification requirement. Airbus Commercial Aircraft suggested the requirement should only require relevant safety hazards to be shared with interfacing persons. RAA stated not all hazards rise to the level of risks, or at least may not rise to that level equally across all carriers as a standard deviation, and noted it is not convinced that this requirement will enhance aviation safety.

Cargo Airline Association noted that this requirement raises many questions concerning the practicality and scope of the requirement. It also expressed concern that this requirement could have a chilling effect on voluntary reporting and ''just culture.''

Collins Aerospace Division of Raytheon Technologies supported the sharing of hazard information with stakeholders; however, it also stated that additional formal documentation and recordkeeping could impede timely information transfer and could preclude reporting in certain situations.

Other commenters expressed concern about protecting proprietary data related to sharing of hazard information. Some commenters raised concerns about whether or how the hazard information disclosures would be protected from public release. They noted that 49 U.S.C. 44735 protects certain SMS information from disclosure under the Freedom of Information Act (FOIA) when submitted to the FAA voluntarily, but they wondered what protections would exist when disclosure to the FAA is mandated by this rule. Other commenters asked whether there is any way to protect proprietary information given that hazard information notification would require them to disclose information to private parties. Commenters indicated that unintended liabilities or other legal consequences could arise between private parties as a result. For example, once a person reports a hazard to a (non-FAA) third-party, nothing would prohibit that party

from releasing that information to the public or to other government regulators. While many commenters supported the concept of reporting hazards to interfacing persons, most objected to disclosing proprietary information to third parties without disclosure protections. For instance, GAMA asserted the notification requirement is vague and said the FAA provided no direction for how proprietary data will be handled, or how Export Administration Regulations would be handled in the case of interfaces with international organizations. This commenter noted some US-based companies contract with foreign Original Equipment Manufacturers to build proprietary components and have been granted an Export Control Classification Number license for rotor systems or transmissions, suggesting that sharing technical data with them may not be legal, and recommended the FAA consider international business communication mandates that may conflict with other U.S. Government restrictions.

3. FAA Response

The FAA seeks to encourage a more collaborative approach in which persons required to have an SMS share hazard information with each other and work together to identify and address hazards and safety issues. Hazard information sharing would enable a network of aviation organizations working collaboratively to manage risk, thereby enhancing the safety benefits of SMS by assuring that hazards are communicated and mitigated effectively. Therefore, the FAA is retaining the intent of the requirements, but making regulatory text changes to better integrate the sending and receiving of hazard information with the other functions in the SMS. To that end, the FAA moved the requirement to provide notification of hazards to subpart C—Safety Risk Management (§ 5.57). The FAA moved the receipt of hazard notifications to subpart D—Safety Assurance (§ 5.71), requiring the aviation organization to investigate hazard notifications received from external sources.

The FAA acknowledges the commenters' concerns regarding sharing information outside an aviation organization. Commenters requested clarification regarding whether the FAA could protect FOIA information disclosure. If an aviation organization reports hazard information to the FAA because the Agency is the interfacing person who could address the hazard, the information is not protected from FOIA disclosure. Once a report is required, FOIA disclosure protections in 49 U.S.C. 44735 no longer apply. However, the FAA would redact trade secret or confidential commercial or financial information before release. If an aviation organization discloses hazard information to a third party, the FAA cannot protect the information. The protection under 44735 only safeguards against public release by the FAA under the FOIA and does not extend to release by other governmental entities or private parties. One option for safeguarding information includes entering into non-disclosure agreements with the interfacing person. Aviation organizations may explore other ways to communicate information about hazards without disclosing proprietary or confidential elements.

Sharing hazard information is an important part of improving safety from which all participants in the aviation eco-system can benefit. The FAA does not expect that sharing hazard information would require the sharing of proprietary or confidential information; it would only require the aviation organization to adequately describe the hazard. The FAA still expects that in instances where the hazard cannot be adequately described without the use of proprietary information, the aviation organization itself would likely be in the best position to address that hazard, and therefore, information sharing probably would not be necessary.

Some commenters raised questions about what would happen if they made a report to a third-party interfacing person and then subsequently reported that same information to the FAA. Under this hypothetical, the third party is an interfacing person, but the FAA is not. This means that the report to the third party would be mandatory, but the subsequent report to the FAA would be voluntary. That voluntary report to the FAA would be excluded from release under the FOIA, except as allowed under section 44735 (*i.e.,* de-identified information).

In addition, the requirement limits reporting of information to ''interfacing persons,'' which creates limits on which information the aviation organization must report. Section 5.57, which is newly adopted in the final rule, is limited to interfacing persons that, to the best of the notifying person's knowledge, could address the hazard or mitigate the risk. Section 5.57 clarifies further that interfacing persons are only those that contribute to the safety of the organization's aviation-related products and services. In practical terms, these limitations will effectively limit the hazard reporting requirement to organizations with which the aviation organization already has a relationship. This limit addresses some of the commenters' concerns regarding the scope and practicality of providing and receiving notification of hazard information to third parties. For example, interfacing persons for a part 135 operator or § 91.147 air tour operator could be any organization that the operator conducts business with, such as a fixed base operator, a repair station, airports where operations are conducted, or the aircraft manufacturer. An operator's customers, however—such as revenue passengers in a passenger-carrying operation—would not ordinarily be considered interfacing persons because passengers are not responsible for or expected to contribute to the safe operation of the aircraft (besides not interfering with the operation). The interfacing person for a design and manufacturing organization providing an aircraft, engine, or propeller would typically be suppliers of parts or engineering services for the aircraft, engine, or propeller. A competing manufacturer, on the other hand, would not be considered an interfacing person because a competitor to a TC and PC holder would not generally have any contribution to the design or production of the product provided by the TC and PC holder.

As an example of hazard information sharing, consider a part 135 air ambulance operator that identified a hazard with the helicopters it is operating. The investigation of one of its helicopters that was involved in a near controlled flight into terrain, identified that the volume of the audio warnings in the helicopter terrain awareness and warning system (HTAWS) fluctuated so the warnings were barely audible at times.

In applying § 5.57, the part 135 operator first determines, to the best of its knowledge, which interfacing person(s) could address the hazard or mitigate the risk. The air ambulance operator examines the HTAWS for wiring damage or wear and tear and, seeing none, determines that the issue is more likely the result of a design or production defect than a maintenance concern. Next, the part 135 operator confirms that the helicopter manufacturer contributes to the safety of the air ambulance services. In a call with the manufacturer's representative, however, the operator learns that the HTAWS was not part of the original helicopter design, but rather, was installed a few years after production by the previous owner through an STC. The operator does some research to

ascertain the identity and contact information of the STC holder, the manufacturer of the particular HTAWS unit. Prior to sending the hazard notification to the HTAWS manufacturer, the air ambulance operator removes any proprietary or confidential information from the hazard report, including proprietary or confidential information involved with how the hazard was identified (*e.g.,* as a result of internal investigation of a near accident), who identified the hazard (*e.g.,* the names of the pilots and crew involved), or any risk mitigating actions the part 135 operator has implemented. Note that the air ambulance operator is not required by § 5.57 to provide notification of the hazard to other helicopter operators that use the same HTAWS model in their helicopters because these other operators do not contribute to the safety of the services provided by the part 135 operator. This example illustrates how aviation organizations can meet the hazard information sharing per § 5.57 without compromising confidential business or personal information, by: (1) identifying the interfacing person who could address the hazard or mitigate the risk; (2) confirming that the interfacing person contributes to the safety of the products or services provided by the aviation organization; and (3) removing any proprietary or confidential information other than the hazard details from the report prior to sending it to the interfacing person.

The FAA emphasizes, however, that providing notification of hazard information to an interfacing person in accordance with § 5.57 does not replace any other regulatory obligations to report or provide notification of safety issues, such as requirements under 14 CFR 135.415 (service difficulty reporting), 49 CFR 830.5 (notification and reporting of aircraft accidents and incidents), or 14 CFR 21.3 (reporting of failures, malfunctions, and defects).

Finally, section 102(a)(2)(B) of the ACSAA mandates that the SMS regulations required to be issued under the statute include ''provisions that would permit operational feedback from operators and pilots qualified on the manufacturers' equipment to ensure that the operational assumptions made during design and certification remain valid.'' The hazard information sharing requirements established in this rule create the structure for the type of feedback Congress intended for part 21 certificate holders.

H. Recordkeeping—Communications Regarding Hazard Information Notifications

In the NPRM, the FAA proposed to amend § 5.97(d) to require the retention of records of all communications that occur under the hazard reporting requirements of proposed § 5.94, for a minimum of 24 consecutive calendar months.

1. Discussion of the Final Rule

The proposed requirement for notification of hazards to interfacing persons in § 5.94 has been incorporated into the safety risk management and safety assurance within subparts C and D (§§ 5.57 and 5.71(a)(8)) (as discussed in Section IV.G.). The FAA is updating § 5.97(d) in order to reference the new § 5.57, but the amendment is otherwise adopted as proposed. Section 5.97(d) now requires covered aviation organizations to retain records of all communications involving the notification of hazards to interfacing persons, as required by § 5.57, for a minimum of 24 consecutive months.

2. Summary of the Comments

Commenters expressed concern regarding the requirements to maintain records of communications pertaining to notifying interfacing parties of hazards. Further, commenters requested additional information and clarification regarding what the FAA's expectations are for compliance, and urged flexibility, noting that recordkeeping could be burdensome for some organizations. NATA commented the FAA should allow operators to use third-party electronic systems that facilitate their participation in SMS. In addition, it indicated that the FAA should ensure that all businesses are able to use electronic systems for their SMS records without requiring them to obtain FAA approval (via Operations Specifications) for an electronic recordkeeping system.

TCCA suggested that the 24-month minimum period for record retention could be too short. TCCA said disposing records after that period could lead to the loss of pertinent information on hazard reporting and prevent the ability to identify historical trends.

3. FAA Response

The new documentation and recordkeeping requirement is necessary because of the requirement for all persons under part 5 to provide notification of hazards. Maintaining records of communications regarding notification of hazards provides objective evidence of compliance similar to the records that are maintained for internal safety communications conducted in accordance with § 5.93. As with the other performance-based and scalable requirements, aviation organizations should determine how they meet these requirements in a way that fits their organization.

Commenters indicated that the FAA should be flexible in allowing aviation organizations to determine how to maintain records. As stated in the NPRM, the operator chooses how it maintains the required SMS records, which can be electronically or in paper format. Regarding NATA's comment on allowing operators to use third-party electronic systems without requiring them to obtain FAA approval (via Operations Specifications or OpSpec) for an electronic recordkeeping system, the FAA has determined that the requirements of § 5.97(d) do not present any unique challenges to justify deviation from standard practices currently applicable to part 135 operators. Authorizations to use electronic recordkeeping are issued to certain operators via OpSpec A025 when they elect to maintain required records electronically. If a certificate holder operating under part 135 seeks to develop and maintain its SMS records utilizing a electronic system (whether third-party or internally developed), and does not already have OpSpec A025 authorization, it should follow the standardized process for obtaining OpSpec A025 for electronic recordkeeping.[37] In contrast, if an air tour operator with an LOA under § 91.147 chooses to maintain its SMS records via an electronic system, the FAA has determined that, as of the publication date of this final rule, no specific authorization via an OpSpec will be needed. Due to the low volume of documentation LOA holders under § 91.147 are required to maintain, creating a special authorization for these operators related to electronic recordkeeping is not warranted as it creates additional work for the operator and the FAA with no added value. For more information regarding the use of services provided by third parties, see Section IV.L.2.iv. For more information regarding scalability, see Section IV.J.

TCCA commented that a 24-month retention period may be too short and could lead to the loss of pertinent information on hazard reporting. The 24-month retention period applies to the

[37] The FAA notes that the procedures for obtaining operations specifications, including the necessity for many operators to obtain OpSpec authorization for electronic recordkeeping, are under continuous review and are subject to change in the future.

records of communications. Any records of outputs of safety risk management processes must be retained for as long as the control remains relevant to the operation. As a result, information regarding identified hazards is not limited to the 24-month retention period related to communications.

I. ''Hazard'' Definition

In the NPRM, the FAA proposed to revise the definition of ''hazard'' to align it more closely with ICAO Annex 19. The definition in original part 5 (§ 5.5) reads as follows: ''*Hazard* means a condition that could foreseeably cause or contribute to an aircraft accident as defined in 49 CFR 830.2.'' In Annex 19, ICAO defines ''hazard'' as ''a condition or an object with the potential to cause or contribute to an aircraft incident or accident.'' [38] The FAA proposed to further align with the ICAO definition by adding after ''a condition'' the phrase ''or an object,'' replacing the phrase ''that could foreseeably'' with ''with the potential to,'' and inserting ''incident'' before ''aircraft accident,'' such that the definition would read as follows: ''*Hazard* means a condition or an object with the potential to cause or contribute to an incident or aircraft accident, as defined in 49 CFR 830.2.''

1. Discussion of the Final Rule

To better align with the ICAO Annex 19 definition, the FAA is adopting the changes to the definition of ''hazard'' as proposed in the NPRM, with the exception of the proposed change from ''foreseeably'' to ''potential to.'' The definition now reads as follows: ''*Hazard* means a condition or an object that could foreseeably cause or contribute to an incident or aircraft accident, as defined in 49 CFR 830.2.'' With these changes, particularly the inclusion of the term ''incident,'' the final rule clarifies that anything that affects or foreseeably could affect the safety of aviation operations is included in the definition of hazard, not just those conditions or objects that could result in serious injury, death, or substantial damage.

2. Summary of the Comments

RACCA, AMOA, Ameristar Air Cargo, GE Aerospace, Small UAS Coalition, RAA, MARPA, and GAMA/AIA expressed opposition to elements of the proposed revision of the definition of ''hazard.'' Some commenters, like AMOA, were opposed to the replacement of the word ''foreseeably'' with ''with the potential to.''

Delta Air Lines supported the FAA's proposed modification of the definition of ''hazard'' to include incidents as well as accidents. It said the FAA's proposed changes would boost safety by expanding the scope of potential hazards to address.

MARPA, GE Aerospace, Pratt & Whitney, and an individual expressed concern that the expanded scope of hazards contemplated by the proposed inclusion of ''incidents'' might introduce additional safety risks as organizations spend more resources on concerns less likely to yield increased safety benefits. Pratt & Whitney urged the FAA to use a consistent definition of ''incident'' in other guidelines and requirements to help maintain a focus on issues that have a potential for an accident.

MARPA said the NTSB's definition of ''incident'' in 49 CFR 830.2 is purposefully defined broadly because it is intended to give the NTSB flexibility in pursuing investigations into aircraft incidents, reflecting a very different context than that of the proposed SMS rule. MARPA said the FAA's proposed definition would encompass many incidents affecting the safety of operations that would be entirely beyond the control of a production approval holder; even though they might be considered foreseeable under an SMS, it would be unreasonable to expect production approval holders to anticipate and mitigate these incidents.

Phoenix Air Group, LLC said the FAA's estimate of the cost and effort of SMS implementation fails to account for companies whose SMS applies across their entire organization, and whose definition of hazard, therefore, encompasses far more than potential causes of aircraft accidents. It advised the FAA to introduce a separate definition for the term ''accident'' to cover instances of injury to personnel or damage to aircraft, equipment, or facilities not associated with an intention for flight, as well as refine the definition of ''hazard'' to go beyond aircraft accidents or events associated with the operation of an aircraft. For example, the commenter said a puddle of oil on a hangar floor is clearly a hazard in its SMS, but it does not meet the definition of a hazard under the SMS rule or Annex 19.

3. FAA Response

The FAA disagrees that the inclusion of the word ''incident'' in the definition expands the scope of ''hazard.'' As stated in the NPRM preamble, many of the same circumstances that result in an incident could just as easily result in an accident. The ''conditions'' and ''objects'' that could ''foreseeably cause or contribute'' to an aircraft accident, such as a mid-air collision, have been found to be the same conditions and objects that cause or contribute to near mid-air collisions (*i.e.,* incidents).[39] Under the previous definition, an aviation organization that applies the SMS requirements may have identified conditions in its systems that could foreseeably result in an aviation accident. Under the revised definition, the same aviation organization will, in general, identify that the same conditions are present that could foreseeably cause or contribute to either incidents or accidents. From the FAA's experience, it would be highly unlikely that the aviation organization would discover new conditions that can cause or contribute to an incident but not an accident. Therefore, the change would not create an additional burden or divert resources to efforts that would not yield safety benefits.

The final rule changes to the definition, notably the addition of ''incident,'' do not result in a substantial expansion in the scope of hazards that a covered person needs to address. First, aircraft incidents are already covered to a large extent under the original part 5 SMS framework, even if the term ''incident'' was not expressly included in the ''hazard'' definition. The part 5 safety assurance processes require investigations of both incidents and accidents (§ 5.71(a)(5)) and subsequent analysis (§ 5.71(b)) and assessments to identify new hazards (§ 5.73(a)(4) and (5)). The safety assurance processes and systems must also include a confidential employee reporting system in which employees can report incidents (in addition to hazards, issues, concerns, and occurrences) (§ 5.71(a)(7)). These changes are consistent with the original SMS rulemaking in 2015, which was designed to improve safety by addressing underlying organizational issues that may result in accidents or incidents.[40]

The FAA disagrees that the term incident is not defined. The term ''incident'' is defined in 49 CFR 830.2 (as is ''aircraft accident''). As defined, ''incident'' means ''an occurrence other than an accident, associated with the operation of an aircraft, which affects or could affect the safety of operations.''

[38] International Civil Aviation Organization, Annex 19 to the Convention on International Civil Aviation, Safety Management, Second Edition, pp. 1–2 (July 2016).

[39] See Tinsley, Catherine H., Robin L. Dillon, and Peter M. Madsen. How to Avoid Catastrophe. Harvard Business Review, *https://hbr.org/2011/04/how-to-avoid-catastrophe* (2011).

[40] 80 FR 1308.

The FAA is not adopting the recommendation to introduce separate definitions for the terms ''accident'' and ''hazard'' to cover non-aviation-related concerns to avoid extending SMS requirements to subject areas such as workplace safety that extend beyond the intended scope of this rule. As noted in the NPRM, however, some aviation organizations might choose to extend their SMS to their non-aviation related activities, such as security and occupational safety and health issues. If an aviation organization elects to do so, the FAA will only conduct oversight of the SMS related to its aviation functions.

The FAA acknowledges the concerns by commenters that the phrase ''with the potential to'' could imply that the definition of hazard includes a boundless set of situations that could not be reasonably foreseen. The FAA agrees that ''with the potential to'' is too open-ended. Thus, the FAA is not adopting the proposal to replace the term ''foreseeably'' with ''potential to.'' The FAA recognizes that keeping the phrase ''that could foreseeably cause'' does not mirror the ICAO definition of hazard (which uses the phrase ''with the potential to''). The principal reason for proposing the changes to the definition of ''hazard'' was to align with the internationally recognized definition of hazard established by ICAO in Annex 19. The FAA seeks to align with ICAO where feasible. Although the FAA aspires to align with ICAO, the Agency also recognizes there may be situations, such as this, in which full alignment may not be the best solution. In addition, using the term ''foreseeably'' is consistent with the Agency's definition of hazard in the recently published Airport SMS rule.[41]

J. Scalability

An SMS is designed to be scalable to the size and complexity of the aviation organization, and to not be unduly burdensome. When part 5 was originally promulgated in 2015, the FAA clarified that small air carriers would not be expected to have an SMS as complex as one for large carriers. Further, the FAA stated in the original § 5.3 that the SMS must be ''appropriate to the size, scope, and complexity'' of the aviation organization.[42] To emphasize the scalability of SMS to the new types of aviation organizations covered under the proposed rule, the NPRM for this rule included examples of how small aviation organizations, such as a single-pilot operator, could scale implementation of their SMS requirements to the size and complexity of their organization.[43] Because the SMS requirements are performance-based and scalable, the FAA proposed to remove as unnecessary the scalability language in former § 5.3.

1. Discussion of the Final Rule

In this final rule, the FAA has decided to retain the express requirement for the SMS to be appropriate to the size, scope, and complexity of the aviation organization, in order to provide a better understanding of scalability as a result of the comments received. This text is moved, along with the other general SMS requirements in former § 5.3, to § 5.5.

2. Summary of the Comments

Commenters, including NBAA, EAA, and AOPA, expressed the need for scalable and flexible requirements. Commenters indicated part 5 is prescriptive and would be difficult for small operators to implement. Commenters also requested clarification regarding how an SMS can be scaled in application, and stated the FAA provided limited explanation or examples.

Several commenters suggested the FAA provide more guidance to small organizations on how to comply with the proposed SMS requirements. The NTSB said it issued Safety Recommendation A–22–15 to address confusion about how SMS applies to smaller operators. The NTSB said the proposed rule's treatment of scalability does not appear to follow its recommendation's call for scalability guidance to include specific details, such as methods and techniques as well as examples addressing several operational sectors. The NTSB also said more explicit guidance on strategies and methods applicable to smaller operators would make it easier for a range of operators to comply with the proposed requirements, as well as help the FAA inspectors in evaluating compliance by smaller operators. It further suggested that the FAA compile an inventory of SMS strategies and methods used by operators of different sizes, noting that the Agency could take advantage of its experience working with the FAA's voluntary SMS program participants, as well as overseeing part 121 operators.

Several commenters recommended that the final rule include an explicit statement establishing that the SMS is intended to be scalable. TCCA, Ameristar Air Cargo, Inc., GAMA, and AIA noted that scalability language in current 14 CFR 5.3(a) (''The SMS must be appropriate to the size, scope, and complexity of the certificate holder's operation. . ..'') was omitted from the proposed rule. These commenters urged the FAA to retain this language to ensure that the rule contains a clear statement of intent to incorporate scalability.

3. FAA Response

The FAA agrees with the commenters that SMS implementation should be appropriately scaled to the aviation organization. Part 5 was designed to be scalable and flexible. Aviation organizations should scale their SMS implementation to fit their operations. This concept is addressed in detail in the NPRM preamble and guidance material. Appendix G in AC 120–92 includes implementation strategies and examples regarding how small operators could comply with part 5 requirements.

The FAA, in an effort to address scalability, has designed part 5 to allow for flexibility in solutions used to meet the requirements. The rule specifies a basic set of processes to form a framework for the SMS but does not specify particular methods for implementing these processes. Aviation organizations can use solutions that are appropriate for their size and complexity. For example, smaller or less complex aviation organizations may use standard word processing software, Excel spreadsheets, email, notebooks, and whiteboards rather than more complex software solutions to document the system, policies, processes, and procedures. Larger or more complex aviation organizations may need more involved solutions that might include databases and layered hierarchical analysis and decision-making.

The following example illustrates how a small operator could scale implementation of SMS to fit its organization. The organization would document its safety policy; again, this could be done on paper or in a digital file. The example provided in the appendix in AC 120–92 could be used as a starting point, but there are also various examples available on the internet that could be used as a starting point.

To meet safety risk management and safety assurance requirements, the operator could use a tool such as the Web-Based Analytical Technology (WBAT) platform which is FAA-supported software, to support employee reporting and SMS. The platform could also be used to meet recordkeeping and documentation requirements. However, simpler options such as digital files on a computer or

[41] 88 FR 11642.

[42] 80 FR 1310.

[43] 88 FR 1952–53.

paper files could be used as well. For instance, AC 120–92 provides worksheets that the operator could use to meet most safety risk management requirements. To meet safety assurance requirements in a simpler way in a small operator, a person could observe how an operation is working and identify trends in real-time. If there are issues, the individual could take appropriate action and reevaluate the results. Any operational process could be observed and does not necessarily require formal audits or forms. Again, all of this could be documented on paper or in a digital file.

To meet communication requirements a small operator might use existing email applications to share information within its organization and with interfacing organizations, as appropriate. To meet documentation and recordkeeping requirements, the organization could use paper or digital files just as they might do for other areas of their operations such as invoicing, service, and rental agreements, etc. The organization could document this using a medium of their choosing, including something as simple as a notebook.

The following example illustrates how SMS might operate in a small, low complexity operator. This example company has two helicopters and four pilots, and it provides air tour services within a 25 nautical mile range of its home airport. The company has developed a safety policy under § 5.21 that reminds everyone safety is the company's number one priority. It contains in bold letters at the bottom, ''If you see something unsafe, say something.'' This policy statement is one page, signed by the company owner, and posted inside the office for all to see.

After a flight, one of the pilots reports to the air tour operator's home base that there is a new hazard in the flightpath of their desired tour route. The hazard is a power line across a canyon and there are no visibility markers on that line. The report of the hazard is the start of the safety risk management process under § 5.51(d). Under § 5.53, the air tour operator researches the location and height of the power line relative to the flight path in the area. The operator calls the power company and learns that the line is ½-inch thick and an expected date of installation for the markers is unknown due to manufacturing delays. This information is recorded in a notebook or digital file. Even the process for conducting this analysis under § 5.53(c) can also be located in the notebook or in a digital file.

Under § 5.53, the air tour operator determines the unmarked power line is an operational hazard. Knowing that helicopters and unseen power lines are a high risk and realizing that the company's air tour route places them in the exact spot of the canyon where the unmarked power line exists, makes this particular risk assessment easy. The air tour company determines the severity of hitting that power line would be catastrophic and the likelihood of encountering that power line is high due to their route of flight. Using a risk matrix, the operator qualitatively determines that the risk of conducting tours with the presence of the unmarked power line is unacceptable and requires risk controls be implemented to reduce the risk to an acceptable level. All this information is placed into the notebook. The operator develops risk controls under § 5.55(c), which, in this case, is a deviation to the planned air tour route. The evaluation of the risk acceptance under § 5.55(d) is done by talking to other employees, brainstorming, or engaging with other operators. The records of meetings or conversations, as well as the risk controls themselves, are documented using a medium of their choosing, including something as simple as a notebook or digital file consistent with the recordkeeping requirements of § 5.97.

The operator's next step is to monitor the controls it put into place through its safety assurance program. The operator will check on the deviation to the route it put in place under § 5.71(a)(1) through (a)(7). This can be done by tracking the flight path or auditing the new procedures and keeping those notes in the notebook. Under § 5.93, the operator will promote safety by informing the pilots of the hazard and communicating the safety action taken, which was providing the air tour route with a deviation. Each pilot can be issued a safety alert via a memo that can be handed to them upon check in and perhaps sent via email before the flight starts.

Just as existing part 5 requirements are performance-based and scalable, each revision proposed in the NPRM was also intended to be scalable. The FAA did not intend for the proposed removal of the scalability language to alter that stance. Based on the comments received, however, the FAA understands that the proposed removal caused confusion regarding its position on SMS scalability. Therefore, the FAA has decided to retain the scalability language, with minor adjustments to conform to general requirements language in § 5.5(a).

K. Code of Ethics

In the NPRM, the FAA proposed requiring a code of ethics be included in an aviation organization's safety policy. This proposal was in response to section 102(f) of ACSAA, which mandates: ''the regulations issued under subsection (a) shall require a safety management system to include establishment of a code of ethics applicable to all appropriate employees of a certificate holder, including officers (as determined by the FAA), which clarifies that safety is the organization's highest priority.'' While Sec. 102 of ACSAA is applicable only to certain part 21 certificate holders, the FAA proposed to apply the code of ethics requirement to all certificate and LOA holders that would be required to meet part 5 requirements.

1. Discussion of the Final Action

The FAA is adopting the code of ethics requirement as proposed. The code of ethics must clarify that safety is the aviation organization's highest priority. Having a code of ethics, applicable to all employees of the aviation organization, influences the safety culture of that organization and is beneficial to overall safety. As a component of an aviation organization's safety policy (§ 5.21(a)(7)), the new requirement helps ensure that every officer, manager, and employee in the organization is aware that safety is a core value for that organization and that safety risk should be reduced to the extent that it is practicable to do so. If employees see their management engaged with safety as the highest priority, then that same safety attitude will likely prevail throughout the entire organization. Therefore, all persons required to have an SMS benefit from having a code of ethics that confirms safety is the aviation organization's highest priority.

2. Summary of the Comments

Several commenters requested that the FAA either remove or modify the proposed requirement in § 5.21(a)(7) to include in an organization's safety policy a code of ethics, applicable to all employees, clarifying that safety is the organization's highest priority. Piper Aircraft and NBAA stated that it would be more appropriate for the code of ethics to state that safety is a ''core value'' of the company.

Commenters also indicated that safety cannot be a company's ''highest priority'' and safety must be balanced with production or the provision of the service they provide. For instance, NBAA stated that organizations are not

in the business of manufacturing safety and that an organization's highest priority is to sustain the business through maximizing profit balanced against appropriate risk control.

Commenters also expressed concern that the requirement may cause confusion or conflict with existing practices. For example, GAMA and AIA noted that the language could be misconstrued as creating a new standard of care or a new performance requirement and requested that the definition be revised to require the company to state their highest priority is compliance with applicable safety standards. Collins Aerospace Division stated that the language in the regulation may create a misunderstanding and lead to actions inconsistent with the FAA's current approach that allows continued temporary air operations with certain non-conformance or non-compliance. It recommended that the FAA reconsider the language to allow more flexibility to applicants to demonstrate in the code of ethics that safety is prioritized. Lockheed Martin Corporation also commented that the FAA should not mandate the use of specific words or phrases in this context.

Additionally, commenters requested clarification regarding the FAA's expectations for the code of ethics. Gulfstream suggested that the FAA clarify whether the code of ethics must be explicitly identified as a ''Code of Ethics'' or if the requirement is satisfied as long as the prescribed statement is present in the safety policy. AACA also asked if compliance would involve adding language to an organization's safety policy that mandates all employees prioritize safety above all else, or if the FAA expects each organization to create a document titled ''Code of Ethics.'' Zipline suggested that the FAA clearly define the expectations of the new code of ethics requirement, or if no additional clarification is provided, remove it.

AMOA's comment recognized the ACSAA mandate for the code of ethics was directed at design and manufacturing organizations and requested that different provisions be created for air transportation operators.

3. FAA Response

The addition of the code of ethics to an aviation organization's safety policy ensures that every officer, manager, and employee in the aviation organization is aware that safety is a core value for that organization and that safety risk should be reduced to acceptable levels. The FAA recognizes there is inherent risk in aviation. An SMS includes processes for aviation organizations to identify hazards and to assess and mitigate the risk associated with those hazards. It is not possible to completely eliminate risk in aviation. However, it is essential for aviation organizations to consider safety and the reduction of risk, and they should use their SMS to reduce safety risk to acceptable levels. As stated earlier in this preamble, an aviation organization is in the best position to mitigate the risk of its products or services. When providing products and services, the aviation organization must consider safety and, if there is a conflict between safety and other considerations, safety must not be compromised.

Section 5.21(a)(7) requires a code of ethics be included in a covered aviation organization's SMS safety policy. The FAA does not expressly require that the code of ethics be a separate document or be entitled ''Code of Ethics.'' Nonetheless, the FAA expects the aviation organization to make clear to its officers, managers, and employees, as well as to reviewing FAA personnel, that this component of the aviation organization's safety policy is a matter of ethics. The addition of this code of ethics does not create a new standard of care or new performance requirement for compliance with part 5. The safety hazard or risk may be identified, addressed, and mitigated using the existing processes and procedures for safety risk management, assurance, and promotion as required by part 5 (as amended by this rule). The addition of the code of ethics does, however, establish a new expectation for an aviation organization to prioritize safety over other concerns in the performance of its SMS processes and requirements.

The FAA acknowledges that section 102(f) of ACSAA requires the FAA to apply the code of ethics requirement to only part 21 design and manufacturing certificate holders. The FAA does not agree with some commenters, however, that the regulatory requirement should be limited to design and manufacturing organizations. Nothing in the ACSAA, express or implied, suggests that the FAA cannot or should not extend the code of ethics to other entities. The FAA seeks consistency in the SMS requirements to the greatest extent possible and, therefore, is extending this requirement to all aviation organizations required to comply with part 5. In general, the changes to part 5 are added to assist in maximizing the potential of an SMS to increase safety across the aerospace system and, as a result, fall within the scope of the FAA's broad safety mandate.

There is benefit to aviation organizations documenting their ethical commitment to safety. If this requirement were limited to only design and manufacturing organizations, the FAA would be concerned about implying some aviation organizations should make safety their highest priority, but others should not. In addition, ethical decision-making in the management of safety should be foundational to any SMS.

L. FAA and Industry Readiness for SMS

Several commenters asserted the FAA lacks the ability to adequately support and oversee the certificate and LOA holders required to develop and implement an SMS as proposed in the NPRM. In addition, several commenters recommended various ways to ensure adequate training is available to industry.

1. Summary of the Comments

Several commenters expressed concern about the FAA's ability to accept and monitor new, mandatory SMS programs in a timely, effective manner. A commenter asserted that the FAA would need to significantly increase staffing to review and approve implementation plans, arguing that Flight Standards District Office staffing levels are critically low. Other commenters suggested that the FAA is not prepared to support part 135 and § 91.147 companies, citing past experience with FAA staffing shortages, lack of effective training for inspectors and industry, unclear inspector guidance, and inconsistent inspector interpretation of guidance. Commenters, including NATA, NBAA, and AMOA, focused on inspector staffing levels, SMS expertise, and ability to oversee part 5. Commenters, including NBAA, and Alaska Air Carriers Association, also expressed concern about the consistency of guidance and the interpretation of guidance.

Several commenters recommended various ways to ensure adequate training is available to industry. Commenters, including WYVERN, Air Charter Safety Foundation, and Priester Aviation/Mayo Aviation LLC, focused on the FAA working with industry to provide training. Commenters, including WYVERN and NBAA, proposed creation of FAA-approved SMS consultant and designee programs, as well as the FAA pre-approving SMS services provided by third-party vendors.

2. FAA Response

The SMS training for FAA inspectors and engineers addresses validation of

operators' regulatory compliance through normal surveillance and oversight activities. The FAA continues to update and prepare its workforce to validate aviation organizations' implementation of SMS in support of this rule. The FAA also updated appropriate policy and guidance regarding oversight for part 5 compliance. To support an aviation organization's implementation of SMS, the FAA expects to conduct outreach with industry to facilitate understanding and implementation of SMS.

Finally, as SMS requirements expand to other aviation organizations, the FAA anticipates more third-party providers will offer services to aid aviation organizations in developing and implementing their part 5 compliant SMSs. Aviation organizations may work with a third party to develop or implement an SMS that meets the regulatory requirements. A third-party SMS provider could include the provider developing the SMS and training the operator to use it. Other options could include not only development and training, but the third-party could also operate some parts of the SMS on behalf of the aviation service provider.

However, there are some aspects of an SMS that must be performed by the aviation organization. For instance, the accountable executive responsibilities and roles cannot be delegated to a contractor. An aviation organization may choose to use third-party providers and other industry resources to assist and support SMS integration and development, as appropriate, but that aviation organization remains fully responsible for regulatory compliance. The FAA does not endorse the use of any specific product or third-party provider, nor does it pre-approve any specific service to meet the regulatory requirements. For more information regarding the use of third-party service providers, please see AC 120–92.

The NPRM did not propose the establishment of a designee or similar program for SMS. At this time, the FAA is not adopting such a program.

M. Aviation Organizations With an Existing SMS

Numerous commenters requested more information regarding how the FAA would approach compliance for existing SMS processes, programs, or certifications.

1. Summary of the Comments

NBAA and other commenters requested that the FAA accept third-party SMS as a means of compliance with part 5, while others requested credit for early adoption of an SMS. NBAA noted that some third-party SMS programs are compliant with ICAO Annex 19, and therefore, should be accepted by the FAA. Individual commenters raised questions about how part 5 relates to other SMS frameworks, and whether demonstration of compliance to ICAO Annex 19 could replace compliance with part 5 requirements.

Other commenters, including GAMA, TCCA, AACA, AMOA, CAMTS, PHI Health, Alaska Seaplanes, and Pratt & Whitney, indicated the need for clarification and assistance in bridging from voluntary SMS to mandatory SMS. They also expressed interest in how the FAA will consider existing voluntary SMS programs. Commenters expressed concerns with restarting the certification process and indicated the NPRM did not address FAA's voluntary SMS programs.

2. FAA Response

The FAA asserts that aviation organizations having an SMS that is certified, approved, or accepted by another entity or through the FAA's voluntary SMS programs does not replace the mandate to meet all applicable part 5 requirements. Companies are nonetheless encouraged to leverage existing processes and procedures to help meet part 5 requirements.

The FAA encourages companies to conduct a gap analysis to identify the areas where their aviation organization complies with part 5 and where requirements are unmet. Additional information about conducting gap analyses is available in AC 21–58 and AC 120–92.

Companies are encouraged to leverage existing SMS processes and procedures to help meet part 5 requirements and to utilize all available industry resources such as educational institutions, international organizations, as well as FAA guidance and support. However, the FAA will not be endorsing the use of any specific product or third-party provider to meet the regulatory requirements. Ultimately, the responsibility for ensuring compliance with part 5 remains with the organization.

N. Employee Reporting

Section 102(e) of ACSAA requires the FAA's SMS regulations to include a confidential employee reporting system through which employees can report, ''without concern for reprisal'', hazards, issues, concerns, occurrences, and incidents. Original part 5, under § 5.71(a)(7) of subpart D—Safety Assurance, already required a confidential employee reporting system, applicable to all covered entities, but did not expressly provide that the system be without concern for reprisal. The FAA proposed to add the text ''without concern of reprisal for reporting'' to the § 5.71(a)(7) confidential employee reporting system requirement, to respond to the mandate in section 102(e) of ACSAA.

1. Discussion of the Final Rule

In the final rule, the FAA is maintaining the revision to the employee reporting system requirements in § 5.71(a)(7). This requirement is applicable to all persons required to comply with part 5, except as identified in § 5.9(e).

2. Summary of the Comments

Several commenters expressed concern or suggested changes to the proposed requirements in § 5.71(a)(7) regarding developing and maintaining a confidential employee reporting system and that employees can report ''without concern of reprisal for reporting.''

NATA commented that the concept of confidential reporting of hazards is critical but becomes unachievable as business size decreases. NATA stated that the FAA should ensure that guidance and training recognizes this issue, as well as educate operators on best practices when business size limits the confidential reporting of hazards.

NBAA stated the proposed § 5.71(a)(7) requirement to implement and maintain a confidential reporting system is a prescriptive requirement, noting that some organizations may wish to implement an anonymous reporting system over a confidential one to provide more comfort in reporting. In addition, NBAA questioned how either a confidential or anonymous reporting system would work in a one or two-person organization.

Cargo Airline Association expressed its support for the proposed change because it increases safety and leads to a just culture. Cargo Airline Association also noted this requirement is consistent with the intent of other voluntary reporting systems, including the Aviation Safety Action Program (ASAP), and that it would support additional information in the guidance materials to provide safeguards like those under ASAP.

Multiple commenters expressed concern regarding not being able to act upon intentional malicious acts that are reported in the employee reporting system due the addition of the clause ''without concern of reprisal.''

3. FAA Response

As described in the original part 5 preamble, the confidential reporting system in § 5.71(a)(7) is a conduit for employees to raise aviation safety issues ''without fear of reprisal'' (see 80 FR 1307, 1318). Although the FAA did not include that express language in the text of original § 5.71(a)(7), the Agency's intent has always been that the confidential reporting system be non-punitive in nature. In this rulemaking, the phrase ''without concern of reprisal'' makes explicit what was already implicit, while also meeting the requirements of section 102(e) of the ACSAA.

With respect to concerns that aviation organizations would not be able to act upon intentional malicious acts by employees, the FAA emphasizes that the addition of the phrase ''without concern of reprisal'' does not alter or supersede the requirement in existing § 5.21(a)(5) for covered aviation organizations to establish policy that defines unacceptable behavior and conditions for disciplinary action. The FAA recognizes that there are instances where disciplinary action is warranted (*e.g.,* the behavior indicates a willful disregard to comply with company procedures or regulations). Confidential reporting and disciplinary action requirements have historically co-existed to address different concerns and behaviors. This allows the aviation organization to gather safety information from employees in a confidential manner while maintaining the freedom to address unacceptable behavior, ultimately supporting a just culture. Nothing in this final rule alters that.

The FAA also notes that although the ACSAA mandate to add the text ''without concern of reprisal for reporting'' to the confidential employee reporting system requirement is specific to part 21 certificate holders, this requirement applies to all persons that must comply with part 5. Protecting employees from reprisal for reporting aviation hazards, issues, concerns, occurrences, or incidents is critical for safety regardless of the type of aviation organization.

Further, some aviation organizations already have reporting systems in place, such as an ASAP. An ASAP would satisfy the confidential reporting program requirement for those aviation organizations that have a memorandum of understanding with the FAA for the specific employee groups. The FAA expects that these programs will continue to be used and be leveraged in the development and implementation of SMS. For employee groups that are not covered by an existing ASAP, the aviation organization must have an alternate means of compliance for confidential employee reporting.

Regarding the comments about a confidential reporting system versus an anonymous reporting system, the requirement does not prohibit an aviation organization from accepting anonymous reports. An anonymous reporting system, if correctly implemented, would satisfy the § 5.71(a)(7) requirements for confidentiality and non-reprisal; however, anonymous reporting is not necessarily the better or preferred system for employee reporting. For instance, with anonymous reports, an aviation's ability to obtain additional information is more difficult as the original reporter would remain unknown. Accordingly, the FAA is not adopting recommendations from commenters for the FAA to require anonymous reporting rather than confidential reporting.

Regarding the comments on the difficulty of maintaining confidentiality in a small aviation organization, the FAA acknowledges that maintaining confidentiality in a small organization may be more challenging. But these challenges do not outweigh the safety benefits of an employee reporting system for hazards and other aviation safety issues. Even if absolute confidentiality is not always possible due to the small numbers of employees in some aviation organizations, the FAA determined that organizations, regardless of size, can establish and communicate formal workplace policies for maintaining confidentiality and for non-reprisal of employee reports under § 5.71(a)(7). Aviation organizations, especially small ones, should strive for a just culture and reporting culture to encourage employees to report hazards and openly share information.

The FAA recognizes, though, that the confidential reporting system is unnecessary in aviation organizations where the pilot is the sole individual performing all necessary safety functions. Thus, employee reporting is not required for certain single-pilot operators, which is discussed further in Section IV.A.

O. Summary of Confidential Employee Reports

In proposed § 5.71(c), the FAA addressed the ACSAA section 102(e) requirement that the FAA require TC and PC holders to submit to the FAA, at least twice a year, a summary of the employee reports received through the confidential reporting system. Summaries of confidential employee reports submitted by certificate holders with both a TC and a PC are protected from public disclosure by 49 U.S.C. 44735(a)(2) if the summaries are requested under the Freedom of Information Act. The FAA did not propose to extend this requirement to all persons required to have an SMS because the information would not be protected under 49 U.S.C. 44735(a)(2) for persons that are not covered by the ACSAA requirement.

1. Discussion of the Final Rule

In the final rule, the FAA is maintaining the requirement in § 5.71(c) as proposed and per ACSAA requirements. Specifically, holders of both a TC and a PC for the same product will be required to submit to the FAA a summary of confidential employee reports received every 6 months.

2. Summary of the Comments

Commenters focused on the chilling effect this requirement may have on existing reporting systems and expressed concerns that employees may be hesitant to raise issues if they believe they may be personally subjected to scrutiny by a regulator. MARPA maintained that these reports create a burden on the holder, drawing resources away from addressing the actual risks raised in these reports. MARPA also maintained that the requirement imposes a burden on the FAA without a directive to do more, stating it is unclear what, if anything, the FAA should do with these reports. U.S.C. Aviation Safety Management Systems Course 23–3, Piper Aircraft, Inc., Gulfstream, and a member of GAMA/AIA highlighted the disparity of this reporting requirement across those required to comply with part 5. They asserted that the requirement should apply equally for those required to comply with part 5 or should not apply at all.

3. FAA Response

This final rule adopts the reporting requirement to part 21 organizations holding both a TC and a PC for the same product because the FAA is statutorily required to promulgate the requirement. Section 102(e) of the ACSAA does not give the FAA discretion with regard to whether this requirement should be imposed on TC/PC holders for the same product. The FAA understands the concerns surrounding confidentiality but reiterates that these semi-annual reports are specifically protected from disclosure under 49 U.S.C. 44735(a)(2). The reports submitted to the FAA should not contain any confidential or proprietary information.

The FAA has determined that this requirement should be applicable only to part 21 organizations holding both a TC and a PC for the same product because 49 U.S.C. 44735(a)(2) protections apply only to those entities. Requiring all covered aviation organizations to compile and submit semi-annual summary reports would result in the inconsistent treatment among regulated entities, because only the part 21 reports would be protected from public disclosure. Therefore, the FAA is limiting this requirement to only those entities specifically covered by the ACSAA requirement.

P. Emergency Response Planning

In the NPRM, the FAA proposed non-substantive edits to the requirements in § 5.27, Coordination of emergency response planning. Specifically, the FAA added a comma that was missing in the introductory text, removed the semi-colon format, and replaced ''certificate holder'' with ''person'' (or, in the case of paragraph (c), simply removed the term) in alignment with the change discussed in Section IV.E.

1. Discussion of the Final Rule

The FAA adopts the edits as proposed. As explained in the FAA response to comments that follows and in AC 21–58, the Agency clarifies that emergency response plans would not ordinarily be necessary for part 21 certificate holders.

2. Summary of the Comments

Several commenters expressed concern about the requirements to coordinate emergency response plans. NBAA asserted that the requirements are unclear, impractical, and burdensome for many part 135 operations and expressed concern regarding the number of interfacing organizations with which a part 135 operator might need to coordinate. The part 21 commenters indicated that the requirements should not apply to design and manufacturing organizations.

3. FAA Response

The FAA clarifies that the emergency response planning requirements of § 5.27 are not, in general, needed by part 21 organizations. Section 5.27 provides that an emergency response plan is required ''[w]here emergency response procedures are necessary.'' As explained further in AC 21–58, a part 21 certificate holder may be involved in the investigation of aircraft accidents or incidents but is likely not involved in the emergency response to the aircraft accident or incident. For this reason, the FAA has determined that emergency response planning is not ordinarily necessary for part 21 certificate holders.

With respect to the concerns from NBAA, the FAA notes that many part 135 operators already have emergency response plans that may be used to fulfill this requirement. One of the primary intents of an emergency response plan is to provide procedures for management decision-making and actions in an emergency, and not necessarily to require the creation and coordination of specific emergency plans for every airport a part 135 on-demand operator might serve. The FAA provides further guidance in AC 120–92 with examples of how various types of operators, including part 135 on-demand operators, interface and coordinate with other aviation organizations. In response to comments related to emergency response plans being impractical and burdensome, the FAA has excepted requirements of § 5.27(a) and (b) for certain single-pilot operations.

Q. Safety Risk Management

In the NPRM, the FAA proposed a new requirement under § 5.53(b)(5) to consider the interfaces of the system when conducting a system analysis as part of the safety risk management process. Interfaces are a point where two or more operations, systems, subjects, or organizations connect and interact. Interfaces can be internal to an aviation organization, or they can be external (*e.g.,* between organizations, between the system being analyzes and other systems, or between a human using the system and the system itself).

1. Discussion of the Final Rule

The FAA adopts the requirement to consider interfaces of the system when conducting a system analysis as proposed in § 5.53(b)(5). Hazards can exist with interfacing aviation organizations, processes, or systems in the way the two interfacing parts interact with each other. Understanding the interfaces while conducting a system analysis is important because the system analysis serves as the basis for identifying and analyzing hazards and their associated risk. As the aviation system becomes more complex, dynamic, and integrated, understanding these interfaces can assist in the identification of related hazards and improve safety overall.

2. Summary of the Comments

Several commenters were concerned with whom and how the safety risk management processes will be accomplished. Other commenters were concerned that requiring organizations to consider external interfaces during safety risk management processes could be too burdensome and may not add value because they do not control the activities of external organizations. Baldwin Safety and Compliance asserted that the requirement in § 5.53(a) requiring a system analysis when ''applying safety risk management'' is prescriptive and limiting.

3. FAA Response

Regarding the comments concerned with the burden and value of having to consider external interfaces during safety risk management processes, the FAA emphasizes, as it did in the NPRM, that an SMS that looks both inward and outward is more effective at identifying hazards, which is a core function of any operational SMS. Developing a good system analysis provides aviation organizations an opportunity to identify internal and external interfaces and will aid in the analysis process of the safety risk management by providing a whole system view. That said, the FAA does not expect external aviation organizations that do not have an input into the process or support the aviation activity to be included in the system analysis or safety risk management process. The system analysis is intended to limit the system only to those areas where the hazard was identified, and mitigations could be implemented. By reaching out to other aviation organizations that may be affected by the hazard, or have input to the system, substitute risks or residual risks to the system could be identified and more easily addressed.

Furthermore, the FAA is not requiring aviation organizations, through § 5.53(b)(5), to compel external interfaces to participate in risk analysis and system-related safety management, but rather, only to consider those interfaces when conducting system analysis. Aviation organizations are in the best position to determine whether those external interfaces should participate (and would be willing and able to participate) in an aviation organization's risk analysis activities.

Because part 5 is a performance-based regulation, the aviation organization can determine how to meet the requirements, which allows the organization to scale and adapt the methods used for safety risk management. The aviation organization can design the process to fit the organization's size and complexity. For more information regarding scalability, see Section IV.J.

R. Part 135 Pilot and Duty Rules ARC

In the NPRM, the FAA included the statement:

The identification of hazards through SMS may include analyzing the potential risk associated with crewmember fatigue when compounded by variations in individual part 135 operations, such as scheduling variances, frequency of operations, distance, and number of pilots.[44] Footnote 44 was linked to this statement and said: See report from the Part 135 Pilot and Duty Rules Aviation Rulemaking Committee dated July 2, 2021, a copy of which has been placed in the docket for this rule.

1. Summary of the Comments

NBAA, NATA, and NJASAP expressed concern and asked questions regarding whether the FAA intends for the rule to address the ARC recommendations.

2. FAA Response

While addressing hazards related to crew fatigue would be a part of a mature SMS, the FAA did not intend to imply that the ARC's recommendations would be covered by this rule. The FAA is evaluating the Part 135 Pilot and Duty Rules ARC's recommendations and weighing options to address them, which would need to be accomplished through a separate regulatory initiative.

S. Consistency With ICAO

The FAA noted throughout the NPRM that the proposed rule would more closely align the United States SMS requirements with ICAO Annex 19.

1. Summary of the Comments

Commenters expressed concerns about elements of the proposed rule that differ from ICAO Annex 19. Specifically, the Business Aviation Safety Consortium (BASC) noted that some elements of the proposed rule differ from the existing ICAO framework, which could lead to difficulties for flight departments that operate domestically and internationally where they must adhere to Annex 19. BASC asked whether these operators would need to operate two separate SMS programs or one hybrid program and cautioned that focusing on compliance with two separate frameworks could jeopardize safety when safety excellence already exists.

University of Southern California Aviation Safety and Security said that requiring an SMS that departs radically from the ICAO standards could require international service providers to maintain two SMS programs, which would be an unacceptable burden and could diminish the effectiveness of SMS. The commenter indicated that the FAA cannot be exercising international leadership in aircraft safety if it departs substantially from ICAO Annex 19, and that the current part 5 requirements should be standardized to reflect ICAO Annex 19 and Document 9589 more closely. Aviation Safety Solutions also said the FAA's reliance on a Quality Management System, rather than ICAO Annex 19, for its SMS rule could create disadvantages for international operators. Minnesota Business Aviation Association recommended that requirements be identically worded to ICAO to facilitate the approval process for ICAO-compliant SMS operators in the United States.

NBAA recommended returning to AC 120–92B because AC 120–92D is too prescriptive and inconsistent with ICAO Annex 19. It noted that several countries (Australia, Canada, Hong Kong, Saudi Arabia) applied Annex 19, Appendix 2 to their respective regulatory frameworks, which helps avoid challenges for international operators. NBAA highlighted the accountable executive requirement as an example where the proposed rule is less flexible than under ICAO, and also cited the code of ethics, data sharing, and systems description requirements as ''outside the scope'' of Annex 19.

2. FAA Response

ICAO Annex 19 directs member States to develop State safety programs for safety management and includes minimum requirements. Ultimately, each State is responsible to develop SMS regulations to implement this requirement. Part 5 fulfills this responsibility for the United States. An important distinction between Annex 19 and part 5 is that Annex 19 applies to the member States and part 5 applies to individual operators. As a result, each member State implements the Annex 19 SMS framework in accordance with its own processes and legal systems; accordingly, Member State regulations can vary to some extent. They meet Annex 19 requirements, however, if they include all of the elements in ICAO's framework. To be clear, Annex 19 does not apply directly to individual entities; its purpose is to direct member States to regulate those entities. Accordingly, the FAA developed part 5 to align with the SMS framework in ICAO Annex 19.

Part 5 includes all the elements in ICAO's Annex 19 framework, which means that the United States and, by definition, U.S. entities compliant with part 5 are in compliance with Annex 19.

Finally, the FAA issued AC 120–92D to be consistent with part 5. As a result, it is also consistent with Annex 19.

T. Safety Policy

In addition to comments regarding proposed amendments to the safety policy, which are addressed in other sections of the preamble, several commenters expressed concern about various safety policy requirements in subpart B of part 5, which were not amended, including the required contents of the safety policy and the responsibilities of the accountable executive.

1. Summary of the Comments

Pratt & Whitney said that the prescriptive list of requirements in § 5.21 for the safety policy requires a lengthy legal document that would not bring about the desired behaviors. The commenter requested industry latitude to develop safety policies, possibly from multiple sources, that satisfy the proposed list of requirements.

Small UAV Coalition questioned why § 5.25(a) requires a single individual to satisfy all four functions of the accountable executive, noting that some companies have specialized executives (*e.g.,* CFOs, Chief Human Resource Officers) that might better oversee a particular function. The coalition also said the requirement in § 5.25(c) for the accountable executive to ''designate sufficient management personnel'' is vague and questioned whether small companies could comply with this requirement if they designated all responsibilities to one person.

The U.S.C. Viterbi School of Engineering noted that the requirement for an accountable executive to review the safety policy is stated in both § 5.21 and § 5.25 and suggested it need only be stated in § 5.25. The commenter also recommended specifying how often this review should be conducted and suggested that annual reviews be required.

2. FAA Response

In response to the comments, the FAA notes that the only substantive addition to § 5.21 is the code of ethics now required under new paragraph (a)(7) (discussed in Section IV.J. of this rule). The other requirements in § 5.21, which were promulgated in the original part 5 rulemaking, are performance-based and are designed to provide the aviation organization with latitude in developing its safety policy. The FAA has included additional explanation in AC 120–92 and AC 21–58 providing suggestions for

[44] 88 FR 1940.

designating the accountable executive and management personnel, defining unacceptable behavior and conditions for disciplinary action, and the expectations for compliance in small entities.

With respect to the concern regarding possible duplication of requirements, the FAA notes that, in some cases, similar language is necessary to tie one SMS component to another SMS component to achieve the desired closed-loop system. For example, although §§ 5.21 and 5.25(b) use similar language, § 5.21 prescribes requirements on the aviation organization while § 5.25(b) prescribes the responsibilities of the accountable executive.

Neither Annex 19 nor part 5 specifies a set time interval, applicable to all covered entities, for reviewing the safety policy. Section 5.21(c) requires that the safety policy be documented and communicated throughout the aviation organization. This is where the aviation organization specifies the interval the safety policy is to be reviewed by the accountable executive, in a timeframe appropriate for its organization.

U. Miscellaneous Amendments

After further consideration, the FAA decided to add ''for the same product'' to § 5.1(e), § 5.1(f), and § 5.1(g) to clarify the applicability of part 5. The additional text clarifies that part 5 does not apply to either an STC holder or a PC holder for an STC because these design and production approvals are for modifications to a product and not for complete products. Similarly, there are persons who may hold a TC and a PC to produce parts or articles only. The final rule does not apply because the PC is only for the production of a part or an article and not for the same product.

In addition, in the NPRM the FAA proposed removing the word ''operations'' from § 5.71(a) to clarify the requirement and avoid confusion with the term ''operator.'' In retrospect, this change created additional confusion. As a result, the FAA is retaining the original part 5 language.

Finally, the FAA proposed amending § 119.8 to clarify that part 119 certificate holders authorized to conduct part 121 or 135 operations must have an SMS that meets part 5 requirements. On further review, the FAA determined that the amended language would have prohibited all operations while not in compliance with part 5, resulting in a new violation each time. This was not what the FAA intended. Accordingly, the FAA removed the language that would have provided for a per-operation violation. Section 119.8 now reads: Certificate holders authorized to conduct operations under part 121 or 135 of this chapter must have a safety management system that meets the requirements of part 5 of this chapter. This change ensures the FAA's approach to § 119.8 is consistent with past practices as well as other provisions in this rule.

V. Benefits and Costs

1. Comments in Support of Benefits

i. Summary of Comments

NetJets Association of Shared Aircraft Pilots claimed that the safety benefits of SMS have been well established over the years. The NTSB stated that in the 15 years since its first aviation safety recommendation for SMS in 2007, its investigations have consistently shown the need for aviation safety providers to implement SMS to ensure its benefits to industry and the public are realized. Aviation Safety Solutions also indicated that it anticipates substantial safety benefits from part 5. The commenter claimed that International Standard for Business Aircraft Operations Stage 3 operators have not had a fatal accident in 20 years, the result of industry-wide safety culture enhancements, continual data analysis, and ensuring that safety is the operator's top priority. Another commenter noted that the level of benefits required to breakeven for certain part 21 design and production approval holders is not much of a challenge.

ii. FAA Response

The FAA agrees with these comments and the potential benefits from SMS (the FAA does not have operator-specific information on International Standard for Business Aircraft Operations stage 3 to confirm the accident rate). SMS identifies hazards so mitigations can be implemented to reduce the potential of an accident occurring. By managing hazards in an operational environment, the potential for an accident is significantly reduced.

2. Comments Contesting Benefits

i. Summary of Comments

Phoenix Air Group asserted that an SMS does not mitigate or reduce the number of accidents in any known definition or study of such programs. One commenter questioned if there are studies that show SMS would have any effect on accident rates or overall safety. One commenter stated that the NPRM shows no data proving that the present SMS has improved safety. Another commenter found the actual accident-based case the FAA made for applying SMS mandates to single-person operations to be unsupported. Finally, one commenter expressed concern about the resources needed to implement an SMS and the lack of realistic practical benefits for certain small part 21 operations, for example, hot air balloon manufacturing.

ii. FAA Response

The FAA acknowledges the lack of studies documenting reduced accident rates under SMS. As stated previously, SMS assists aviation organizations in identifying hazards that could result in an accident so the organization can implement mitigations to reduce accident probability.[45] The FAA has determined that the requirements would be beneficial even applied to small entities, including small manufacturers, and implementation can also be scaled accordingly, as discussed in Section IV.J.

3. Comments on Costs

i. Summary of Comments

Phoenix Air Group, Inc. stated that incompatibility between the rule and ICAO Annex 19 Standards and Recommended Practices would require the company to maintain two different safety programs, increasing costs by 75%. It stated that it has a third-party provided SMS that meets the ICAO Annex 19 requirements for all its operations under multiple CFR parts. The commenter stated that the current annual cost would be much higher than the RIA estimate, and the costs after the addition of part 5 would also be much higher. Regarding the cost of risk mitigations, Phoenix Air Group stated the company's mitigations have ranged from no cost actions to actions that added hundreds of thousands of dollars requiring the company to modify one or more aircraft, including the purchase of a supplemental type certificate, which added hundreds of thousands of dollars to the cost for each installation and removed each aircraft from operation for many weeks.

ii. FAA Response

The FAA's estimates would not have accounted for the company's part 91 operations (other than § 91.147) or its repair station, or activity not affecting the safety of flight, which could explain the difference in costs. The commenter

[45] In the data for recent years (2020–2021), the FAA identified an additional 9 part 135 accidents and 1 § 91.147 accident (resulting in 27 fatalities and 8 serious injuries) in which SMS could potentially have prevented the accident. These accidents include the 2020 helicopter crash in Calabasas, CA resulting in 9 fatalities (the NTSB determined that a contributing factor to the accident was the lack of use and oversight of the company's SMS). These accidents also include single-pilot operations (NTSB accident number CEN20CA119).

also did not identify the gaps that would need to be addressed between the proposed rule and its current ICAO Annex 19 conforming SMS that would produce the projected additional costs. Although more specific in several areas, part 5 is harmonized with ICAO Annex 19, and the FAA disagrees that the rule would require separate SMS. The FAA acknowledges the potential range in mitigation costs, which will be specific to an aviation organization and the hazards identified.

iii. Summary of Comments

LifeFlight of Maine/LifeFlight Aviation Services LLC stated that it is in the small operator proposed cost profile in the NPRM with between 1–99 employees and 1–9 aircraft with costs estimates ranging from $7,500–$38,120 initial and $4,380–$39,420 annual recurring. It believed the cost estimates in the NPRM are significantly understated, citing a threefold increase in the NPRM proposed discounted costs from experience to date. It stated that, as a percentage of overall costs of operations, the NPRM proposed SMS mandate and timing are a significantly higher burden for smaller entities. Additionally, air medical operators are unable to pass through compliance costs via price increases as neither Medicare, Medicaid, nor commercial medical reimbursement recognize or allow costs associated with implementing and maintaining an SMS. The commenter stated that an effective SMS in a smaller program will look and feel quite different than the same in a large operation and spreading out implementation costs is essential for smaller operators.

iv. FAA Response

The commenter did not provide additional detail for the FAA to evaluate the cited threefold difference in costs incurred. As described elsewhere in this preamble, the FAA maintains that SMS processes, and thus costs, are scalable to the size and complexity of the aviation organization. Aviation safety regulatory compliance costs represent costs of air medical service provision. If insurance reimbursement rates do not fully cover service provision costs, then such costs could negatively impact profit or service provision. However, as also explained elsewhere, the FAA has determined that the requirement for SMS in part 135 operations should apply to small and large operators alike. The FAA is providing an additional 12 months for compliance to assist in the spreading out of implementation costs for small operators.

v. Summary of Comments

MARPA stated that the code of ethics provision affects a broad swath of individuals not reflected in the cost-benefit analysis, based on the requirement of the rule to ''be applicable'' to all employees. The Aviation Suppliers Association stated that many certificate holders who would be subject to the SMS regulations will flow down the requirements to aircraft parts suppliers and distributors through commercial obligations in contracts and other similar documents. The association found that flow-down appears to be an unintended consequence that exceeds the planned scope (and the cost-benefit analysis). It also suggested that a supplier to multiple certificate holders may be faced with adopting the disparate SMS requirements of several certificate holders, at a cost much greater than the cost of adopting its own SMS. The association also expressed concern that SMS requirements from other nations may not be consistent with the FAA's requirement, but nonetheless applied to suppliers from the United States. The commenter suggested that, for businesses that supply more than one certificate holder (directly or indirectly), having their own voluntary SMS program that is recognized by the FAA may be a more efficient model. MARPA and Aviation Suppliers Association also stated that the proposed requirement of § 5.94 to notify interfacing persons of identified hazards creates flow-down risks to persons not intended to have SMS and could impose significant cost on those parties. They suggested that the FAA audit the extent to which the interfacing provisions result in flow down requirements, and if the actual reach of the regulations is beyond the stated scope, then consider preparing a revised cost-benefit analysis for the rule.

vi. FAA Response

The FAA disagrees with these comments regarding costs. With respect to the code of ethics applying to all employees, the method the FAA used for extrapolating unit costs to design and manufacturing organizations entailed multiplying unit costs by the number of employees. Therefore, the costs estimates reflect the number of employees. With respect to hazard notification and the potential for flow down of SMS requirements, there are already flow down requirements from type and production certificate holders to suppliers to manage the quality of parts supplied (§ 21.137, Quality system). For example, type and production certificate holders already expect suppliers to fix defective parts. Regarding a voluntary SMS for suppliers, the FAA's voluntary SMS program is currently available to TSOA holders and PMA holders.

vii. Summary of Comments

GAMA and AIA stated it is unclear if additional mandates (interfacing communications, confidential hazard reporting, addition of system description, and record keeping) are included in the FAA's cost estimates. They stated that costs for a summary of confidential reports could approach $100,000 a year, is not part of the cost analysis, and that there is no value added from this requirement. They requested clarification that the Executive Order 12866 requirement to only adopt a regulation upon reasoned determination that benefits justify the cost is met. They also requested clarification that the Unfunded Mandates Reform Act of 1995 requirement that agencies prepare a written assessment of costs, benefits, and other effects of proposed or final rules is met.

viii. FAA Response

The FAA captures the costs of additions to part 5 in Tables 25 and 27 of the RIA. In the final rule, the organizational system description applies only to part 21 certificate holders and is only a summary-level description. Also, for part 135 and § 91.147, confidential hazard reporting is not applicable for certain single-pilot organizations. The FAA does not expect the summary of confidential employee reports for part 21 organizations to cost $100,000 per year. SMS requires analysis of safety performance data, including information obtained through confidential employee reporting systems. Therefore, these reports would already be consolidated, reviewed, and acted on as part of the company's SMS. The commenter's assertion of needing to cull out any military and international reports from a summary does not seem to explain this cost. As stated in the preamble to the proposed rule, the FAA maintains that benefits justify the cost, and that the costs do not meet the threshold in Unfunded Mandates Reform Act of 1995.

ix. Summary of Comments

AMOA disputed the Agency's cost analysis that includes part 135 operators with one employee-pilot. The commenter also found that the FAA assumes that third-party consultants or trade associations would provide ready tools for compliance by a small operator, yet the NPRM does not appear

to have examined the cost of third-party resources. The association urged the FAA to include a table specifically examining the costs of each SMS regulatory element for single-pilot operators to provide a better foundation for cost benefit analysis.

x. FAA Response

Regarding the FAA's cost estimate for single-pilot/employee operations, see also the FAA's response to comments regarding Applicability to part 135 operators and LOA holders under § 91.147 (in Section IV.A.), as well as Scalability (in Section IV.J.). Aviation organizations can use solutions that are appropriate for their size and complexity. For example, smaller or less complex aviation organizations may use notebooks and whiteboards rather than more sophisticated software solutions. The costs of these solutions would scale as well. The FAA subject matter experts reviewed the estimates used for part 135 operators, considering the experience of aviation organizations already implementing SMS and including higher cost areas such as Alaska, and found them reasonable.

The FAA did solicit costs of third-party resources as part of developing the NPRM. However, these resources and costs depend on the particular offering and pricing structure. For the NPRM and final rule, the FAA instead relied on the information from the FAA's voluntary SMS program participants. For part 135 and § 91.147, the FAA developed average costs based on number of aircraft for general categories of costs rather than element-by-element for single-pilot operators. As described in the RIA, the SMS ARC identified these sources of additional incremental initial and recurring costs that could be incurred as a result of an SMS rule, noting that these costs are highly dependent on the existing safety programs and systems within the aviation organization (see AC 120–92 for additional guidance). Table 26 in the RIA provides the results (based on the limited industry outreach documented in Tables 21 and 23). Whether existing processes in place would meet the external interface identification and notification requirements would also be operator specific. In addition, in the final rule, certain requirements are not applicable to certain single-pilot operators.

xi. Summary of Comments

Aviation Safety Solutions provided one-time and annual costs for emergency response plan manual, emergency response exercise, SMS manual, safety manager, SMS software, and training.

xii. FAA Response

Aviation Safety Solutions did not provide the size of the aviation organization these costs are relevant to (other than commenting that for an organization size of close to 100, one individual running the SMS would be insufficient). The FAA also notes that these items and positions may not be incremental at all aviation organizations and incremental costs would depend on the extent of processes and procedures in place, as well as the scaled methods that the entity choses for compliance (*e.g.,* small operators utilizing notebooks rather than SMS software). Therefore, the commenters' cost estimates may be relevant for some entities as one potential means of compliance with some requirements, rather than representative costs.

The FAA summarizes and responds to comments regarding the Initial Regulatory Flexibility Analysis in Section V.B.

W. Severability

As discussed earlier in this document, Congress authorized and required the FAA by statute to promote safety in aircraft manufacturing and operations. Consistent with that mandate, the FAA is requiring certain persons to implement an SMS that applies to their processes that have a direct effect on aviation safety. The purpose of this rule is to operate holistically in addressing a range of hazards in aviation. However, the FAA recognizes that certain provisions of this final rule will affect different organizations in different ways. Therefore, the FAA finds that the various provisions of this final rule are severable and able to operate functionally if severed from each other. In the event a court were to invalidate one or more of this final rule's provisions, the remaining provisions should stand, thus allowing the FAA to continue to fulfill its Congressionally authorized role of promoting safety in air commerce.

V. Regulatory Notices and Analyses

Federal agencies consider impacts of regulatory actions under a variety of executive orders and other requirements. First, Executive Order 12866 and Executive Order 13563, as amended by Executive Order 14094 (''Modernizing Regulatory Review''), direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a 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. The current threshold after adjustment for inflation is $177 million using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. The FAA has provided a detailed Regulatory Impact Analysis (RIA) in the docket for this rulemaking. This portion of the preamble summarizes the FAA's analysis of the economic impacts of this rule.

A. Summary of the Regulatory Impact Analysis

The FAA estimated quantified annualized costs of $47.4 million using a 7 percent discount rate over a 5-year period of analysis. The costs represent the value of resources that regulated entities would need to develop and implement an SMS. Mitigation costs, which are yet to be identified and thus unknown, are not quantified. The benefits are the value that would result from avoided fatalities, serious injuries, aircraft damage, and investigation costs, which the FAA evaluated qualitatively.

1. Baseline for the Analysis

The baseline for the analysis of incremental benefits and costs of the rule includes existing regulations and standards, existing practices, affected entities, and current risks of aircraft accidents and incidents. The FAA already requires part 121 operators to implement an SMS. The FAA also provides voluntary SMS programs for certificate holders under parts 21, 135, and 145. The FAA's voluntary SMS programs are based on the requirements in part 5. There are 5 aircraft design and manufacturing organizations and 40 part 135 operators in active conformance (full implementation of the certificate holder's SMS) under the voluntary

program.[46] In addition, some part 121 operators have covered their part 135 operations and part 145 repair station services under their SMS. Finally, certain aircraft design and production approval holders (and certificated repair stations[47]) subject to requirements of EASA (applicable March 7, 2023) are required to develop and implement an SMS under that agency's SMS requirements.

The FAA estimated that the rule would apply to approximately 65 aircraft design and production approval holders. Also, there are approximately 1,848 part 135 operators that would be required to implement an SMS, which includes 203 entities that also hold an LOA to conduct commercial air tours under § 91.147. Additionally, there are 715 LOA holders operating under § 91.147 that are not associated with a part 135 certificate that would be required to implement an SMS under the rule.

With respect to aircraft accidents, although risks associated with regularly scheduled commercial air carriers in the United States are low, there have been accidents involving fatalities and serious injuries. Under part 135, there has been an average of 43 accidents and 24 fatalities annually from 2015 to 2019, mostly in on demand operations. There have also been recent fatal accidents involving air tours conducted under § 91.147 (an average of 7 accidents and 3 fatalities annually from 2015 to 2019).

2. Benefits

The benefits of the rule include the value of the reductions in safety risks associated with requiring additional entities to implement SMS. The information available for estimating such benefits includes data on accident consequences, accident investigation reports identifying the probable causes, and information on the values associated with avoiding consequences. The FAA used aviation accident data from the NTSB for the years 2015 to 2019 and standard values for estimating avoided consequences including fatalities, serious injuries, property damage, and investigation costs.

The FAA evaluated benefits by determining average annual aviation accident consequences, the share of those consequences that could be mitigated under the rule, and the probability of mitigation. The FAA determined the share of consequences that could potentially be mitigatable by the rule by looking at the causes of individual accidents. Requiring aircraft design and production approval holders to implement SMS has the potential to mitigate accidents in operations conducted under 14 CFR parts 121, 135, and 91. Requiring part 135 operators and § 91.147 LOA holders to implement SMS has the potential to mitigate accidents in operations conducted under part 135 and § 91.147. The probability of mitigation is uncertain.

The FAA identified 11 accidents of which the risk could have been mitigated through SMS in aircraft design and production. The FAA also identified 35 accidents related to operations under part 135 and 4 accidents related to § 91.147 LOA holders of which the risk could have been mitigated through SMS. Because the FAA focused on accidents involving fatalities and injuries, not all accidents indicative of the potential for benefits from the rule may have been identified. Additionally, requiring SMS for certain part 21 certificate holders will have beneficial impacts beyond domestic operations (*i.e.,* to citizens of foreign countries).

3. Costs

To estimate compliance costs, the FAA developed average one-time SMS development and implementation costs and recurring SMS maintenance costs. Then, the FAA extrapolated these costs to entities that fall under the expanded applicability of part 5 who would not already be required to implement an SMS and are not already implementing an SMS voluntarily. To develop these estimates, the FAA conducted limited outreach to industry participants in the FAA's voluntary SMS program to obtain data on implementation costs. To properly scale costs for company size, the FAA calculated these costs per employee for certificate holders under part 21 and per aircraft for operators under part 135 and § 91.147. The FAA then extrapolated the costs based on number of employees or number of aircraft. The FAA estimated only minor costs for entities that have already implemented an SMS voluntarily or under existing requirements for part 121.

There are uncertainties in the analysis, including that costs are based on information from a small sampling. As a result, costs could be lower or higher than estimated. The outreach indicated a high level of variability depending on the individual circumstances of the entity (*e.g.,* existing processes and capabilities). For this analysis, the FAA intends for the estimates to represent an average across entities.

4. Summary

Table 2 provides a summary of annualized and 5-year present value costs using 3 percent and 7 percent discount rates.

TABLE 2—SUMMARY OF COSTS [1]
[Millions $2022]

Category	Annualized	Present value (5 years)
3% Discount Rate		
Part 21 [2]	$4.9	$22.5
Part 135	35.9	164.5
§ 91.147	7.2	33.2
Part 121	0.05	0.2
Total	48.1	220.4
7% Discount Rate		
Part 21 [2]	4.9	20.1
Part 135	35.3	144.9
§ 91.147	7.1	29.2
Part 121	0.05	0.2
Total	47.4	194.5

[1] Based on quantified impacts. Excludes costs of mitigation.
[2] Includes FAA administrative costs.

[46] See FAA Order 8900, Volume 17, Chapter 3, Safety Management System Voluntary Program.

[47] The rule will not apply to repair stations.

5. Regulatory Alternatives

The FAA considered two alternatives to the rule. Each alternative would change the applicability of the requirements for an SMS:

- *Alternative 1:* Extend applicability of part 5 to include most design and production approval holders under part 21, with some exceptions.
- *Alternative 2:* Exclude from the applicability of part 5 the part 135 operators that use only one pilot-in-command in their operations and the § 91.147 LOA holders that conduct fewer than 100 flights per year.

The FAA considered an alternative to the part 21 applicability (Alternative 1) based on recommendations from a part 21 SMS ARC. Under Alternative 1, the SMS requirements would apply beyond holders of both a type and production certificate for the same product and would include most design and production approvals holders. This alternative would exclude design and production approval holders of products, articles, or changes to existing type certificated products that are not typically used for carrying passengers or property for compensation or hire. Also, as part of this alternative, the FAA considered a process that would allow design and production approval holders to apply to be excluded from SMS requirements if their article or approved product alteration would have little or no effect on the continued safe flight or landing of the aircraft.

Under Alternative 1, the FAA estimated that over 3,000 additional entities would be required to implement SMS and over 3,000 additional entities (not associated with the entities in the previous sentence) would likely apply to be excluded from the SMS requirements.

Alternative 1 would increase benefits through SMS implementation by the approximately 3,000 entities who design or produce certain safety-critical parts under any design or production approval. The alternative would also hold entities who design and produce safety-critical parts to the same SMS standard required of entities holding both a type certificate and a production certificate for the same product. This alternative would increase benefits by requiring SMS for all entities involved in the design or production of safety-critical aircraft parts compared to the final rule baseline that requires SMS for the approximately 60 type and production certificate holders that design or manufacture products (aircraft, aircraft engines, or propellers). The approximately 3,000 additional entities that would be required to implement SMS under this alternative include STC holders that modify product designs, TSOA holders that design and produce aircraft articles, and PMA holders that design and produce aircraft replacement and modification parts. The FAA expects requiring SMS for these additional entities would increase SMS benefits (reducing or eliminated accidents) through improved identification of safety hazards, enhanced management of safety risk, and better assurance of the effectiveness of safety risk controls across a larger ecosystem of aircraft design and production organizations. However, as of the date of this analysis, the FAA was not able to estimate these risks or benefits due to a lack of specific data.

The FAA estimated that costs could be $37 million for Alternative 1, using a number of assumptions because it does not have information for these entities on the size of their aviation design and production processes. The costs would include SMS development and implementation costs, costs to apply for an exception from the requirement to implement SMS, and FAA review and approval costs. Compared to the rule, the increase in costs is approximately $32 million (annualized using a 7% discount rate).

The FAA considered an alternative for part 135 and § 91.147 (Alternative 2) that would limit the number of small operators affected. Under Alternative 2, the FAA considered excluding from the applicability of part 5 the part 135 operators that use only one pilot-in-command in their operations and the § 91.147 LOA holders that conduct fewer than 100 flights per year. The FAA estimated that 1,300 part 135 operators would be affected under Alternative 2 compared to 1,848 under the rule. The FAA does not have data on the number of § 91.147 LOA holders that conduct less than 100 flights per year. As an estimate, the FAA used LOA holders with one aircraft listed on the LOA. The FAA estimated that 338 § 91.147 LOA holders would be affected under Alternative 2 compared to 715 under the rule.

The reduced applicability under Alternative 2 would lower both costs and benefits. For part 135, costs would be $3.0 million lower compared to the rule. For § 91.147, costs would be $1.6 million lower compared to the rule. With respect to benefits, one of the potentially mitigatable accidents involved an operator that used only one pilot-in-command. These types of operators would not be required to implement an SMS.

Table 3 provides a summary of the analysis of the alternatives. The uncertainty associated with the analysis of benefits and costs of the proposal also applies to the estimates of the alternatives. Section IV.C., Expansion of Proposed Applicability and Section IV.A., Applicability to Part 135 and LOA Holders under § 91.147, of the preamble to the rule provides the Agency's rationale for selecting the option.

TABLE 3—SUMMARY OF ALTERNATIVES ANALYSIS

Scenario	Change from proposed rule		
	Affected entities	Benefits	Costs (millions)
Alternative 1: Extend applicability to include additional design and production approval holders under part 21.	SMS: +3,000 Exception: +3,000.	Data not available to quantify change in risk.	+$32.0.
Alternative 2: Limit applicability for certain part 135 operators (exclude operators that use only one pilot-in-command) and § 91.147 LOA holders (exclude fewer than 100 flights per year).	Part 135: −548 § 91.147: −377.	Lower (would not mitigate risks identified in 1 part 135 accident).	Part 135: −$3.0 § 91.147: −$1.6.

See the RIA available in the docket for more details.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) of 1980, (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) and the Small Business Jobs Act of 2010 (Pub. L. 111–240), requires Federal agencies to consider the effects

of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term ''small entities'' comprises small businesses and 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 FAA published an Initial Regulatory Flexibility Analysis (IRFA) in the proposed rule to aid the public in commenting on the potential impacts to small entities. The FAA considered the public comments in developing the final rule and this Final Regulatory Flexibility Analysis (FRFA). A FRFA must contain the following:

(1) A statement of the need for, and objectives of, the rule;

(2) A statement of the significant issues raised by the public comments in response to the IRFA, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

(3) The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;

(4) A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

(5) A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(6) A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

1. Need for and Objectives of the Rule

As described elsewhere in this preamble, the rule addresses a Congressional mandate as well as recommendations from the NTSB and various ARCs. Additionally, the rule would move the United States closer to harmonizing with ICAO Annex 19. The FAA intends for the rule to improve aviation safety by requiring organizations to implement a proactive approach to managing the safety performance of an organization. The successful use of SMS by part 121 operators suggests potential benefits of expanding SMS into other sectors of the aviation system.

The objective of implementing an SMS is to proactively identify hazards, assess the risk of those hazards, and apply effective mitigations before an accident or incident occurs. The rule expands the use of SMS in the aviation industry by making the SMS requirements applicable to part 135 operators, § 91.147 LOA holders, and certain part 21 design and production certificate holders. The rule also increases the opportunities for communication of identified hazards between part 119 certificate holders, § 91.147 LOA holders, and manufacturers. The rule is therefore intended to increase the overall safety of the national airspace system. Additionally, the rule fulfills the statutory mandate in section 102 of ACSAA. Section II. of this preamble describes the FAA's authority to issue rules on aviation safety under title 49 U.S.C. and the Congressional mandate in section 102 of ACSAA.

2. Significant Issues Raised in Public Comments

Significant issues raised in the public comments relate to duplicative rules and the economic impact on small part 135 operations. MARPA stated that applying SMS to design and production holders creates duplicate or overlapping obligations for design and production holders. The association recommended that the FAA consider the duplications already identified in past ARC reports, as well as the facial duplication within the proposed rule, and amend the regulation to eliminate those already-identified as overlaps.

The FAA does not agree that the requirements contained in part 5 are duplicative of elements contained in part 21 as they serve different purposes. The provisions in part 21 are focused on the product; part 21 ensures a product's design is safe and compliant and it is produced in conformance with its approved type design. For example, when certifying an aircraft engine, an organization must conduct a safety analysis of the engine to demonstrate that the likelihood of engine failure effects is below specified levels. Part 5, on the other hand, is focused on identifying hazards and mitigating risks with the organization's systems that are used to design, certify, produce, and maintain continued airworthiness of the products they provide. For example, when revising a system for designing an engine (*e.g.,* implementing a new design process), part 5 requires the organization to analyze, assess, and mitigate the risk of the system revision producing an engine safety issue.

Within the proposed rule, the FAA determined the provisions are necessary for emphasis or to tie one SMS component to another SMS component to achieve the desired closed-loop system. In addition, many of the requirements map to the SMS Framework in ICAO Annex 19, Appendix 2.

NATA stated that SMS solutions for small businesses must not be cost-prohibitive or so burdensome that business closure becomes imminent. The association recommended a staggered compliance schedule of at least 5 years for small carriers to address this concern. NATA also raised issues related to feasibility of provisions not possible at many small businesses, such as confidential reporting of hazards, and stated that the FAA needs to ensure that guidance and training recognize this issue. It stated a need for communications retention procedures where communications are largely oral, and more articulation of precisely how the small operator will implement SMS. The FAA's assessment and response to these issues can be found in Sections IV.A., IV.D., IV.H., and IV.N. of this preamble.

LifeFlight of Maine/LifeFlight Aviation Services LLC stated that as a percentage of overall costs of operations, the SMS mandate and timing are a significantly higher burden for smaller entities. Also, air medical operators have no methodology to pass these costs via price increases as neither Medicare/Medicaid nor commercial medical reimbursement recognize or allow these costs. It stated that an effective SMS in a smaller program will look and feel quite different than the same in a large operation and the spreading out of implementation costs is essential for smaller operators. An individual commenter found that the NPRM fails to meet the requirements of the RFA. The individual disputed single-person operations can increase fares to cover additional administrative responsibilities because they have neither the extra time for SMS management nor the market elasticity in which to raise prices. Another individual stated that it is unclear how small manufacturers of simple aircraft will absorb the initial and ongoing cost of implementation.

The FAA evaluated these potential impacts and made two changes to the final rule: extending the compliance period for operators by 12 months and excepting certain requirements of part 5 for certain single-pilot operators. The FAA discusses these changes in Section IV.D. of this preamble. The FAA's rationale for maintaining the proposed applicability of the rule with respect to small and single-pilot operations is discussed in Sections IV.A. and IV.J. of this preamble.

3. Response to SBA Comments

The SBA did not comment on the proposed rule.

4. Small Entities to Which the Rule Will Apply

The FAA used the definition of small entities in the RFA for this analysis. The RFA defines small entities as small businesses, small governmental jurisdictions, or small organizations. In 5 U.S.C. 601(3), the RFA defines ''small business'' to have the same meaning as ''small business concern'' under section 3 of the Small Business Act. The Small Business Act authorizes the Small Business Administration (SBA) to define ''small business'' by issuing regulations.

SBA has established size standards for various types of economic activities, or industries, under the North American Industry Classification System (NAICS). These size standards generally define small businesses based on the number of employees or annual receipts. Table 4 shows the SBA size standards for example industrial classification codes relevant for the proposed rule. Note that the SBA definition of a small business applies to the parent company and all affiliates as a single entity.

TABLE 4—SMALL BUSINESS SIZE STANDARDS: AIR TRANSPORTATION

NAICS code	Description	Size standard
336411	Aircraft Manufacturing	1,500 employees.
336412	Aircraft Engine and Engine Parts Manufacturing	1,500 employees.
336413	Other Aircraft Part and Auxiliary Equipment Manufacturing	1,250 employees.
481111	Scheduled Passenger Air Transportation	1,500 employees.
481112	Scheduled Freight Air Transportation	1,500 employees.
481211	Nonscheduled Chartered Passenger Air Transportation	1,500 employees.
481212	Nonscheduled Chartered Freight Air Transportation	1,500 employees.
481219	Other Nonscheduled Air Transportation	$16.5 million.
487990	Scenic and Sightseeing Transportation, Other	$8.0 million.

NAICS = North American Industrial Classification System.

i. Part 21

As described in the RIA, the FAA estimated that there may be approximately 65 design or production certificate holders under part 21 that will need to implement SMS under this rule. Fifteen of these entities are already implementing SMS under the FAA's voluntary program or are large businesses (based on publicly available information regarding number of employees). Of the remaining 50 entities, 31 may meet the size standard for a small business in Aerospace Product and Parts Manufacturing (NAICS 33641).

ii. Part 135

Approximately 1,848 part 119 certificate holders operating under part 135 will need to implement SMS under this final rule. Internal FAA data indicate that all but four of these certificate holders have fewer than 1,500 employees. Thus, to the extent that the industrial classification of the parent company of these entities is scheduled passenger or freight, or nonscheduled chartered passenger or freight air transportation (NAICS 481111, 481112, 481211, or 481212), most would be small businesses. Table 5 shows the distribution of certificate holders by total employment.

TABLE 5—DISTRIBUTION OF PART 135 EMPLOYMENT

Number of employees	Number of certificate holders	Percent of certificate holders (%)
1	275	15
2–9	812	44
10–19	258	14
20–49	288	16
50–99	113	6
100–499	79	4
500–999	15	1
1000+	6	0

Source: FAA data as of June 2023.

iii. Section 91.147

Approximately 694 air tour operators will have to implement SMS under the final rule. To the extent that the industrial classification of the parent company of these entities is Scenic and Sightseeing Transportation, Other, the relevant size standard is $8.0 million. Internal FAA data does not include revenue or number of flights for these operations. However, 362 of these LOA holders have only one aircraft listed on the LOA. Many may meet the small business size standard.

5. Projected Reporting, Recordkeeping, and Other Compliance Requirements

Section IV.G. of this preamble discusses the reporting requirements of

the rule. Affected entities who identify a hazard in their operating environment must provide notice of the hazard to the interfacing person or persons who would best be able to address the hazard or mitigate the risk.

Section IV.H. of this preamble describes the recordkeeping requirements of the proposed rule. Affected entities must maintain records of the outputs of safety risk management for as long as risk controls remain relevant to the operation. In addition, entities must retain outputs of safety assurance processes for a minimum of 5 years, SMS training records for as long as each individual is employed by the person, and communication records retained for a minimum of 24 months.

Recordkeeping and reporting requirements, like the rest of part 5, are scalable to a wide variety of business models and sizes, as discussed in Section IV.J. of this preamble. As a result, entities could potentially accomplish the recordkeeping and reporting requirements through the use of existing personnel rather than require additional professional skills.

Section III.B. of the preamble describes the primary requirements for an SMS, which include safety policy, safety risk management, safety assurance, and safety promotion, as well as documentation. As described in the RIA, the FAA estimated the cost of compliance with all the requirements based on number of employees for part 21 certificate holders and based on fleet size for part 135 operators and § 91.147 LOA holders. Table 6 and Table 7 provide the results for example size categories and expressed as a percentage of overall average receipts (using NAICS 336411 for part 21 and 336411 for part 135 as examples [48]). Not included in the costs are mitigation costs that are yet unknown. The RIA provides additional detail on the cost estimates.

TABLE 6—EXAMPLE SMS COMPLIANCE COSTS BY NUMBER OF EMPLOYEES: PART 21

Number of employees	One-time cost	Annual cost	One-time cost/ receipts [1]	Annual cost/ receipts [1]
1–99	$8,100–$28,140	$540–$10,940	0.2%–1.2%	0.1%–0.1%
100–499	$28,420–$141,830	$11,050–$55,130	0.2%–1.2%	0.1%–0.5%
500–10,000	$142,110–$2,842,190	$55,240–$1,104,870	0.03–0.1%	0.01%–0.04%

[1] Source for receipts: 2017 County Business Patterns and Economic Census (*https://www2.census.gov/programs-surveys/susb/tables/2017/us_state_naics_detailedsizes_2017.xlsx*). Adjusted for inflation using the Consumer Price Index. Based on NAICS 336411.

TABLE 7—EXAMPLE SMS COMPLIANCE COSTS BY NUMBER OF AIRCRAFT: PART 135 AND 91.147

Number of aircraft	One-time cost	Annual cost	One-time cost/ receipts [1]	Annual cost/ receipts [1]
1–9	$8,100–$41,180	$4,730–$42,580	0.1%–0.7%	0.1%–0.4%
10–49	$45,750–$224,180	$47,310–$231,820	0.1%–0.9%	0.1%–0.9%
50–99	$228,750–$452,930	$236,550–$468,370	0.2%–0.9%	0.2%–0.9%
100–500	$457,500–$2,287,510	$473,100–$2,365,510	0.2%–0.3%	0.2%–0.3%

[1] Source for receipts: 2017 County Business Patterns and Economic Census (*https://www2.census.gov/programs-surveys/susb/tables/2017/us_state_naics_detailedsizes_2017.xlsx*). Adjusted for inflation using the Consumer Price Index. Based on NAICS 481111 and median number of employees per number of aircraft for part 135 operators.

Total annualized costs (using a 7 percent discount rate) for small businesses may be in the range of $0.3 million for part 21 and $35.3 million for part 135. The FAA does not have data to identify § 91.147 LOA holders that may meet the size standard. However, total annualized costs for this sector are estimated at $7.1 million.

6. Significant Alternatives Considered

The FAA has taken steps to minimize the significant economic impact on small entities. As described in Section IV.D., the FAA is providing part 135 operators and § 91.147 LOA holders 3 years for submission of a declaration of compliance. Design and manufacturing companies will have 6 months to submit an implementation plan for FAA approval, and 3 years to implement SMS. These timelines will enable small businesses to spread development costs over a 3-year period. Also, as described in Section IV.A., the FAA is excepting part 135 operators and § 91.147 LOA holders that use a single-pilot from certain part 5 provisions that will not be applicable in such small organizations. Finally, as described in Section IV.J., the FAA is providing additional information on how SMS is scalable to small entities.

The FAA considered an alternative to the applicability for part 135 and § 91.147 that would have limited the number of small operators affected. The FAA considered excluding part 135 operators that use only one pilot-in-command in their operations and the § 91.147 LOA holders that conduct less than 100 flights per year. However, the alternative does not meet the Agency's safety objective of having all commercial operations comply with part 5, which is also consistent with the recommendations of the NTSB.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of

[48] The ratios are similar using NACIS 336412 and 336413 for part 21 and 481112, 481113, 481211, 481212, and 481213 for part 135. For § 91.147, the FAA does not have number of employees associated with the number of aircraft on the LOA. However, assuming LOA holders of 1 and 2 registered aircraft have less than 5 employees, the ratios for one-time and annual costs as a percentage of inflation adjusted receipts in this smallest employment size category in NAICS 487990 would be 1.8% and 1.1%, respectively.

international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this rule and determined that it will improve aviation safety and does not exclude imports that meet this objective. As a result, the FAA does not consider this rule as creating an unnecessary obstacle to foreign commerce.

D. Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal government having first provided the funds to pay those costs. The FAA determined that this final rule will not result in the expenditure of $177 million or more by State, local, or tribal governments, in the aggregate, or the private sector, in any one year. Therefore, the requirements of title II of the Unfunded Mandates Reform Act of 1995 do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

This rule contains new information collection requirements and amendments to the existing information collection requirements previously approved under OMB Control Number 2120–0763. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA has submitted these information collection amendments to OMB for its review.

Summary: This rule requires the following information collection activities (Table 8):

TABLE 8—INFORMATION COLLECTIONS

Information	Section	Description
Organizational system description	5.11(a) 5.13(b)(1) 5.15(b)(1) 5.15(c)(1)	Any person that holds a type certificate or a production certificate issued under part 21 of this chapter must develop and maintain an organizational system description.
Compliance declarations	5.9(a)(2) 5.9(b)	Submit compliance information in a form and manner acceptable to the Administrator.
Implementation plan	5.11(b) 5.13(b)(2) 5.15(b)(2) 5.15(c)(2)	Submit an implementation plan for FAA approval in a form and manner acceptable to the Administrator.
Safety policy	5.21(a)	Any person required to have an SMS under this part must have a safety policy.
Summary of confidential employee reports	5.71(c)	Any person that holds both a type certificate and a production certificate issued under part 21 for the same product must submit a summary of the confidential employee reports to the Administrator every 6 months.
Notification of hazards to interfacing persons	5.57	If a person required to have an SMS under this part identifies a hazard in the operating environment, the person must provide notice of the hazard to the interfacing person or persons who, to the best of their knowledge, could address the hazard or mitigate the risk.
SMS documentation	5.95	Any person required to have an SMS under this part must develop and maintain the following SMS documentation: (a) Safety policy, (b) SMS processes and procedures.
SMS records	5.97	Any person required to have an SMS under this part must: (a) Maintain records of outputs of safety risk management processes for as long as the control remains relevant to the operation (b) Maintain records of outputs of safety assurance processes for a minimum of 5 years (c) Maintain records of all training provided under § 5.91 for each individual for as long as the individual is employed (d) Retain records of all communications provided under § 5.93 and § 5.57 for a minimum of 24 consecutive calendar months.

Public Comments: The FAA received two comments on the information collection requirements. One individual stated that the requirement for SMS documentation by small businesses goes against the Paperwork Reduction Act. The individual stated that the FAA did not provide evidence of proven benefit to single person operators for SMS mandates and asserted that the FAA's justification of potential safety gains is a statutorily unacceptable justification for hardship. Wing Aviation LLC suggested that SMS has the capability to be used to reduce the burdensome regulations and paperwork necessary for routine unmanned aviation operations that have already proven themselves to be sustainably safe.

The FAA has taken actions in the final rule in response to concerns regarding paperwork burden for small entities. In the final rule, the FAA is excepting certain single-pilot operations from SMS requirements that would not be applicable in organizations of this size. These exceptions will eliminate the reporting and recordkeeping burden associated with the reporting of safety hazards, disciplinary action, and communication under § 5.21(a)(4) and (5), and the retention of safety communication records under § 5.93 [§ 5.97(d)].

Additionally, in the final rule, the requirement for an organizational system description is only applicable to design and manufacturing organizations under part 21.

Use: The information collection will be used to provide a basis for the FAA's review during the development and implementing phases, used by the

certificate or LOA holder in its SMS processes and procedures, and used to demonstrate compliance with the part 5 requirements.

Collection and analysis of safety data is an essential part of an SMS. Types of data to be collected, retention procedures, analysis processes, and organizational structures for review and evaluation will be documented in the SMS. These records will be used by a certificate holder or LOA holder in the operation of its SMS and to facilitate continuous improvement through evaluation and monitoring. While this rule does not require a certificate holder or LOA holder to submit these records to the FAA, it requires a certificate holder or LOA holder to make these records available upon request.

Respondents (including number of): Table 9 provides the FAA's estimates of the number of respondents by affected entity category (by part 21 certificate holders, 121 operators, part 135 operators, and § 91.147 LOA holders) that would be impacted by the paperwork requirements in this rule.

TABLE 9—NUMBER OF RESPONDENTS

Affected entity category	Number of respondents
Organizational system description:	
Part 21	65
Compliance declarations:	
Part 135	1,848
§ 91.147	715
Total	2,563
Implementation plan:	
Part 21	65
Safety policy:	
Part 21	65
Part 135	1,848
§ 91.147	715
Total	2,628
Summary of employee reports:	
Part 21	65
Notification of hazards:	
Part 21	65
Part 135	1,848
§ 91.147	715
Part 121	66
Total	2,694
SMS documentation:	
Part 21	65
Part 135	1,848
§ 91.147	715
Total	2,628
SMS records:	
Part 21	65
Part 135	1,848
§ 91.147	715
Total	2,628

Frequency: The frequency of new information collection requirements and amendments to the existing information collection requirements is shown below in Table 10 with the annual burden estimate for each.

Annual Burden Estimate: The FAA estimated the paperwork burden for up to 2,694 certificate and approval holders impacted by the rule as shown below in Table 10.

TABLE 10—PAPERWORK BURDEN

Category	Number of respondents	Frequency of response [1]	Total number of responses	Burden hours [2]	Costs (millions) [3]
Organizational system description:					
Part 21	65	1	65	520	$0.05
Compliance declarations:					
Part 135	1,848	1	1,848	3,696	0.34
§ 91.147	715	1	715	1,430	0.13
Total	2,563	NA	2,563	5,126	0.47
Implementation plan:					
Part 21	65	1	65	2,080	0.19
Safety policy:					
Part 21	65	1	65	260	0.02
Part 135	1,848	1	1,848	7,392	0.68
§ 91.147	715	1	715	2,860	0.26
Total	2,628	NA	2,628	10,512	0.97
Summary of employee reports:					
Part 21	65	6	390	1,560	0.14
Notification of hazards:					
Part 21	65	3	195	1,560	0.14
Part 135	1,848	3	5,544	44,352	4.10
§ 91.147	715	3	2,145	17,160	1.59
Part 121	66	3	198	1,584	0.14
Total	2,694	NA	8,082	64,656	5.98
SMS documentation:					
Part 21	65	1	65	2,080	0.19
Part 135	1,848	1	1,848	59,136	5.47
§ 91.147	715	1	715	22,880	2.12
Total	2,628	NA	2,628	84,096	7.78
SMS records:					
Part 21	65	3	195	1,560	0.14
Part 135	1,848	3	5,544	44,352	4.10
§ 91.147	715	3	2,145	17,160	1.59
Total	2,628	NA	7,884	63,072	5.84

NA = not applicable

[1] Frequency over three-year period.

[2] Calculated as number of respondents × hours per respondent.

[3] Calculated as burden hours × average labor rate including benefits. The FAA used an average wage including benefits of $92.53, which is the mean average wage for aerospace engineers ($61.10) divided by the percent of total employer costs of employee compensation represented by wages (66%) to account for benefits (34%). Wages and benefits information available at: *https://www.bls.gov/oes/current/oes172011.htm* and *https://www.bls.gov/news.release/ecec.t04.htm#ect_table4.f.1.*

Table 11 provides a summary of the implied annual responses and burden (total divided by three).

TABLE 11—SUMMARY OF ANNUAL BURDEN [1]

Category	Reporting	Recordkeeping	Disclosure
Organizational system description:			
# of respondents	22	0	0
# of responses per respondent	1	0	0
Time per response (hours)	8	0	0
Total # of responses	22	0	0
Total burden (hours)	173	0	0
Compliance declarations:			
# of respondents	854	0	0
# of responses per respondent	1	0	0
Time per response (hours)	2	0	0
Total # of responses	854	0	0
Total burden (hours)	1,709	0	0
Implementation plan:			
# of respondents	65	0	0
# of responses per respondent	1	0	0
Time per response (hours)	10.7	0	0
Total # of responses	65	0	0
Total burden (hours)	693	0	0
Safety policy:			
# of respondents	0	876	0
# of responses per respondent	0	1	0
Time per response (hours)	0	4	0
Total # of responses	0	876	0
Total burden (hours)	0	3,504	0
Summary of employee reports:			
# of respondents	65	0	0
# of responses per respondent	2	0	0
Time per response (hours)	4	0	0
Total # of responses	130	0	0
Total burden (hours)	520	0	0
Notification of hazards:			
# of respondents	2,694	0	0
# of responses per respondent	1	0	0
Time per response (hours)	8	0	0
Total # of responses	2,694	0	0
Total burden (hours)	21,552	0	0
SMS documentation:			
# of respondents	0	2,628	0
# of responses per respondent	0	1	0
Time per response (hours)	0	10.7	0
Total # of responses	0	2,628	0
Total burden (hours)	0	28,032	0
SMS records:			
# of respondents	0	2,628	0
# of responses per respondent	0	1	0
Time per response (hours)	0	8	0
Total # of responses	0	2,628	0
Total burden (hours)	0	21,024	0

[1] Calculated as total burden from Table 10 divided by 3.

F. International Compatibility

ICAO Annex 19 establishes an SMS Framework for managing aviation safety risk, as well as identifies the types of aviation organizations that should implement an SMS. This rule moves the United States closer to harmonization with ICAO Annex 19. The rule aligns with Annex 19 by requiring the following service providers to implement SMS: (1) commercial operators of airplanes or helicopters, and (2) certain organizations responsible for the design or manufacture of products. The FAA has already implemented SMS across the FAA's Air Traffic Organization.[49] Additionally, the FAA published an update to part 139 on February 23, 2023, to require SMS implementation for certain airports.[50] Both of these recent rules bring the

[49] See FAA Order JO 1000.37 for implementation details.

[50] 88 FR 11642.

United States closer to alignment with ICAO Annex 19 because Annex 19 also includes air traffic service providers and airports.

When part 5 was originally constructed, it was based on the SMS framework in ICAO Annex 19. Part 5 currently also includes requirements for recordkeeping, which are not part of the ICAO's SMS framework. However, recordkeeping requirements facilitate FAA's oversight functions, and they assist the person implementing SMS in demonstrating compliance with the regulations. In addition, the rule requires the communication of information regarding safety hazards. While this requirement is not in the ICAO's SMS framework, the FAA believes that it is beneficial to the persons implementing SMS. In addition, it is consistent with ICAO's intent as ICAO notes in Annex 19 that other aviation organizations that interface with a product or service provider can make a significant contribution to the safety of its products or services.

1. Air Carriers and Operators

The ICAO SMS requirements for commercial operators are contained in Annex 19, but Annex 6 defines the scope of the requirements. Part I of Annex 6 covers international commercial operations in airplanes. This part of Annex 6 makes no distinction in its requirements on the basis of an aviation organization's size. The Annex applies to all commercial air transportation operations in airplanes. In the United States, this includes operators certificated under part 119 and authorized to operate under part 121 or part 135. Part III of Annex 6 covers commercial air transportation operators of helicopters. In the United States, these operations are conducted under part 135. Annex 6, part I addresses international flight operations; in the United States, these international flights are operated under either part 121 or part 135. The FAA previously only required part 121 operators to implement and maintain an SMS, and this rule extends the requirement for an SMS to part 135 operators, further harmonizing the United States with ICAO's SMS requirements.

2. Aircraft Design and Manufacturing

ICAO Annex 19 requires SMS for organizations responsible for the type design or manufacture of aircraft, engines, or propellers. This rule extends part 5 applicability to holders of both a TC and a PC for the same product, applicants for a PC where the applicant is the holder or licensee of the TC, and holders of a TC that allow other persons to use their TC to obtain a PC. This rule brings the United States into closer harmonization with the ICAO Annex 19 SMS requirement for certain organizations responsible for the design or manufacture of products.

3. Development and Implementation of SMS by Foreign Jurisdictions

Many States have made significant progress in developing, implementing, and maintaining requirements for SMS, aligned with ICAO's SMS framework, including certificating authorities in Europe (EASA), Canada, Brazil, the United Kingdom, Japan, and Australia. Of those authorities, most have SMS requirements for international commercial operations, and some have SMS requirements for design and manufacturing. Most that do not have SMS requirements for design and manufacturing plan to adopt such requirements in the future. Some States also have SMS requirements for other operations in the aviation system: airports, maintenance organizations, training organizations, international general aviation operations, and for safety data collection, protection, and exchange.

Harmonization of requirements, to the extent feasible, is important to reduce the regulatory burden on those holding certificates or authorizations from multiple States. The FAA continues to work with other States to harmonize SMS requirements. The rule aligns with sections of the ICAO SMS framework and furthers harmonization with other States requiring SMS. Consistency with international standards reduces the likelihood that U.S.-based aviation organizations providing products or services would need to duplicate efforts to meet SMS requirements of other States in which they do business. As a result, the rule likely reduces the regulatory burden on those holding certificates or authorizations across multiple States.

4. Other FAA Support for Harmonization and Standards Development

The FAA is a founding member and active participant in the Safety Management International Collaboration Group, a group representing 18 international regulatory authorities. The primary purpose of the Safety Management International Collaboration Group is to promote international harmonization of SMS regulations, guidance material, and oversight strategies. The FAA is also an active participant on the ICAO Safety Management Panel.

The FAA also participated with the Aerospace Industries Association to develop an international industry standard for SMS: ''Implementing a Safety Management System in Design, Manufacturing and Maintenance Organizations.'' This standard is intended to enable the aviation industry to implement an SMS consistent with the ICAO Annex 19 ''Safety Management'' Second Edition, Appendix 2.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6f for regulations and involves no extraordinary circumstances.

H. Regulations Affecting Intrastate Aviation in Alaska

Section 1205 of the FAA Reauthorization Act of 1996 (110 Stat. 3213) requires the Administrator, when modifying 14 CFR regulations in a manner affecting intrastate aviation in Alaska, to consider the extent to which Alaska is not served by transportation modes other than aviation, and to establish appropriate regulatory distinctions. Because this rule applies to: (1) any person authorized to conduct operations under part 135, (2) any person operating under an LOA issued under § 91.147, and (3) certain holders of a TC or a PC, it could affect intrastate aviation in Alaska. The use of SMS may improve aviation safety in Alaska. The FAA analyzed NTSB part 135 accident data from 2015 to 2019 and found that of all part 135 air carrier accidents studied, 43 percent of these accidents occurred in Alaska. Because implementation of SMS can be scaled to the size and complexity of an aviation organization, SMS requirements will not be overly burdensome for smaller part 135 operators (see discussion in Section IV.J.). The increase in safety benefits to intrastate operations in Alaska will positively impact air commerce in Alaska with the same requirements applicable to every organization under part 5.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of

Executive Order 13132, Federalism. The FAA has determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, will not have federalism implications.

B. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Consistent with Executive Order 13175, Consultation and Coordination with Indian Tribal Governments,[51] and FAA Order 1210.20, American Indian and Alaska Native Tribal Consultation Policy and Procedures,[52] the FAA ensures that Federally Recognized Tribes (Tribes) are given the opportunity to provide meaningful and timely input regarding proposed Federal actions that have the potential 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; or to affect uniquely or significantly their respective Tribes. At this point, the FAA has not identified any unique or significant effects, environmental or otherwise, on tribes resulting from this final rule.

C. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The FAA has determined that it is not a ''significant energy action'' under the executive order and is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

D. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609 and has determined that this action may improve regulatory cooperation by moving FAA requirements for SMS closer to ICAO Standards and Recommended Practices that other States are adopting or considering adopting.

VII. Additional Information

A. Electronic Access and Filing

A copy of the NPRM, all comments received, this final rule, and all background material may be viewed online at *https://www.regulations.gov* using the docket number listed above. A copy of this final rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *https://www.federalregister.gov* and the Government Publishing Office's website at *https://www.govinfo.gov.* A copy may also be found at the FAA's Regulations and Policies website at *https://www.faa.gov/regulations_policies.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this final rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit *https://www.faa.gov/regulations_policies/rulemaking/sbre_act/.*

List of Subjects

14 CFR Part 5

Air carriers, Aircraft, Airmen, Aviation safety, Reporting and recordkeeping requirements, Safety, Transportation.

14 CFR Part 21

Aircraft, Aviation safety, Exports, Imports, Reporting and recordkeeping requirements.

14 CFR Part 91

Air carriers, Air taxis, Aircraft, Airmen, Aviation safety, Charter flights, Reporting and recordkeeping requirements.

14 CFR Part 119

Administrative practice and procedure, Air carriers, Aircraft, Aviation safety, Charter flights, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 5—SAFETY MANAGEMENT SYSTEMS

■ 1. The authority citation for part 5 is revised to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40113, 40119, 41706, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 46105; Sec. 102, Pub. L. 116–260, 134 Stat. 2309; Sec 215, Pub. L. 111–216, 124 Stat. 2366.

■ 2. Revise subpart A to read as follows:

Subpart A—General

Sec

Subpart A—General

§ 5.1 Applicability.

This part applies to all of the following:

(a) Any person that holds or applies for a certificate issued under part 119 of this chapter authorizing the person to conduct operations under part 121 of this chapter.

[51] 65 FR 67249.

[52] FAA Order No. 1210.20 (Jan. 28, 2004), available at *https://www.faa.gov/documentLibrary/media/1210.pdf.*

(b) Any person that holds or applies for a certificate issued under part 119 of this chapter authorizing the person to conduct operations under part 135 of this chapter.

(c) Any person that holds or applies for a Letter of Authorization issued under § 91.147 of this chapter.

(d) Any person that holds both a type certificate and a production certificate issued under part 21 of this chapter for the same product.

(e) Any person that holds a production certificate issued under part 21 of this chapter for a product for which the person is a licensee of the type certificate for the same product.

(f) Any person that applies for a production certificate under part 21 of this chapter for a product for which the person is the holder or licensee of the type certificate for the same product.

(g) Any person that holds a type certificate issued under part 21 of this chapter for a product, except for persons that hold only type certificates issued under § 21.29 of this chapter, that allows another person to use the type certificate to manufacture the same product under a production certificate.

§ 5.3 Definitions.

Hazard means a condition or an object that could foreseeably cause or contribute to an incident or aircraft accident, as defined in 49 CFR 830.2.

Risk means the composite of predicted severity and likelihood of the potential effect of a hazard.

Risk control means a means to reduce or eliminate the effects of hazards.

Safety assurance means processes within the SMS that function systematically to ensure the performance and effectiveness of safety risk controls and that the organization meets or exceeds its safety objectives through the collection, analysis, and assessment of information.

Safety Management System (SMS) means the formal, top-down, organization-wide approach to managing safety risk and assuring the effectiveness of safety risk controls. It includes systematic procedures, practices, and policies for the management of safety risk.

Safety objective means a measurable goal or desirable outcome related to safety.

Safety performance means realized or actual safety accomplishment relative to the organization's safety objectives.

Safety policy means the person's documented commitment to safety, which defines its safety objectives and the accountabilities and responsibilities of its employees in regards to safety.

Safety promotion means a combination of training and communication of safety information to support the implementation and operation of an SMS in an organization.

Safety Risk Management means a process within the SMS composed of describing the system, identifying the hazards, and analyzing, assessing, and controlling risk.

§ 5.5 General requirements.

(a) *SMS components.* An SMS under this part must be appropriate to the size, scope, and complexity of the person's organization and include, at a minimum, all of the following components:

(1) Safety policy that meets the requirements of subpart B of this part.

(2) Safety risk management that meets the requirements of subpart C of this part.

(3) Safety assurance that meets the requirements of subpart D of this part.

(4) Safety promotion that meets the requirements of subpart E of this part.

(b) *Continuing requirements.* Any person required to develop and implement an SMS under this part must maintain the SMS in accordance with this part.

§ 5.7 Requirements for domestic, flag, and supplemental operations.

(a) Any person authorized to conduct operations under part 121 of this chapter that has an SMS acceptable to the FAA on or before May 28, 2024, must revise its SMS to meet the requirements of this part no later than May 28, 2025.

(b) Any person applying for authorization to conduct operations under part 121 of this chapter or with such application pending on or after May 28, 2024, must develop and implement an SMS that meets the requirements of this part.

(c) Any person required to develop and implement an SMS under this section must maintain the SMS as long as the person is authorized to conduct operations under part 121 of this chapter.

(d) Any person required to develop and implement an SMS under this section must make available to the Administrator, upon request, all necessary information and data that demonstrates that the person has an SMS that meets the requirements set forth in this part.

§ 5.9 Requirements for commuter and on-demand operations or passenger-carrying flights for compensation or hire.

(a) Any person authorized to conduct operations under part 135 of this chapter or that holds a Letter of Authorization issued under § 91.147 of this chapter before May 28, 2024, must:

(1) Develop and implement an SMS that meets the requirements of this part no later than May 28, 2027.

(2) Submit to the FAA, a declaration of compliance with this part in a form and manner acceptable to the Administrator no later than May 28, 2027.

(b) Any person applying for authorization to conduct operations under part 135 of this chapter or a Letter of Authorization under § 91.147 of this chapter, or with such application pending on or after May 28, 2024, must develop and implement an SMS that meets the requirements of this part.

(c) Any person required to develop and implement an SMS under this section must maintain the SMS as long as the person is authorized to conduct operations under either part 135 or § 91.147 of this chapter.

(d) Any person required to develop and implement an SMS under this section must make available to the Administrator, upon request, all necessary information and data that demonstrates that the person has an SMS that meets the requirements set forth in this part.

(e) The following requirements do not apply to those organizations with a single pilot who is the sole individual performing all necessary functions in the conduct and execution related to, or in direct support of, the safe operation of the aircraft: §§ 5.21(a)(4), 5.21(a)(5), 5.21(c), 5.23(a)(2), 5.23(a)(3), 5.23(b), 5.25(b)(3), 5.25(c), 5.27(a), 5.27(b), 5.71(a)(7), 5.93, and 5.97(d) of this part.

§ 5.11 Requirements for production certificate holders that are holders or licensees of a type certificate for the same product.

Any person that holds a production certificate issued under part 21 of this chapter for a product for which the person is the holder or licensee of the type certificate for the same product on or before May 28, 2024, must:

(a) Develop and maintain an organizational system description in accordance with § 5.17 of this subpart.

(b) Submit an implementation plan in accordance with § 5.19 of this subpart for FAA approval in a form and manner acceptable to the Administrator no later than November 28, 2024.

(c) Develop an SMS that meets the requirements of this part.

(d) Implement the SMS in accordance with this part no later than May 28, 2027.

(e) Make available to the Administrator, upon request, all necessary information and data that demonstrates that the person has an SMS that meets the requirements set forth in this part.

(f) Maintain the SMS as long as the person is both a holder of a production certificate and a holder or licensee of a type certificate for the same product.

§ 5.13 Requirements for type certificate holders or licensees applying for a production certificate for the same product.

(a) This section applies to any holder or licensee of a type certificate for a product who either:

(1) Applies for a production certificate for that same product under part 21 of this chapter on or after May 28, 2024, or

(2) Has an application for a production certificate for that same product under part 21 of this chapter pending on May 28, 2024.

(b) Any person that meets paragraph (a) of this section must:

(1) Develop and maintain an organizational system description in accordance with § 5.17 of this subpart.

(2) Submit an implementation plan in accordance with § 5.19 of this subpart for FAA approval in a form and manner acceptable to the Administrator during the certification process.

(3) Develop an SMS that meets the requirements of this part.

(4) Implement the SMS in accordance with this part no later than 36 months after submission of the implementation plan.

(5) Make available to the Administrator, upon request, all necessary information and data that demonstrates that the person has an SMS that meets the requirements set forth in this part.

(6) Maintain the SMS as long as the person is both a holder of a production certificate and a holder or licensee of a type certificate for the same product.

§ 5.15 Requirements for type certificate holders that allow another person to use the type certificate to obtain a production certificate for the same product.

(a) This section applies to any person that holds a type certificate issued under part 21 of this chapter for a product, except for persons that hold only type certificates issued under § 21.29 of this chapter, that allows another person to use the type certificate to manufacture the same product under a production certificate.

(b) Any person that meets paragraph (a) of this section and has a licensing agreement in accordance with § 21.55 of this chapter on May 28, 2024, must:

(1) Develop and maintain an organizational system description in accordance with § 5.17 of this subpart.

(2) Submit an implementation plan in accordance with § 5.19 of this subpart for FAA approval in a form and manner acceptable to the Administrator no later than November 28, 2024.

(3) Develop an SMS that meets the requirements of this part.

(4) Implement the SMS in accordance with this part no later than May 28, 2027.

(5) Make available to the Administrator, upon request, all necessary information and data that demonstrates that the person has an SMS that meets the requirements set forth in this part.

(6) Maintain the SMS as long as the person continues to meet paragraph (a) of this section.

(c) Any person that meets paragraph (a) of this section and enters into a licensing agreement in accordance with § 21.55 of this chapter after May 28, 2024, must:

(1) Develop and maintain an organizational system description in accordance with § 5.17 of this subpart.

(2) Submit an implementation plan in accordance with § 5.19 of this subpart for FAA approval in a form and manner acceptable to the Administrator when providing written licensing agreements in accordance with § 21.55 of this chapter.

(3) Develop an SMS that meets the requirements of this part.

(4) Implement the SMS in accordance with this part no later than 36 months after submission of the person's implementation plan.

(5) Make available to the Administrator, upon request, all necessary information and data that demonstrates that the person has an SMS that meets the requirements set forth in this part.

(6) Maintain the SMS as long as the person continues to meet paragraph (a) of this section.

§ 5.17 Organizational system description.

An organizational system description developed and maintained under this part must include a summary of the following information about the safety of the aviation products or services provided by the person:

(a) The person's aviation-related processes, procedures, and activities.

(b) The function and purpose of the aviation products or services.

(c) The operating environment.

(d) The personnel, equipment, and facilities necessary for operation.

§ 5.19 Implementation plan.

(a) An implementation plan filed under this part must be based on the organizational system description as defined in § 5.17 and describe the means of compliance (including, but not limited to, new or existing policies, processes, or procedures) used to meet the requirements of this part.

(b) A person required to submit an implementation plan under this part must make available to the Administrator, upon request, all necessary information and data that demonstrates that the SMS has been or will be implemented in accordance with the implementation plan.

Subpart B—Safety Policy

■ 3. Amend § 5.21 by:
■ a. Revising paragraph (a) introductory text and paragraphs (a)(1) and (2);
■ b. Adding paragraph (a)(7); and
■ c. Revising paragraphs (c) and (d).

The revisions and addition read as follows:

§ 5.21 Safety policy.

(a) Any person required to have an SMS under this part must have a safety policy that includes at least the following:

(1) The person's safety objectives.

(2) The person's commitment to fulfill the safety objectives.

* * * * *

(7) A code of ethics that is applicable to all employees, including management personnel and officers, which clarifies that safety is the organization's highest priority.

* * * * *

(c) The safety policy must be documented and communicated throughout the person's organization.

(d) The safety policy must be regularly reviewed by the accountable executive to ensure it remains relevant and appropriate to the person.

■ 4. Amend § 5.23 by revising paragraph (a) introductory text, paragraphs (a)(3) and (b) to read as follows:

§ 5.23 Safety accountability and authority.

(a) Any person required to have an SMS under this part must define in its safety policy the accountability for safety of the following individuals:

* * * * *

(3) Employees relative to the person's safety performance.

(b) The person must identify the levels of management with the authority to make decisions regarding safety risk acceptance.

■ 5. Revise § 5.25 to read as follows:

§ 5.25 Designation and responsibilities of required safety management personnel.

(a) *Designation of the accountable executive.* Any person required to have an SMS under this part must identify an accountable executive who, irrespective of other functions, satisfies the following:

(1) Is the final authority over operations authorized to be conducted under the person's certificate(s) or Letter(s) of Authorization.

(2) Controls the financial resources required for the operations to be conducted under the person's certificate(s) or Letter(s) of Authorization.

(3) Controls the human resources required for the operations authorized to be conducted under the person's certificate(s) or Letter(s) of Authorization.

(4) Retains ultimate responsibility for the safety performance of the operations conducted under the person's certificate(s) or Letter(s) of Authorization.

(b) *Responsibilities of the accountable executive.* The accountable executive must accomplish the following:

(1) Ensure that the SMS is properly implemented and is performing across all pertinent areas.

(2) Develop and sign the safety policy.

(3) Communicate the safety policy throughout the person's organization.

(4) Regularly review the safety policy to ensure it remains relevant and appropriate to the person.

(5) Regularly review the safety performance and direct actions necessary to address substandard safety performance in accordance with § 5.75.

(c) *Designation of management personnel.* The accountable executive must designate sufficient management personnel who, on behalf of the accountable executive, are responsible for the following:

(1) Coordinate implementation, maintenance, and integration of the SMS throughout the person's organization.

(2) Facilitate hazard identification and safety risk analysis.

(3) Monitor the effectiveness of safety risk controls.

(4) Ensure safety promotion throughout the person's organization as required in subpart E of this part.

(5) Regularly report to the accountable executive on the performance of the SMS and on any need for improvement.

■ 6. Revise § 5.27 to read as follows:

§ 5.27 Coordination of emergency response planning.

Where emergency response procedures are necessary, any person required to have an SMS under this part must develop, and the accountable executive must approve as part of the safety policy, an emergency response plan that addresses at least the following:

(a) Delegation of emergency authority throughout the person's organization.

(b) Assignment of employee responsibilities during the emergency.

(c) Coordination of the emergency response plans with the emergency response plans of other organizations it must interface with during the provision of its services.

Subpart C—Safety Risk Management

■ 7. Amend § 5.51 by revising the introductory text to read as follows:

§ 5.51 Applicability.

Any person required to have an SMS under this part must apply safety risk management to the following:

* * * * *

■ 8. Amend § 5.53 by:

■ a. Revising paragraph (a);

■ b. Adding paragraph (b)(5); and

■ c. Revising paragraph (c).

The revisions and addition read as follows:

§ 5.53 System analysis and hazard identification.

(a) When applying safety risk management, any person required to have an SMS under this part must analyze the systems identified in § 5.51. Those system analyses must be used to identify hazards under paragraph (c) of this section and in developing and implementing risk controls related to the system under § 5.55(c).

(b) * * *

(5) The interfaces of the system.

(c) Any person required to have an SMS under this part must develop and maintain processes to identify hazards within the context of the system analysis.

■ 9. Revise § 5.55 to read as follows:

§ 5.55 Safety risk assessment and control.

Any person required to have an SMS under this part must:

(a) Develop and maintain processes to analyze safety risk associated with the hazards identified in § 5.53(c).

(b) Define a process for conducting risk assessment that allows for the determination of acceptable safety risk.

(c) Develop and maintain processes to develop safety risk controls that are necessary as a result of the safety risk assessment process under paragraph (b) of this section.

(d) Evaluate whether the risk will be acceptable with the proposed safety risk control applied before the safety risk control is implemented.

■ 10. Add § 5.57 to subpart C to read as follows:

§ 5.57 Notification of hazards to interfacing persons.

If a person required to have an SMS under this part identifies a hazard in the operating environment, the person must provide notice of the hazard to any interfacing person that, to the best of the person's knowledge, could address the hazard or mitigate the risk. For the purpose of this section, interfacing persons are those that contribute to the safety of the certificate or Letter of Authorization holder's aviation-related products and services.

Subpart D—Safety Assurance

■ 11. Revise and republish § 5.71 to read as follows:

§ 5.71 Safety performance monitoring and measurement.

(a) Any person required to have an SMS under this part must develop and maintain processes and systems to acquire data with respect to its operations, products, and services to monitor the safety performance of the organization. These processes and systems must include, at a minimum, the following:

(1) Monitoring of operational processes.

(2) Monitoring of the operational environment to detect changes.

(3) Auditing of operational processes and systems.

(4) Evaluations of the SMS and operational processes and systems.

(5) Investigations of incidents and accidents.

(6) Investigations of reports regarding potential non-compliance with regulatory standards or other safety risk controls established by the person through the safety risk management process established in subpart C of this part.

(7) A confidential employee reporting system in which employees can report hazards, issues, concerns, occurrences, incidents, as well as propose solutions and safety improvements, without concern of reprisal for reporting.

(8) Investigations of hazard notifications that have been received from external sources.

(b) Any person required to have an SMS under this part must develop and maintain processes that analyze the data acquired through the processes and systems identified under paragraph (a) of this section and any other relevant data with respect to its operations, products, and services.

(c) Any person that holds both a type certificate and a production certificate issued under part 21 of this chapter for the same product must submit a summary of the confidential employee reports received under paragraph (a)(7) of this section to the Administrator once every 6 months.

■ 12. Amend § 5.73 by revising paragraph (a) introductory text, and paragraphs (a)(1) and (b) to read as follows:

§ 5.73 Safety performance assessment.

(a) Any person required to have an SMS under this part must conduct assessments of its safety performance against its safety objectives, which include reviews by the accountable executive, to:

(1) Ensure compliance with the safety risk controls established by the person.

* * * * *

(b) Upon completion of the assessment, if ineffective controls or new hazards are identified under paragraphs (a)(2) through (5) of this section, the person must use the safety risk management process described in subpart C of this part.

■ 13. Revise § 5.75 to read as follows:

§ 5.75 Continuous improvement.

Any person required to have an SMS under this part must establish and implement processes to correct safety performance deficiencies identified in the assessments conducted under § 5.73.

Subpart E—Safety Promotion

■ 14. Revise § 5.91 to read as follows:

§ 5.91 Competencies and training.

Any person required to have an SMS under this part must provide training to each individual identified in § 5.23 of this part to ensure the individuals attain and maintain the competencies necessary to perform their duties relevant to the operation and performance of the SMS.

■ 15. Amend § 5.93 by revising the introductory text to read as follows:

§ 5.93 Safety communication.

Any person required to have an SMS under this part must develop and maintain means for communicating safety information that, at a minimum:

* * * * *

Subpart F—SMS Documentation and Recordkeeping

■ 16. Amend § 5.95 by revising the introductory text to read as follows:

§ 5.95 SMS documentation.

Any person required to have an SMS under this part must develop and maintain the following SMS documentation:

* * * * *

■ 17. Revise § 5.97 to read as follows:

§ 5.97 SMS records.

Any person required to have an SMS under this part must:

(a) Maintain records of outputs of safety risk management processes as described in subpart C of this part. Such records must be retained for as long as the control remains relevant to the operation.

(b) Maintain records of outputs of safety assurance processes as described in subpart D of this part. Such records must be retained for a minimum of 5 years.

(c) Maintain a record of all training provided under § 5.91 for each individual. Such records must be retained for as long as the individual is employed by the person.

(d) Retain records of all communications provided under § 5.93 or § 5.57 for a minimum of 24 consecutive calendar months.

PART 21—CERTIFICATION PROCEDURES FOR PRODUCTS AND ARTICLES

■ 18. The authority citation for part 21 is revised to read as follows:

Authority: 42 U.S.C. 7572; 49 U.S.C. 106(f), 106(g), 40105, 40113, 44701–44702, 44704, 44707, 44709, 44711, 44713, 44715, 45303; Sec. 102, Pub. L. 116–260, 134 Stat. 2309.

§ 21.55 Responsibilities of type certificate holders who license the type certificate.

■ 19. Revise § 21.55 to read as follows:

< A type certificate holder who allows a person to use the type certificate to manufacture a new aircraft, aircraft engine, or propeller must meet the applicable requirements of part 5 of this chapter and provide that person with a written licensing agreement acceptable to the FAA.

■ 20. Amend § 21.135 by adding paragraph (c) to read as follows:

§ 21.135 Organization.

* * * * *

(c) Each applicant for or holder of a production certificate, except those based only on a supplemental type certificate or on the rights to the benefits of a supplemental type certificate under a licensing agreement, must meet the applicable requirements of part 5 of this chapter.

■ 21. Amend § 21.147 by revising paragraph (b) to read as follows:

§ 21.147 Amendment of production certificates.

* * * * *

(b) An applicant for an amendment to a production certificate to add a type certificate or model, or both, must comply with §§ 21.135(c), 21.137, 21.138, and 21.150.

* * * * *

PART 91—GENERAL OPERATING AND FLIGHT RULES

■ 22. The authority citation for part 91 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40103, 40105, 40113, 40120, 44101, 44111, 44701, 44704, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506–46507, 47122, 47508, 47528–47531, 47534, Pub. L. 114–190, 130 Stat. 615 (49 U.S.C. 44703 note); articles 12 and 29 of the Convention on International Civil Aviation (61 Stat. 1180), (126 Stat. 11).

■ 23. Revise § 91.147 to read as follows:

§ 91.147 Passenger-carrying flights for compensation or hire.

(a) *Definitions.* For the purposes of this section, *Operator* means any person conducting nonstop passenger-carrying flights in an airplane, powered-lift, or rotorcraft for compensation or hire in accordance with §§ 119.1(e)(2), 135.1(a)(5), or 121.1(d) of this chapter that begin and end at the same airport and are conducted within a 25-statute mile radius of that airport.

(b) *General requirements.* An Operator conducting passenger-carrying flights for compensation or hire must meet the following requirements unless all flights are conducted under § 91.146. The Operator must:

(1) Comply with the safety provisions of part 136, subpart A of this chapter.

(2) Register and implement its drug and alcohol testing programs in accordance with part 120 of this chapter.

(3) Comply with the applicable requirements of part 5 of this chapter.

(4) Apply for and receive a Letter of Authorization from the responsible Flight Standards office.

(c) *Letter of Authorization.* Each application for a Letter of Authorization must include the following information:

(1) Name of Operator, agent, and any d/b/a (doing-business-as) under which that Operator does business.

(2) Principal business address and mailing address.

(3) Principal place of business (if different from business address).

(4) Name of person responsible for management of the business.

(5) Name of person responsible for aircraft maintenance.

(6) Type of aircraft, registration number(s), and make/model/series.

(7) Antidrug and Alcohol Misuse Prevention Program registration.

(d) *Compliance.* The Operator must comply with the provisions of the Letter of Authorization received.

PART 119—CERTIFICATION: AIR CARRIERS AND COMMERCIAL OPERATORS

■ 24. The authority citation for part 119 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40101, 40102, 40103, 40113, 44105, 44106, 44111, 44701–44717, 44722, 44901, 44903, 44904, 44906, 44912, 44914, 44936, 44938, 46103, 46105; sec. 215, Pub. L. 111–216, 124 Stat. 2348.

■ 25. Revise § 119.8 to read as follows:

§ 119.8 Safety Management Systems.

Certificate holders authorized to conduct operations under part 121 or 135 of this chapter must have a safety management system that meets the requirements of part 5 of this chapter.

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC

Michael Gordon Whitaker,

Administrator.

[FR Doc. 2024–08669 Filed 4–22–24; 4:15 pm]

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Part VII

Department of Housing and Urban Development

Department of Agriculture

Final Determination: Adoption of Energy Efficiency Standards for New Construction of HUD- and USDA-Financed Housing; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

DEPARTMENT OF AGRICULTURE

[Docket No. FR–6271–N–03]

RIN 2506–AC55

Final Determination: Adoption of Energy Efficiency Standards for New Construction of HUD- and USDA-Financed Housing

AGENCY: Department of Housing and Urban Development and Department of Agriculture.

ACTION: Notice of final determination.

SUMMARY: The Energy Independence and Security Act of 2007 (EISA) establishes procedures for the U.S. Department of Housing and Urban Development (HUD) and the U.S. Department of Agriculture (USDA) to consider adopting periodic revisions to the International Energy Conservation Code (IECC) and to ANSI/ASHRAE/IES Standard 90.1: Energy Standard for Buildings, Except Low-Rise Residential Buildings (ASHRAE 90.1), subject to a determination by the agencies that the revised codes do not negatively affect the availability or affordability of new construction of single and multifamily housing covered by EISA, and a determination by the Secretary of Energy that the revised codes ''would improve energy efficiency.'' At the time of developing the preliminary determination, the most recent editions of the codes for which DOE had issued efficiency determinations were ASHRAE 90.1–2019, and the 2021 IECC. This notice follows the notice of preliminary determination published on May 18, 2023, and announces the final determination of HUD and USDA as required under section 481(d)(1) of EISA. After consideration of public comments, HUD and USDA determine that the 2021 IECC and ASHRAE 90.1–2019 will not negatively affect the affordability and availability of housing covered by EISA.

DATES:

Effective Date of this Determination: May 28, 2024.

Compliance Date: Compliance is required according to the implementation schedule described in Section VI of this notice; compliance dates vary according to program type.

FOR FURTHER INFORMATION CONTACT:

HUD: Michael Freedberg, Office of Environment and Energy, Department of Housing and Urban Development, 451 7th Street SW, Room 10180, Washington, DC 20410; telephone number 202–402–4366 (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 or 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.*

USDA: Meghan Walsh, Rural Housing Service, Department of Agriculture, 1400 Independence Avenue SW, Room 6900–S, Washington, DC 20250; telephone number 202–205–9590 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

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I. Background

A. Statutory Requirements

Section 481 of the Energy Independence and Security Act of 2007 (''EISA,'' Pub. L. 110–140) amended section 109 of the Cranston-Gonzalez National Affordable Housing Act of 1990 (Cranston-Gonzalez) (42 U.S.C. 12709), which establishes procedures for setting minimum energy standards for the following three categories of housing financed or assisted by HUD and USDA:

- New construction of public and assisted housing and single family and multifamily residential housing (other than manufactured homes) subject to mortgages insured under the National Housing Act; [1]
- New construction of single family housing (other than manufactured homes) subject to mortgages insured, guaranteed, or made by the Secretary of Agriculture under title V of the Housing Act of 1949; [2] and,
- Rehabilitation and new construction of public and assisted housing funded by HOPE VI revitalization grants under section 24 of the United States Housing Act of 1937 (42 U.S.C. 1437v).

In addition to these EISA-specified categories, two HUD programs apply EISA to new construction projects through their program statutes and regulations: the HOME Investment Partnerships Program (HOME) and the Housing Trust Fund. Sections 215(a)(1)(F) and (b)(4) of Cranston-Gonzalez (42 U.S.C. 12745(a)(1)(F) and (b)(4)) make new construction of rental housing and homeownership housing assisted under the HOME program subject to section 109 of Cranston-Gonzalez (42 U.S.C. 12709) and, therefore, to section 481 of EISA. Although the energy standards at 24 CFR 92.251(a)(2)(ii) are reserved in the July 2013 HOME final program rule, the statutory requirements of section 109 of Cranston-Gonzalez (42 U.S.C. 12709) continue to apply to all newly constructed housing funded by the HOME program.

For the Housing Trust Fund, program regulations at 24 CFR 93.301(a)(2)(ii), Property Standards, require compliance with the minimum standards required under Cranston Gonzalez section 109 (42 U.S.C. 12709).

EISA references two standards: the International Energy Conservation Code (IECC) and ANSI/ASHRAE/IES Standard 90.1.[3] The IECC standard applies to single family homes and multifamily low-rise buildings (up to 3 stories), while the ASHRAE 90.1 standard applies to multifamily residential buildings with 4 or more stories.[4] For both agencies, applicability is limited to newly constructed housing and does not include the purchase or repair of existing housing.[5]

Sections 109(c) and (d) of Cranston-Gonzalez, as amended by EISA, establish procedures for updating HUD and USDA energy standards following periodic revisions to the IECC and ASHRAE 90.1 codes, typically every three years. Specifically, section 109(d) of Cranston-Gonzalez (42 U.S.C. 12709) provides that revisions to the IECC or ASHRAE 90.1 codes will apply to the three categories of housing financed or assisted by HUD or USDA described above if: (1) the agencies ''make a determination that the revised codes do not negatively affect the availability or affordability'' of such housing, and (2) the Secretary of Energy has made a determination under section 304 of the Energy Conservation and Production Act (42 U.S.C. 6833) that the revised codes would improve energy efficiency (42 U.S.C. 12709(d)). On July 28, 2021, the Department of Energy (DOE) published final determinations that the 2021 IECC and ASHRAE 90.1–2019 standards would improve energy efficiency (86 FR 40529 and 86 FR 40543).

Through this notice, HUD and USDA issue their final determination that the 2021 IECC and ASHRAE 90.1–2019 energy codes will not negatively impact the affordability or availability of housing covered by EISA.

Note that manufactured housing is not covered in this notice: the relevant

[1] This subsection of EISA refers to HUD programs. See Table 2 for specific HUD programs covered by the Act.

[2] See Table 2 for specific USDA programs covered by the Act.

[3] ANSI—American National Standards Institute; ASHRAE—American Society of Heating, Refrigerating, and Air-Conditioning Engineers; IES—Illuminating Electrical Society.

[4] Note the IECC addresses both residential and commercial buildings. ASHRAE 90.1 covers commercial buildings only, including multifamily buildings four or more stories above grade. IECC Section C 401.2 adopts, by reference, ASHRAE 90.1; *i.e.* compliance with ASHRAE 90.1 qualifies as compliance with the IECC for commercial buildings.

[5] The statute covers rehabilitation as well as new construction of housing assisted by HOPE VI revitalization grants; however, as noted below, the HOPE VI program is no longer funded.

section of the EISA statute specifically excludes manufactured housing; DOE has issued a separate final rule under EISA section 413 that establishes energy conservation standards for manufactured housing (42 U.S.C. 17071).[6] Those standards are also based on the 2021 edition of the IECC adapted for the unique features of manufactured housing, as well as feedback received during interagency consultation with HUD and extensive public comments from stakeholders.

B. Energy Codes Overview

There are two primary benefits of adopting energy-saving building codes: a private benefit for residents—either homeowners or renters—in the form of lower energy costs, and the external social value of reducing the emission of greenhouse gases (GHGs). Additional benefits include improved health and resilience against extreme hot or cold weather events. The affordability analysis contained in this notice focuses exclusively on the first of these benefits: the direct costs and savings to the consumer, both in the short and long term, for both renters and homebuyers. The affordability analysis recognizes the unique nature of the energy efficiency investment: while there is a one-time incremental cost, the benefits in terms of energy and utility cost savings to the consumer persist over time, for as long as the property exists. This is especially important for low- and moderate-income renters and homeowners, who share a disproportionate energy cost burden, spending a significantly higher share of their incomes on energy than other households. The accompanying Regulatory Impact Analysis (RIA) also addresses a second benefit, the external cost savings in the ''social cost of carbon,'' but these are larger societal benefits that may result from lowering energy use in the HUD- and USDA-financed housing and are not directly reflected in the cost of buying, owning, or renting a home, and therefore are not included in the affordability analysis.

As discussed in more detail below, states or localities typically adopt the IECC and ASHRAE 90.1 standards on a voluntary basis one or more years after their publication. As of December 2023, only a small number of states (five) have adopted the 2021 IECC or its equivalent (California, Washington, Connecticut, New Jersey, and Vermont), another five states have adopted the 2021 IECC with weakening amendments (Florida, Louisiana, Montana, Maryland, and Oregon), while another twenty or more states are actively considering and are likely to adopt some version of this code in the near future.

Adoption of ASHRAE 90.1–2019 for multifamily buildings has been more advanced, with ten states and the District of Columbia (DC) having adopted this standard as of December 2023. Another two states (Florida and Louisiana) have adopted the 2019 standards with weakening amendments.

DOE has determined that the 2021 IECC represents an approximately 40 percent improvement in energy efficiency for residential and commercial buildings compared to the 2006 edition and 34.3 percent compared to the 2009 edition.[7] The 2021 IECC also for the first time includes a Zero Energy Appendix. The Appendix is an optional add-on to the 2021 IECC that—if adopted by a state or local jurisdiction—will result in residential buildings having net zero energy consumption over the course of a year.

DOE has also determined that the 2019 edition of ASHRAE 90.1 represents a 2.65 percent efficiency improvement over the 2016 edition, and approximately 33 percent over the 2007 edition. As explained in DOE's State Portal, DOE assesses state energy code adoption based on a quantitative analysis of energy savings impacts within the state.[8] This approach analyzes the energy use of a state base code along with accompanying state amendments through DOE's energy modeling framework to determine an overall ''state energy index.'' The state index is then compared to the index of the last six national model energy codes to characterize each state at a specific code equivalency. The current state adoption of the IECC- and ASHRAE 90.1-equivalent standards is as follows:

Table 1. Distribution of State Adoption of IECC and ASHRAE 90.1 Equivalent Standards

IECC Equivalent Code* Single Family and Low-Rise Multifamily		ASHRAE 90.1 Equivalent Code* Mid-Rise and High-Rise Multifamily	
Code Equivalent Year	**Number of States**	**Code Equivalent Year**	**Number of States**
IECC 2024	0	ASHRAE 90.1 – 2022	0
IECC 2021	5	ASHRAE 90.1 – 2019	10 + DC
IECC 2018	11 + DC	ASHRAE 90.1 – 2016	3
IECC 2015	2	ASHRAE 90.1 – 2013	17
IECC 2012	0	ASHRAE 90.1 – 2010	3
IECC 2009	23	ASHRAE 90.1 – 2007	7
Less stringent than IECC 2009, No Statewide Code or Home Rule	9	Less stringent than ASHRAE 90.1-2007, No Statewide Code or Home Rule	10

*As of December 2023.

[6] 87 FR 32728 (May 31, 2022); 10 CFR part 460.

[7] Lucas R.G., Z.T. Taylor, V.V. Mendon, and S. Goel. 2012. National Energy and Cost Savings for New Single- and Multifamily Homes: A Comparison of the 2006, 2009, and 2012 Editions of the IECC. Richland, WA: Pacific Northwest National Laboratory.

[8] DOE State Portal, *https://www.energycodes.gov/state-portal.*

C. Covered HUD and USDA Programs

Table 2 lists the specific HUD and USDA programs covered by EISA, with certain exclusions noted, as discussed below. Apart from the HOPE VI program, where rehabilitation is referenced, only new construction of housing financed or assisted under these programs is covered by EISA.

Table 2. Covered HUD and USDA Programs (New Construction)

HUD Programs	Legal Authority	Regulations or Notices
Public Housing Capital Fund	Section 9(d) and Section 30 of the U.S. Housing Act of 1937 (42 U.S.C. 1437g(d) and 1437z-2)	24 CFR part 905
Capital Fund Financing Program	Section 9(d) and Section 30 of the U.S. Housing Act of 1937 (42 U.S.C. 1437g(d) and 1437z-2).	24 CFR part 905 subpart E
*HOPE VI Revitalization of Severely Distressed Public Housing	Section 24 of the U.S. Housing Act of 1937 (42 U.S.C. 1437v)	FR-5415-N-07
Choice Neighborhoods Implementation Grants	Section 24 of the U.S. Housing Act of 1937 (42 U.S.C. 1437v)	Implementation Grants notice of Funding Opportunity (NOFO)
Project-Based Voucher Program	Section 8 of the U.S. Housing Act of 1937 (42 U.S.C. 1437f)	24 CFR part 983
Section 202 Supportive Housing for the Elderly	Section 202 of the Housing Act of 1959 (12 U.S.C. 1701q), as amended.	24 CFR part 891
Section 811 Supportive Housing for Persons with Disabilities	Section 811 of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 8013) as amended.	24 CFR part 891
Rental Assistance Demonstration (RAD)	Consolidated and Further Continuing Appropriations Act of 2012 (Public Law 112-55), as amended by Consolidated Appropriations Act, 2014 (Public Law 113-76) and subsequent HUD	RAD notice Revision 4 (H 2019-09 PIH 2019-23)

HUD Programs	Legal Authority	Regulations or Notices
	Appropriations Acts.	
FHA Single Family Mortgage Insurance Programs	National Housing Act, Sections 203(b) (12 U.S.C. 1709(b)), Section 251 (12 U.S.C. 1715z-16), Section 247 (12 U.S.C. 1715z-12), Section 203(h) (12 U.S.C. 1709(h)), Housing and Economic Recovery Act of 2008 (Public Law 110-289), Section 248 of the National Housing Act (12 U.S.C. 1715z-13)	24 CFR part 203, subpart A; 203.18(i); 203.43i; 203.49; 203.43h.
FHA Multifamily Mortgage Insurance Programs	Sections 213, 220, 221, 231, and 232 of the National Housing Act (12 U.S.C.1715e, 12 U.S.C.1715v, 12 U.S.C.1715k, 12 U.S.C.17151, 12 U.S.C.1715w).	24 CFR parts 200, subpart A, 213; 220; 221, subparts C and D; 231; and 232
HOME Investment Partnerships (HOME) [By regulation]	Cranston-Gonzalez sections 215(b)(4) and 215(a)(1)(F) (42 U.S.C. 12745(b)(4) and 42 U.S.C. 12745(a)(1)(F)) require HOME units to meet minimum energy efficiency standards promulgated by the Secretary in accordance with Cranston-Gonzalez section 109 (42 U.S.C. 12745).	Final HOME Rule at www.onecpd.info/home/home-final-rule/ reserves the energy standard for a separate rulemaking at 24 CFR 92.251.
Housing Trust Fund [By regulation]	Title I of the Housing and Economic Recovery Act of 2008, Section 1131 (Public Law 110-289, 12 U.S.C. 4568.)	24 CFR 93.301(a)(2)(ii), Property Standards, requires compliance with Cranston Gonzalez section 109 (42 U.S.C. 12709).
USDA Programs	**Legal Authority**	**Regulations**
Section 502 Guaranteed Housing Loans	Section 502 of Housing Act of 1949 (42 U.S.C. 1472)	7 CFR part 3555
Section 502 Rural Housing Direct Loans	Section 502 of Housing Act of 1949 (42 U.S.C. 1472)	7 CFR part 3550
Section 523 Mutual Self Help Technical Assistance Grants, homeowner participants	Section 523 of Housing Act of 1949 (42 U.S.C. 1472)	7 CFR part 1944 subpart I

* Program no longer funded or no longer funds new construction.

Several exclusions are worth noting, *i.e.,* programs which, while classified as public or assisted housing, or may be specified in the statute, are no longer funded or do not fund new construction:

- HOPE VI. While EISA references the ''rehabilitation and new construction of public and assisted housing funded by HOPE VI revitalization grants,'' funding for HOPE VI revitalization grants was discontinued in fiscal year (FY) 2011; the program is therefore not covered by this notice.
- Project Based Rental Assistance (PBRA). HUD is no longer authorized to provide funding for new construction of units assisted under the Section 8 PBRA program, except under the Rental Assistance Demonstration (RAD). Apart from RAD, current authorization and funding that Congress provides for the PBRA program is for the limited purpose of renewing expiring Section 8 rental-assistance contracts. Accordingly, this notice does not apply to the current Section 8 PBRA program except through RAD, as referenced in Table 2. If in the future Congress were to appropriate funds for new PBRA assisted units, such developments would be covered by this determination.

In addition, other HUD programs that provide financing for new construction are not covered because they do not constitute ''assisted housing'' as specified in EISA and/or are not authorized under statutes specifically referenced in EISA, as follows:

(1) Indian Housing. With the exception of Section 248 FHA-insured mortgages, Indian housing programs are excluded because they do not constitute assisted housing and are not authorized under the National Housing Act (12 U.S.C. 1701 *et seq.*) as specified in EISA. For example, the Section 184 guaranteed loan program is authorized under Section 184 of the Housing and Community Development Act of 1992 (42 U.S.C. 1715z–13a).

(2) Community Development Block Grants. Housing financed with Community Development Block Grant (CDBG) funds is excluded since CDBG, which is authorized by the Housing and

Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*), is neither an assisted housing program nor a National Housing Act mortgage insurance program.

(3) USDA Multifamily Housing and assisted housing financed by USDA Community Facilities loans and grants. These programs are excluded because they are not authorized under the National Housing Act (12 U.S.C. 1701 *et seq.*) as specified by EISA.

D. Current Above-Code Standards or Incentives

Some HUD and USDA competitive grant programs covered by EISA (as well as other programs) already require grantees to comply with energy efficiency standards or green building requirements with energy performance requirements that exceed state or locally adopted IECC and ASHRAE 90.1 standards, while other programs provide incentives to do so. A list of current programs that require or incentivize a green building standard is shown in Table 3. This standard is typically Energy Star Certified New Homes for single family properties, Energy Star for Multifamily New Construction, or a green building standard recognized by HUD that includes a minimum energy efficiency requirement. Nothing in EISA or this notice precludes HUD or USDA competitive programs from requiring these higher standards or raising them further, nor from providing incentives for above-code energy requirements.

Table 3 includes a listing of current HUD and USDA programs with either requirements or incentives for funding recipients to build to standards above the current 2009 IECC and/or ASHRAE 90.1–2007 standards (see ''Exceeds Current Energy Standard'' column). Contingent on the energy standard selected, and the minimum energy efficiency requirements established for each standard, projects built to the energy or green building standards listed in Table 3 may also meet or exceed the 2021 IECC and ASHRAE 90.1–2019 standards discussed in this notice (see ''Meets or Exceeds Proposed Standards'' column). These green building or energy performance standards typically have multiple certification levels with varying energy baseline requirements (gold, green, platinum etc.); these baseline requirements are updated over time at some point after publication of newer editions of the energy codes. HUD and USDA intend to seek certifications from the standard-setting bodies as to which of these programs, or which certification levels, meet the 2021 IECC or ASHRAE 90.1–2019 standards referenced in this notice.

Table 3. Current Energy Standards and Incentives for HUD and USDA Programs (New Construction)[9]

Program	Type of Assistance	Current Energy Efficiency Requirements or Incentives	Exceeds Current Energy Standards	Meets or Exceeds Proposed Standards
Programs Covered by EISA				
HUD				
Choice Neighborhoods Implementation	Competitive Grant	Required: Requirements of ENERGY STAR Single Family New Homes or Multifamily New Construction. Plus certification by recognized green rating such as EPA Indoor airPLUS, Enterprise Green Communities, National Green Building Standard, LEED-H, LEED-NC, or regional standards such as Earthcraft or Built Green. Use ENERGY STAR products.	Exceeds 2009 IECC/ASHRAE 90.1-2007	May meet or exceed 2021 IECC/ ASHRAE 90.1-2019 standard[10]
Choice Neighborhoods – Planning	Competitive Grant	Required: Eligible for Stage 1 Conditional Approval LEED for Neighborhood Development (LEED-ND) or equivalent. Plus certification by recognized green rating program.	Exceeds 2009 IECC/ASHRAE 90.1-2007	May meet or exceed 2021 IECC/ ASHRAE 90.1-2019 standard
Section 202 Supportive Housing for the Elderly	Competitive Grant	Required: 2021 IECC and ASHRAE 90.1-2019. Incentive: Additional competitive rating points for developments that meet a green building or energy performance standard that includes a Zero Energy Ready or Net Zero Energy requirement.	Exceeds 2009 IECC/ASHRAE 90.1-2007	Meets 2021 IECC/ ASHRAE 90.1-2019 standard
Section 811 for Persons with Disabilities	Competitive Grant	Required: 2021 IECC and ASHRAE 90.1-2019. ENERGY STAR Residential New Construction certification.	Exceeds 2009 IECC/ASHRAE 90.1-2007	
Rental Assistance Demonstration (RAD)	Conversion of Existing Units	2009 IECC or ASHRAE 90.1-2007 or any successor code adopted by HUD; applicants encouraged to build to ENERGY STAR Residential New Construction certification. Minimum WaterSense and ENERGY STAR appliances required and the most cost-effective measures identified in the Physical Condition Assessment.		

Program	Type of Assistance	Current Energy Efficiency Requirements or Incentives	Exceeds Current Energy Standards	Meets or Exceeds Proposed Standards
FHA Multifamily Mortgage Insurance	Mortgage Insurance	Incentive: Discounted Mortgage Insurance Premium (Green MIP) for a recognized Green Building Standard. ENERGY STAR Score of at least 75 in EPA Portfolio Manager.	Incentives exceed 2009 IECC/ASHRAE 90.1-2007	May meet or exceed 2021 IECC/ ASHRAE 90.1-2019 standard
FHA Single Family Mortgage Insurance	Mortgage Insurance	2009 IECC		
HOME Investment Partnerships Program	Formula Grant	2009 IECC/ASHRAE 90.1-2007		
Housing Trust Fund	Formula Grant	2009 IECC/ASHRAE 90.1-2007		
Public Housing Capital Fund	Formula Grant	2009 IECC/ASHRAE 90.1-2010 or successor standards. ENERGY STAR appliances also required unless not cost effective.		
Project-Based Vouchers	Rental Assistance	2009 IECC/ASHRAE 90.1-2007		
USDA				
Section 502 Guaranteed Housing Loans	Loan Guarantee	2009 IECC at minimum. Stretch ratio of 2 percent on mortgage qualifications for complying with above-code standards.		
Section 502 Rural Housing Direct Loans	Direct Loan	2009 IECC at minimum. Stretch ratio of 2 percent on mortgage qualifications for complying with above-code standards.		
Section 523 Mutual Self Help	Grant Program	2009 IECC at minimum. State adopted versions of more recent codes vary.		
Programs Not Covered by EISA				
HUD CDBG-DR, CDBG-Mitigation (MIT)	Grants to states or localities	For new construction of substantially damaged buildings, meet a minimum energy standard and green building standard recognized by HUD.	Exceeds 2009 IECC/ASHRAE 90.1-2007 requirements	May meet or exceed 2021 IECC/ ASHRAE 90.1-2019 standard
USDA Multifamily: Sec 515 New Construction, Sec 514/516 Farmworker Housing, Sec 538 Guaranteed Loans; USDA	Direct Loans, Guaranteed Loans and Grants	Meet minimum state or local energy codes; Incentive for Sections 514/515/516: ENERGY STAR Residential New Construction certification, Enterprise Green Communities, NGBS, DOE Zero Energy Ready, LEED, Passive House, Living Building Challenge.	Incentives exceed 2009 IECC/ASHRAE 90.1-2007	May meet or exceed 2021 IECC/ ASHRAE 90.1-2019 standard

Program	Type of Assistance	Current Energy Efficiency Requirements or Incentives	Exceeds Current Energy Standards	Meets or Exceeds Proposed Standards
Community Facilities				

E. Current Housing Market Affordability Trends

HUD and USDA recognize the current affordable housing shortage across the United States, caused by high mortgage interest rates, increased construction costs driven in part by COVID-related supply chain shortages, and an inadequate supply of new housing sufficient to meet demand due to a range of regulatory barriers such as local land use laws and zoning regulations that may limit the production of affordable housing.[11] (Land use regulations that mandate home sizes and volumetric massing are particularly relevant to energy-efficiency because some local zoning policies restrict homes of smaller sizes, which inherently have the potential to be more affordable and better performing homes.) The publication of this notice occurs at a time when housing prices for both new and existing homes have risen significantly over the past three years, increases in mortgage interest rates have reached their highest levels in more than two decades, and it has become increasingly difficult for low-moderate income households to afford a home purchase. The National Association of Realtors' annual survey of homebuyers and home sellers reports that median homebuyer income increased to $107,000 in 2023, an increase of 22 percent from $88,000 in 2022.[12] Median home sales prices increased to $417,700 in the fourth quarter of 2023, a decrease of 14 percent over the prior year but a significant increase since the fourth quarter of 2020, when the median home sales price was $358,700.[13] These trends are mirrored in the FHA-insured market. In 2023, the median price for all FHA-insured purchases, including existing homes, was $290,000, and new construction was approximately $330,000—a nearly $100,000 cost increase in the three-year period since 2020,[14] although still well below the median home sales price for all new homes of $414,600.[15]

The shortage of affordable housing is driven by larger trends in the housing and mortgage markets. In light of these larger trends, it is important to note that a key finding of this notice is that given the relatively modest incremental costs of building to the new standards, the adoption of the proposed codes in this final determination will have a limited impact on overall affordability for low- or moderate-income buyers. Also, energy efficiency is one of the few features of a home that contributes to affordability, in that significant cost savings are projected to be realized from this investment. These savings persist over time. Investments in energy efficiency will also ensure that the next generation of Federally-financed new housing is built to a high-performance standard that realizes lower energy bills, improved comfort, and healthier living conditions for residents. These benefits are long-lasting and will be passed on to future owners.

F. Changes From the Preliminary Determination to the Final Determination

In response to the public comments received, HUD and USDA are adopting several changes in this final determination to incorporate public feedback on the preliminary determination, and address questions and concerns expressed by commenters.

1. Adjusted Economic Factors

In response to several comments about the economic factors used in the affordability analysis, HUD and USDA have updated several economic and cash flow factors to account for changes in the economy as well as the building industry since the original analysis was conducted by Pacific Northwest National Laboratory (PNNL) for DOE using 2020—2021 cost data and economic factors. These revisions address the distortions in the current housing market caused by COVID–19 and global supply chain issues, which significantly increased the cost of construction materials and energy, as well as significant increases in mortgage interest rates during this period.

Construction cost increase. A supply chain cost increase factor has been applied to the incremental cost of adopting the new code to account for the increase in residential construction costs for 2020–23. The 37 percent increase utilizes Bureau of Labor Statistics' Producer Price Index for inputs to residential construction less energy, as reported by the National Association of Home Builders (NAHB).[16]

Energy price increase (2020–22). An energy price increase factor was developed by averaging prices for electricity, natural gas, and heating oil for 2020 through 2022. The three-year averages were used to find the rate of increase of energy prices for each source over this period. These rates were averaged based on the residential energy mix for 2022. Data for calculating the energy price increase factor was sourced from the U.S. Energy Information Administration.[17] [18] [19]

[9] Table 3 includes HUD and USDA programs supporting new construction with energy code requirements. Does not include other HUD or USDA programs that may have appliance or product standards or requirements only, *e.g.,* Energy Star appliances or WaterSense products.

[10] Pursuant to discussion of alternative compliance paths, Section VI, Implementation, some green building standards will meet or exceed the 2021 IECC/ASHRAE 90.1–2019, others may not, HUD and USDA will publish a list of those green building certifications that meet or exceed these codes.

[11] White House Housing Supply Action Plan, President Biden Announces New Actions to Ease the Burden of Housing Costs, May 16, 2022. *www.whitehouse.gov/briefing-room/statements-releases/2022/05/16/president-biden-announces-new-actions-to-ease-the-burden-of-housing-costs/.*

[12] National Assn of Realtors, *2023 Profile of Home Buyers and Sellers,* November 2023. *www.nar.realtor/newsroom/nar-finds-typical-home-buyers-annual-household-income-climbed-to-record-high-of-107000.*

[13] St. Louis Fed, FRED Economic Data, St. Louis Fed, Median Sales Prices of Houses Sold for the United States, Q4 2023. *https://fred.stlouisfed.org/series/MSPUS*

[14] Internal FHA data on median home price for all FHA-insured purchases.

[15] St. Louis Fed, FRED Economic Data, Median Sales Price for New Houses Sold in the United States, October 2023, *https://fred.stlouisfed.org/series/MSPNHSUS.*

[16] David Logen, *Building Materials Prices Fall for Second Month Straight,* June 15, 2023. *https://eyeonhousing.org/2023/06/wbuilding-materials-prices-fall-wfor-second-month-straight/.*

[17] U.S. Energy Information Administration, *Natural Gas Prices. https://www.eia.gov/dnav/ng/ng_pri_sum_a_EPG0_PRS_DMcf_a.htm.*

[18] U.S. Energy Information Administration, *Petroleum & Other Liquids. https://www.eia.gov/dnav/pet/hist/LeafHandler.ashx?n=PET&s=M_EPD2F_PRS_NUS_DPG&f=M.*

Energy price escalator. A new fuel price escalator of 1.9 percent is based on the estimated 30-year trends in the Energy Information Administration's (EIA) 2023 Annual Energy Outlook. This escalator applies to estimates of future energy price increases, over the baseline established under the Energy Price Increase described above. This escalator was developed from the growth rate for nominal fuel prices (natural gas, heating oil, and electricity) based on the share of energy mix for 2022, which was the most recently available annual data at the time.

Mortgage interest rate. An updated nominal mortgage interest rate of 5.3 percent has been adopted, reflecting approximate two-year Freddie Mac average rates (February 2022–2024).[20] While Freddie Mac interest rates reached a twenty-year high of 7.79 percent for a 30-year fixed rate mortgage, as of November 2023, a moderating trend has begun that is projected to continue, and HUD has accordingly adopted an interest rate that is aligned with the rate currently established by DOE of 5 percent, that reflects the average of the recent 2022–24 two year period rather than rely on a specific rate from a specific point in time that may or may not continue at the same level in the future. In addition, a 6.5 percent example has also been provided (Table 16) to reflect mortgage rates of between 6 and 7 percent forecast for the next year, as well as a 3.5 percent downpayment rate that reflects the minimum FHA downpayment requirement.[21]

Discount rate. A 5.3 percent discount rate (equivalent to a 3 percent discount rate with a 2.24 percent inflation rate) has been adopted to match the mortgage interest rate. The discount rate reflects the time value of money. Following established DOE methodology, the discount rate has been set equal to the mortgage interest rate in nominal terms. The mortgage payment is an investment available to consumers who purchase homes using financing, which makes the mortgage interest rate a reasonable estimate for a consumer's alternative investment rate.

2. Adjusted Cash Flow and Financing Factors

In addition to an updated mortgage interest rate, several adjustments have been made to reflect typical financing factors utilized by FHA and USDA borrowers, as well as likely differences between the house type assumed by PNNL in their original calculations.

Down payment. The down payment contribution for home purchases has been revised to better reflect the typical HUD and USDA borrower. The down payment requirement for FHA borrowers is a minimum of 3.5 percent, distinct from a typical 20 percent down payment requirement for conventional financing without private mortgage insurance (PMI), or the 12 percent down payment rate used by DOE–PNNL and utilized by HUD and USDA in the preliminary determination. The downpayment rate has been updated to 5 percent in the Final Determination.

Mortgage Insurance. The preliminary determination was silent on mortgage insurance requirements, which have now been included in the Final Determination's affordability analysis: FHA's 1.75 percent upfront mortgage insurance premium (MIP) and 0.55 percent annual MIP that took effect in March, 2023.

Adjustment for Home Size. Cost and savings factors have been applied to the affordability analysis to better reflect the typical home FHA or USDA-sized home. These factors revise the analysis to better reflect the smaller home size of a typical FHA or USDA property (2,000 square feet (sf)) compared to a conventionally financed house modeled by PNNL (2,376 sf). While this is a 14 percent ''smaller house'', lower cost and savings factors have been used to approximate the reduced cost and associated savings that are anticipated from the smaller-house size (5 percent and 3 percent respectively).

Note that the revised analysis largely indicates that the proposed standards, while better reflecting the status of the post-COVID housing market conditions, do not change the affordability determination. The relevant tables (Tables 13–20) have been updated with the revised affordability analysis.

3. *Updated State Code Adoption:* Since publishing the preliminary determination, multiple states have adopted new building code requirements, including the codes referenced in this notice, *i.e.* 2021 IECC and ASHRAE 90.1–2019. HUD and USDA have accordingly updated the relevant tables in the Final Determination (Tables 11 and 23) to reflect the new landscape of energy code adoption at the state level, following the latest DOE determinations as of December 2023.

4. *Alternative Compliance Pathways:* HUD and USDA encourage the use of codes and standards that exceed the 2021 IECC and ASHRAE 90.1–2019. HUD and USDA are adding that future versions of the IECC and ASHRAE 90.1 codes, including the 2024 IECC, will be deemed to meet the code requirements of this notice subject to a positive efficiency determination by DOE. Additional information has been added to reflect the compliance paths for certain energy efficiency and green building standards, including EPA's Energy Star for New Construction and DOE's Zero Energy Ready Homes (ZERH) standards.

5. *Implementation and Compliance Timelines.* HUD and USDA have adjusted compliance timetables to better enable the industry to adapt to these code requirements, including an extended compliance period for persistent poverty rural areas where capacity to adopt above-code standards may be challenging.

6. *Inflation Reduction Act (IRA) Tax Credits and Rebates.* This notice addresses the availability of tax credits that are now available for builders to support the cost of building to Energy Star for New Construction and ZERH homes. Both Energy Star (Versions 3.2 single family and 1.2 multifamily) and ZERH specify the 2021 IECC as the minimum standard to qualify for these certifications. In addition, the notice references Home Energy and Appliance Rebates that when implemented by the states will provide an additional source of financing for increasing the energy efficiency of new homes. Note, however, that these tax credits and rebates are not factored into the cost benefit analysis in this determination.

II. Public Comments

HUD and USDA published a notice on May 18, 2023, announcing the preliminary determination that the 2021 IECC and ASHRAE 90.1–2019 do not negatively affect the availability or affordability of houses covered by EISA and seeking public comment (88 FR 31773). The public comment period was extended to, and closed on, August 7, 2023. HUD received and reviewed 120 public comments from a wide range of stakeholders, including one state (Montana); the two code bodies represented in this notice (the International Code Council and ASHRAE); multiple national associations representing mortgage lenders, home builders, environmental and energy efficiency advocates;

[19] U.S. Energy Information Administration, *Electricity Data Browser. Average retail price of Electricity, Annual*

[20] The nominal interest rate used here aligns with a 3 percent real interest rate with a 2.24 percent inflation factor.

[21] Economic, Housing and Mortgage Market Outlook—December 2023—Freddie Mac, *https://ww.freddiemac.com/research/wforecast/20231220-us-economy-wexpanded-in-2023.*

consumers; state energy offices; insulation and other building product trade associations; as well as individuals and other interested parties. The majority of the comments expressed support for HUD and USDA's preliminary determination. Of these supportive comments, most expressed support for HUD and USDA's methodology and conclusions and urged HUD and USDA to rapidly adopt the more recent IECC or ASHRAE 90.1 codes that have been promulgated since the publication of the 2009 IECC and ASHRAE 90.1–2007. In addition, several commenters suggested that HUD and USDA allow alternative compliance pathways for these standards through equivalent or higher state standards or one or more green building standards.

Other commenters highlighted the importance of energy standards in reducing greenhouse gas emissions and increasing the climate resilience of HUD and USDA-supported housing. This will help the country meet national climate goals. Many commenters noted that more efficient homes will reduce stress on the power grid during peak times.

Several commenters suggested that the preliminary determination will help to improve the health and comfort of those living in HUD and USDA-assisted housing in addition to saving on healthcare costs. Many commenters stated that the byproducts of burned methane gas contribute to premature mortality and increase the risk of health complications and respiratory diseases, and that updated energy codes will address health inequities.

In addition to the many supportive comments, several commenters expressed concerns or opposition to one or more features of the preliminary determination. The concerns raised were in four primary areas: the need to update the economic factors used in the preliminary determination to reflect current market conditions, including interest rates, inflation, and energy prices; the first cost estimates used by HUD and PNNL and larger concerns regarding the availability test; an ''appraisal gap'' in valuing the additional cost likely to be incurred when adopting these standards; and the proposed timetable for implementing the standards after a final determination is published.

In the preliminary determination, HUD and USDA sought public comment on all aspects of the determination but were especially interested in responses to eight questions posed in the preliminary determination. This section addresses responses to those questions first, then addresses public comments on additional aspects of the determination.

A. Impact of Higher First Costs Associated With Adopting the 2021 IECC on Availability of Covered Housing to Otherwise-Qualified Buyers or Renters

HUD and USDA requested comments on whether the higher first costs associated with adopting the 2021 IECC over the current 2009 IECC standard for USDA- or HUD-assisted housing, or relative to the most recent 2018 IECC, may lower homebuyer options, despite the significant life-cycle cost savings over the life of the mortgage described in this notice. In other words, whether adoption of the 2021 IECC may limit the availability of such housing to otherwise-qualified buyers or renters.

1. General Support for Preliminary Determination

The large majority of comments supported the findings of the preliminary determination. These comments generally agreed with HUD and USDA's methodology in arriving at the determination that the 2021 IECC and ASHRAE 90.1–2019 would, on balance, not negatively impact the affordability and availability of the housing covered by the determination. For the purpose of this notice, ''affordability'' is assumed to be a measure of consumer demand (whether a home built to the updated energy code is affordable to potential homebuyers or renters), while ''availability'' of housing is a measure of builder supply whether builders will make such housing available to consumers at the higher code level, *i.e.,* whether the higher cost per unit will impact whether that unit is likely to be built or not.

Several commenters agreed with the preliminary determination's finding indicating that the higher first costs associated with adopting the 2021 IECC over the current 2009 IECC would not lower homebuyer options or generally limit the availability of housing to otherwise-qualified buyers or renters. Many commenters agreed with the preliminary determination's analysis that the housing stock in question will remain available. One commenter noted that ''[n]othing in the model codes would prevent builders from building homes that receive federal support. The codes are based on widely available, commercial technologies and provide multiple pathways for complying.'' One commenter cited that these energy codes have already been adopted by many states and therefore will not affect availability. Several commenters emphasized that building housing to the 2021 IECC standard is essential and can be done while maintaining or improving affordability for consumers. Two commenters suggested that reduced energy bills would offset any additional first costs incurred from the new code requirements.

HUD–USDA Response: HUD and USDA appreciate the support expressed by these commenters for the analysis included in the preliminary determination. These comments indicate confidence in HUD's and USDA's use of DOE and PNNL cost-benefit analysis of the subject codes. HUD and USDA conducted thorough affordability and availability analyses to assess the impact of adopting the 2021 IECC, ultimately finding that these codes will not negatively impact the affordability or availability of the covered housing.

2. Cumulative Costs Over 2009 IECC

One commenter noted that the significance of the costs is due to the baseline code being the 2009 IECC instead of the multiple, intermediary energy code updates. One commenter stated that HUD and USDA may overestimate the number of homes that will be impacted by the proposed standards as additional states and cities are likely to adopt either of the codes addressed in this notice in the near future (at which point they will come into compliance with the code requirements).

HUD–USDA Response: The commenter's observation that these costs are higher because they are based on the 2009 edition of the IECC rather than a more recent edition is accurate in that these costs represent the cumulative cost of amendments to several editions of the code since the 2009 edition; the 2012, 2015, and 2018 editions, as well as the current 2021 edition.

Adoption by states of the 2021 IECC is an iterative process: while five states have already adopted a code that meets or exceeds the 2021 IECC, others have adopted an energy code more recent than the 2009 IECC, and a significant number of states are actively considering adoption of the 2021 standard or have already done so with amendments.

Where states have adopted more recent editions (*e.g.,* the 2018 edition), the incremental cost to meet the requirements of the 2021 standard is significantly lower, as shown in Table 19 in the final determination. Note, however, that the cumulative costs represented by the 2009–2021 figures also yield significant cumulative savings: 34 percent in improved energy

efficiency over this period, compared to just 8.3 percent over the most recent 2018 edition.

3. Proposals for Financing and Tax Credits

While generally supportive of the preliminary determination's findings, several commenters recommended measures that HUD and USDA could take to mitigate first cost impacts. Commenters suggested HUD and USDA provide programs and advance policy that allow for reduced downpayments, changes in amortization schedules, changes in underwriting standards, downpayment assistance, tax credits, and other forms of financing assistance. One commenter stated that tax credits and incentives further enable compliance and serve to reduce upfront costs to builders. Commenters also recommended that HUD and USDA identify programs and resources, at the state or federal levels, that will address first cost barriers and make information on accessing these resources available for low-income consumers. One commenter recommended HUD and USDA identify alternative solutions to advance energy efficiency measures that avoid the first cost impacts.

HUD–USDA Response: HUD and USDA appreciate these financing proposals, both with possible HUD–USDA financing incentives, as well as action that HUD–USDA could take to maximize the use of new IRA or BIL tax credits, rebates, or other financing that will become available.

Proposals from commenters for ''reduced downpayments or other forms of flexible financing'' including for example, ''changes in amortization schedules,'' while potentially longer-term options for HUD and USDA consideration, are beyond the scope of this notice. However, regarding comments recommending ''tax credits and other funding mechanisms that could reduce the impact of added first costs,'' there are now significant new resources available through the Inflation Reduction Act (IRA) which provide unprecedented financial support for building energy efficient housing. HUD has already taken, and will continue to take, steps to train and educate builders and developers on how these may be used in conjunction with HUD financing.

The IRA makes available significant tax credits for builders that can potentially offset some of the incremental costs associated with building to the 2021 IECC. Though not considered in the preliminary determination's affordability analysis, energy efficient new homes the section 45L tax credit (45L) encourage builders to consider building and certifying to the Energy Star New Homes (up to $2,500 credit) or DOE's Zero Energy Ready Home (up to $5,000 credit) standards. Energy Star Version 3.2 is estimated to yield additional savings of at least 10 percent over the 2021 IECC, while the ZERH standard is designed to exceed the 2021 IECC by at least 15–20 percent depending on whether multifamily or single family. Note that the 2021 IECC is a minimum baseline requirement for both Energy Star Version 3.2, and DOE's ZERH Version 2 standard, currently in effect. Energy Star Version 3.1 currently qualifies (through December 31, 2024) for the IRA tax credit in those states that have not yet adopted the 2021 IECC.[22]

HUD and USDA recognize that qualifying for these tax credits will require builders to build to a higher overall energy efficiency standard than the 2021 IECC, and that while this will entail additional costs, these costs will be offset—in some cases entirely—when taking advantage of available tax credits. While DOE does not have estimates of the added cost of building to the ZERH standard, EPA provides cost estimates of the incremental costs that would typically be required over the 2021 IECC to build to the new Energy Star Version 3.2 standard. Table 4 provides estimates of these additional costs; the additional cost for building to Energy Star for New Homes ranges from $1,010 in Climate Zone 3 (Memphis) to $1,668 in Climate Zones 6, 7, and 8 (Fairbanks) for all-electric homes; and $1,176 to $2,815 for mixed fuel homes (natural gas + electric). Note that for Energy Star Version 3.2, estimated costs of $1,211—$1,463 in Climate Zones 1–3—where a significant share of housing likely to be impacted by this notice are located—are significantly lower than the $2,500 tax credit, thereby providing builders a significant incentive to build to this standard. These estimates demonstrate that building to Energy Star Version 3.2 in these Climate Zones will in fact lower builder outlays by between $1,000-$1,300 while achieving a higher energy efficiency standard than the 2021 IECC.[23]

Table 4. Incremental Cost of Energy Star Version 3.2 (Above 2021 IECC) in Select Cities

Climate Zone	City	All-Electric	Mixed Fuel
1	Miami	$1,211	$1,377
2	Houston	$1,463	$1,629
3	Memphis	$1,010	$1,176
4	Baltimore	$1,635	$1,935
5	Chicago	$1,920	$2,563
6	Burlington	$1,668	$2,815
7	Duluth	$1,668	$2,815
8	Fairbanks	$1,668	$2,815

[22] Energy Star Version 3.1 is modeled to perform at 10 percent above the 2018 IECC but it does not include a thermal backstop provision required under the 2021 IECC standard.

[23] Cost estimates for Energy Star from U.S. EPA, *National Version 3.2 Costs and Savings, https://www.energystar.gov/sites/default/files/asset/document/ENERGY%20STAR%20Version%203.2%20Cost%20%20Savings%20Summary.pdf.*

Both the Energy Star for New Homes and ZERH tax credits are also available for multifamily new construction. A $500 per unit tax credit is available for homes certified to eligible ENERGY STAR Multifamily New Construction (MFNC) program requirements, with a larger tax credit ($2,500 per unit) available when prevailing wage requirements are met.[24] For ZERH homes, the tax credit is $1,000 per dwelling unit, unless the project meets prevailing wage requirements, in which case the 45L tax credit is $5,000 per dwelling unit.[25]

In addition to these tax credits for new construction, the IRA expanded the Section 179(d) commercial building tax credits for multifamily buildings. The new law increased the maximum deduction from $1.88 to $5 per square foot and cannot exceed the cost of the improvement. However, the taxpayer must meet a prevailing wage and apprenticeship requirement.[26]

In addition to the tax credits and deductions available through the IRA, there is another potential source of IRA funds that states may make available for new construction: Home Energy and Appliance Rebates that provide $4.5 billion in rebates for certain energy efficiency and electrification measures such as heat pumps, upgraded electrical service, or solar panels that may be leveraged to lower the first cost of construction for these measures. These funds will be administered by the states and are expected to become available in most states in 2024 or 2025.[27] Home Electrification and Appliance Rebates will also be available to (1) low- or moderate-income households; (2) individuals or entities that own a multifamily building with low- or moderate-income households comprising at least 50 percent of the residents; and (3) governmental, commercial, or nonprofit entities that are carrying out projects for low- or moderate-income households or multifamily building owners.[28] Rebates can be used to offset the cost of the following items: ENERGY STAR-certified electric heat pump water heater; ENERGY STAR-certified electric heat pump for space heating and cooling; ENERGY STAR-certified electric heat pump clothes dryer; ENERGY STAR-certified electric stove, cooktop, range, or oven (note: Energy Star-certified ovens are pending); electric load service center (*i.e.,* electrical panel); electric wiring; insulation, air sealing, and mechanical ventilation. For low-moderate income households, the rebates may be used for as much as 100 percent of the cost of installation.

In addition to these multiple new sources of funding for energy efficiency measures, there are also tax credits and financing sources for the addition of renewables through the IRA. Builders may be able to take advantage of certain EPA Greenhouse Gas Reduction Fund programs, especially the Solar for All initiative. Builders may also be able to utilize the Investment Tax Credit under Section 48 of the Internal Revenue Code focusing on investment in on-site renewable energy production through wind and solar, which has increased incentives for low-income communities, Tribal entities, and specifically for residential buildings.[29]

When using solar energy for housing, creating an energy efficient home is a critical first step towards optimizing energy performance. Energy efficiency in homes has a point at which better energy performance requires the addition of a source of renewable energy. As shown in 2021 IECC Zero Energy Appendix, (Table 5 below), the maximum ERI score of 43–47 for the 2021 IECC, provides a reasonable backstop for energy efficiency and adding renewable energy. Since minimum ERI scores or equivalent HERS ratings are required for Energy Star for Homes, ZERH, and Passive House, to the 2021 IECC provides a sound baseline for home energy efficiency performance before the addition of renewable energy sources to get to net zero energy.

Table 5. Maximum Energy Rating Index – 2021 IECC Appendix RC

Climate Zone	Energy Rating Index	Energy Rating Index
1	43	0
2	45	0
3	47	0
4	47	0
5	47	0
6	46	0
7	46	0
8	46	0

HUD and USDA will work with DOE and states to maximize participation by HUD and USDA stakeholders in these programs. Steps that HUD has already taken to increase use of both the tax credits and rebates now available to support builders wishing to build more energy efficient housing include the new Climate Funding Navigator, which provides a user-friendly portal to all funding opportunities in the IRA and the Bipartisan Infrastructure Law (BIL),

[24] EPA. *https://www.energystar.gov/about/federal-tax-credits/ss-45l-tax-credits-home-builders.*

[25] DOE, 179D Commercial Buildings Energy-Efficiency Tax Deduction Buildings, *https://www.energy.gov/eere/buildings/179d-commercial-buildings-energy-efficiency-tax-deduction.*

[26] A separate $4 billion for HOMES rebates is for existing homes only, and does not cover new construction.

[27] DOE, Home Energy Rebates: Frequently Asked Questions. *https://www.energy.gov/scep/home-energy-rebates-frequently-asked-questions.*

[28] The section 48 investment tax credit offers an up to 30 percentage point credit (if prevailing wage and apprenticeship requirements are met) with an additional 10 percentage point credit for facilities in low-income and Tribal communities and additional 20 percentage point tax credit available for facilities that serve federally-subsidized housing or provide economic benefits to low-income households (information available at *https://www.whitehouse.gov/cleanenergy/clean-energy-updates/2023/08/10/treasury-issues-final-rules-and-procedural-guidance-to-drive-clean-energy-investments-in-low-income-communities-across-the-country/*).

as well as other programs administered by HUD and other Federal agencies.[30]

4. Proposals for Technical Assistance

One commenter recommended protecting homebuyers who may lose eligibility due to the proposed standards by providing technical assistance for state officials, builders, construction workers, and others; addressing differential rural impacts; making adjustments as needed to account for ASHRAE 90.1 standards; and expanding strong energy efficiency requirements to additional assisted housing programs.

HUD–USDA Response: HUD and USDA appreciate the range of comments received that recommended training, technical assistance (TA), and information for builders and developers impacted by this determination. HUD and USDA intend to provide TA to support the implementation of the 2021 IECC and ASHRAE 90.1–2019. The agencies recognize that there may be an ''information gap'' regarding the latest codes in places where prior codes have been adopted by states or local jurisdictions, and that in some locations there may be a learning curve for builders to become familiar with the requirements of the latest editions of the codes. HUD has allocated FY 2022 Community Compass TA funds for this purpose and expects to implement an extensive TA and training effort to ensure that stakeholders are both aware of the new requirements and knowledgeable about the specific updates that are included in the new codes.[31] This may include both webcasts as well as printed and/or online resources that builders, developers, and appraisers can use to familiarize themselves with the new code requirements. Additional on-call TA that responds to builder, consumer, lender, or developer questions may also be available. The specific topics that will be covered have not been identified at this point; however, the agencies will widely circulate any resources or webinars developed in support of the implementation of these new standards. HUD will also work with trade associations to promote these resources to their members, through targeted trainings or at regular association meetings, conferences, or training events. In addition, HUD and USDA will work with DOE and its state and local grantees to leverage $1.2 billion in IRA and BIL energy code TA funds: $330 million to adopt the latest building energy codes, $670 million to adopt building energy codes that meet or exceed the zero energy provisions in the 2021 IECC or other codes and standards with equivalent or greater energy savings, and $225 million to support code adoption and training.

5. Appraisal Gap in Valuing Energy Efficiency Improvements in Home Appraisals

Four commenters raised concerns over challenges with the appraisal process that could impact the ability of FHA and USDA home buyers to afford the added cost of the IECC code. The commenters noted that the analysis included in the preliminary determination assumed construction and production costs would be passed on to homebuyers. Multiple commenters identified the issue of an appraisal gap for energy-efficient homes. The gap arises from the limited ability of the traditional appraisal process to properly account for energy efficiency measures, such as those required by the 2021 IECC, into the valuation of the property. They pointed out that a home may appraise for a value that is less than the cost of materials and labor and that energy efficiency enhancements are often not accounted for in the appraisal. Several commenters stated that this results in development costs exceeding home values, making appraisal practices a major obstacle. One commenter suggested that HUD and USDA establish effective energy-efficient mortgage programs in response.

HUD–USDA Response: The appraisal gap issue discussed by the commenters is larger than just an energy codes issue, as it not only addresses broader issues of how the market values energy efficiency but also how the market values homes generally in underserved markets. HUD and USDA agree that the valuation of energy efficiency in appraisals could act (depending on location) as a market barrier to the adoption of energy-efficient codes. HUD and USDA reviewed these arguments in a section on ''market barriers'' in the Regulatory Impact Analysis (RIA) and provided empirical evidence in a section on capitalization of energy efficiency. From a broader regulatory perspective, there are at least three separate issues that could impact appraisals: (1) cost pass-through rates, which depend on the flexibility of buyers and sellers; (2) imperfect valuation by buyers and sellers due to limited information and thin markets; and (3) the role of experts, including appraisers, in valuing energy-efficient improvements.

- *Pass-through rate:* HUD assumed in much of the analysis that the pass-through rate of costs from builders to buyers was equal to one, *i.e.,* builders pass on the full cost of construction to the buyer. However, another acceptable scenario would have been to assume a pass-through rate less than one, where the buyer will only bear a portion of the costs. HUD mentioned in the RIA that the pass-through rate would vary with the price elasticity of demand and supply.
- *Imperfect information:* HUD explored the possibility that energy efficiency may not be perfectly capitalized in the value of a home. If the value of energy efficiency is not transparent to a prospective buyer, then insufficient capitalization reduces the incentive to build energy-efficient housing. In addition to imperfect information, thin markets (few buyers and sellers) could lead to an undervaluation of less common goods (such as above-average energy efficiency).
- *Role of the appraiser:* A well-informed appraiser is expected to perform valuation services competently and assess the market value of an energy-efficient building relative to other buildings. Increasing education and awareness of energy-efficient improvements for appraisals will contribute to stronger valuations as market and cost data become more available.

HUD and USDA therefore understand that lenders, buyers, and builders of energy efficient housing may be impacted in the short-term, particularly in markets where comparable sales are not yet available, and that intervention can be helpful in certain areas to raise awareness of the value of these improvements. One study finds that approximately 1-in-10 homes are undervalued, while thirty percent are appraised at their sales price.[32]

A study of home appraisals conducted for DOE by the Building Industry Research Alliance identified several barriers to valuing energy efficiency improvements in residential appraisals.[33] These included: (1) lack of comparable sales, surveys of property performance and return expectations in most markets (where limited data is available, appraisers may resort to ''assessing arbitrary values'' for energy efficiency improvements); (2) variations

[30] *https://www.hudexchange.info/programs/build-for-the-future/funding-navigator/.*

[31] *https://www.hud.gov/program_offices/comm_planning/cpdta.*

[32] Calem, Paul, et al, ''Appraising home purchase appraisals.'' Real Estate Economics 49.S1 (2021): 134–168,

[33] Victoria Doyle, Abhay Barghava, *The Role of Appraisals in Energy Efficiency Financing,* Building Industry Research Alliance for the Department of Energy, May 2012.

in occupancy behavior, plug loads and/or weather conditions that could impact the actual energy consumption of a household relative to modeled or estimated energy use; (3) knowledge gaps in the lending and housing industries, both on the part of appraisers and underwriters; (4) lack of energy efficiency appraisal training and education (all states require education, experience and licensing for appraisers but energy efficiency requires a different kind of knowledge, and appraiser licensing does not recognize this specialty as distinct); and (5) ''resistance to change'' by the appraisal industry with the current appraisal methods developed in the 1940s that provide market valuations for aesthetic and structural improvements (the proverbial ''granite countertop'') but do not necessarily recognize energy efficiency as a factor in homeownership cost or property value.

These are inherent limitations in the appraisal industry's current approach to valuing energy efficiency, but there are also important developments that are addressing these barriers. These include the introduction of sustainable building science education and certifications such as the Appraisal Institute's Sustainable Buildings Professional Development Programs that include Introduction to Green Buildings, Case Studies in Appraising Residential Green Buildings, and Case Studies in Appraising Commercial Green Buildings. The National Association of Realtors has expanded its curriculum for the General Accredited Appraiser program to include an introduction to energy-efficient homes, and there is also now a ''Green Designation'' for real estate practitioners including Realtors.

At the same time, to the extent that an appraisal overlooks or does not appropriately value one or more features or improvements of a home, buyers can dispute an appraisal that they feel did not consider all relevant information, so an incentive exists for lenders to engage appraisers who have sufficient competency to appraise energy efficient properties. Sellers in turn have an incentive to provide information that would generate buyer interest in the added improvements.

Information prepared jointly by the Appraisal Institute, the Building Codes Assistance Project, and National Association of Home Builders provides practical solutions, such as how to communicate energy efficiency and where to find qualified appraisers.[34] An appraiser who lacks experience in valuing an energy-efficient building may find that they are passed over for more qualified appraisers with more training. An analysis of energy-efficient buildings in the American Economic Review indicated that the diffusion of energy-efficient technology is enhanced by educating building professionals.[35]

In response to the comments received, HUD reviewed the FHA-insured portfolio from fiscal year 2020 through 2023 to ascertain the extent to which the appraised value of new homes is below, equal to, or above the sales price of the home. One key data point is that, for many FHA borrowers, home appraisal valuations exceed sales prices: 87 percent of 450,000 FHA-insured new home purchases over the past four years had appraisals that exceeded the sales price, and, for 32 percent of new home purchases, appraised values exceeded the sales price by $5,000 or more. The above sales price appraisals indicate that for a significant share of FHA borrowers, even first-time home buyers, there may be a sufficient cushion in the appraisal valuation to allow for some or all of the added cost of an energy-efficient new home, ranging from $2,945 to $7,115 depending on climate zone. While the sales price-home valuation differential shown in Table 6 does not specifically address energy efficiency valuations, the $5,000 or more above-sales price appraised value is important because this buffer is sufficient to cover all or most of the additional cost of the energy improvements, despite any superadequacy or other market failure to recognize the value of the energy improvements.

Table 6. Appraised Values Relative to Sales Price – FHA Insured New Homes 2020-23

	No. of Units				
	FY 2020	**FY 2021**	**FY 2022**	**FY 2023**	**All Yrs**
Appraised Value < Sales Price	2,692	5,614	4,415	2,235	14,956
Appraised Value = Sales Price	13,711	12,341	8,304	9,776	44,132
Appraised Value > Sales Price	102,619	112,669	88,921	87,383	391,592
Total	119,022	130,624	101,640	99,394	450,680
% Appraised Value < or = Sales Price	14%	14%	13%	12%	13%
% Appraised Value > Sales Price	86%	86%	87%	88%	87%
% Appraised Value > $5k above sales Price	21%	27%	42%	41%	32%

Another important development that can support the recognition of energy efficiency in home appraisals has been the growth of regional Multiple Listing Service (MLS) databases that include energy efficiency and other sustainable measures in their listings. The National Association of Realtors (NAR) published its Green MLS Toolkit as an educational resource for homebuyers, homeowners, realtors, and appraisers to use to develop a better understanding of energy-efficient homes.[36]

The importance of this initiative cannot be understated. A key concern from the housing, financing and appraisal industries has been the lack of

[34] Appraisal Institute, New Appraisal Guidance Addresses Green Housing, 2015, *https://nationalmortgageprofessional.com/news/56670/new-appraisal-guidance-addresses-green-housing* See also *https://www.appraisalinstitute.org/education/education-resources/green-resources.*

[35] Kok, Nils, Marquise McGraw, and John M. Quigley. ''The diffusion of energy efficiency in building.'' American Economic Review 101.3 (2011): 77–82.

[36] National Association of Realtors, Green MLS Implementation Guide, https://green.realtor/sites/files/2019-02/2014%20NAR%20Green%20MLS%20Implementation%20Guide.pdf.

data or access to supporting documentation for valuing energy efficiency improvements. A Green MLS mediates this concern, documenting both measures that are visible and apparent, as well as high-impact energy efficiency measures that are less visible, such as wall insulation and/or low-e windows. The development of the Green MLS Toolkit is ''pivotal for the proper valuation of efficiency. . .For appraisers, a Green MLS supports an apples-to-apples comparison for energy efficient features; without a Green MLS, the appraiser may not have sufficient information and data to support an assessment of energy efficiency improvements.'' [37]

Another significant development has been the development of the Residential Energy Efficiency and Green Addendum for use with the Uniform Residential Appraisal Report, one of the most commonly used forms for completing a home appraisal. It provides standardized reporting and analysis for single family home valuations. The 3-page form provides appraisers the opportunity to recognize energy improvements as part of a home evaluation assessment, including appliance efficiency or insulation levels, whether the home achieves an energy efficiency certification such as Energy Star or other green building standards, and other salient characteristics of the home. By enabling appraisers to collect and document the additional information needed to form an Opinion of Value on a high-performance home, appraisers will be better equipped to identify recent comparable sales. If the home has a HERS rating, RESNET or other third-party energy raters can verify and pre-populate the Addendum for the appraiser. This removes the responsibility of the appraiser to attempt to provide an energy assessment of home performance as it relates to other homes when they lack the training and certifications to do energy assessments.

There is also growing evidence that new energy-efficient homes are in demand and valued at higher prices than other homes. A new study conducted by Freddie Mac reported on 70,000 homes rated under RESNET's HERS between 2013 and 2017.[38] The report's goal was to ''understand the value and the loan performance associated with energy-efficient homes to support the consideration of energy efficiency in mortgage underwriting practices.'' The findings include analysis of property value, loan performance, default risk, borrower characteristics, and demographics. The report found that HERS rated homes sold, on average, 2.7 percent more than comparable unrated homes. In addition, homes that received lower (*i.e.,* more energy efficient) HERS Index Scores sold for 3–5 percent more than homes with higher HERS Index Scores. The study also looked at loan performance, with several important findings: the default risk of energy-rated homes is not on average different from un-rated homes—and loans in a high debt-to income (DTI) range (45 percent and above) that have energy ratings ''appear to have a lower delinquency rate than unrated homes.'' In rural areas, there are reports of energy efficient and resilient homes commanding higher sales prices: two homes of two bedrooms and one bath each, built by Habitat for Humanity to high performance standards of Phius and ZERH as well as to the hurricane standard of FORTIFIED in Opelika, Alabama appraised at the equivalent amount of the standard Habitat for Humanity home of three bedrooms and two bathrooms.[39]

The cost and income approaches to valuation may help assign a contributory value to energy efficiency features of a home. The FHA Single Family Housing Policy Handbook 4000.1 provides for three types of home appraisal approaches applied to one-to-four-residential unit properties: the sales comparison approach, the cost approach, and the income approach.[40] However, the Handbook states that ''(t)he Appraiser must obtain credible and verifiable data to support the application of the three approaches to value. The Appraiser must perform a thorough analysis of the characteristics of the market, including the supply of properties that would compete with the subject and the corresponding demand. The Appraiser must perform a highest and best use of the Property, using all four tests and report the results of that analysis.''

HUD and USDA are considering taking several steps to address the appraisal gap issue:

First, FHA will provide outreach and training to market participants, including lenders and appraisers detailing the impact of this Final Determination and promoting awareness and education about energy efficient improvements. This will include training for both underwriters and appraisers on how the cost or income approaches can be used as part of appraisals in certain markets.

Second, HUD will work with USDA to provide a package of training through HUD's Community Compass Technical Assistance program aimed at educating appraisers and lenders about acceptable methods and techniques for accurately appraising energy efficient homes financed with an FHA-insured mortgage, including the proper use of the cost and income approaches. HUD has allocated FY22 funding to support this technical assistance.

Third, FHA's four Homeownership Centers (HOCs), which already provide training for appraisers and lenders, will include targeted training for the roster of FHA-approved appraisers, with an emphasis on places with a high volume of FHA-insured new home sales in the south and southwest.

Ultimately, the extent and impact of the appraisal gap for energy efficiency measures is a concern but does not change HUD and USDA's overall determination. While the appraisal gap indicates a failure in the market to keep pace with innovative energy efficiency measures, the gap does not exist in all markets, and its impacts can be alleviated by interventions such as increased market awareness, appraiser education, and resources such as the Green MLS for greater transparency and the Green Addendum to appraisal reports, as well as by the higher valuation of new construction that can cover some or all of the costs of the energy efficient improvements. The resources outlined in this notice, along with HUD and USDA efforts outlined above, will aid in closing the gap for FHA borrowers and should serve as further motivation to overcome market barriers that impede efficiency.

6. Delegation of Legislative Power

Two commenters stated that the Cranston Gonzalez Act is either an improper delegation of legislative power to a private entity, the International Code Council and ASHRAE which promulgate the IECC and ASHRAE–90.1 respectively, or an improper divestment of the executive power to a private entity, and that HUD and USDA should rescind the preliminary determination until Congress passes legislation that affirms what standards should apply.

HUD–USDA Response: In issuing this determination, HUD and USDA are following the statutory directive of 42 U.S.C. 12709(d). The Cranston Gonzalez

[37] Doyle, Victoria and Bhargava, Abhay, The Role of Appraisals in Energy Efficiency Financing, Building Industry Research Alliance, National Renewable Energy Laboratory.

[38] Argento, Robert et al, Energy Efficiency: Value Added to Properties and Loan Properties, *https://sf.freddiemac.com/docs/pdf/fact-sheet/energy_efficiency_white_paper.pdf.*

[39] Rural Studio, *https://ruralstudio.org/auburn-opelika-habitat-homes/.*

[40] *https://www.hud.gov/program_offices/administration/hudclips/handbooks/hsgh.*

National Affordable Housing Act of 1990 (Cranston-Gonzalez), as amended by the Energy Independence and Security Act of 2007 (EISA) (Pub. L. 110–140), requires HUD and USDA to establish energy efficiency standards for housing specified in 42 U.S.C. 12709(a)(1).

The original efficiency standards were required to meet or exceed the requirements of the 2006 International Energy Conservation Code (2006 IECC) and the American Society of Heating, Refrigerating, and Air-Conditioning Engineers Standard 90.1–2004 (ASHRAE 90.1–2004). (42 U.S.C. 12709(a)(2)). If the requirements of the 2006 IECC or the ASHRAE 90.1–2004 are revised, HUD and USDA must, within a year, amend their standards to meet or exceed the revised requirements of the 2006 IECC or the ASHRAE 90.1–2004, or issue a determination that compliance with the revised standards would ''not result in a significant increase in energy efficiency or would not be technologically feasible or economically justified'' (42 U.S.C. 12709(c)).

If HUD and USDA have not adopted the revised standards or made the determination under 42 U.S.C. 12709(c), then all new construction and rehabilitation of specified housing must meet the requirements of the revised IECC and ASHRAE 90.1 standards if HUD and USDA determine that the revised codes do not negatively affect the availability or affordability of certain housing stock specified in 42 U.S.C. 12709(d)(1) and DOE determines that the revised codes would improve energy efficiency. 42 U.S.C. 12709(d)). The present HUD/USDA determination fulfills HUD and USDA's statutory directive to determine whether the updated standards negatively affect availability and affordability. The commenter's stated interpretation of the Act does not dismiss HUD and USDA's statutory requirement to make this determination.

7. Lower Availability of Affordable Homes for Home Buyers

Several commenters shared concerns that the higher first or incremental costs associated with adopting the 2021 IECC over the current 2009 IECC would lower homebuyer options and/or limit the availability of housing to otherwise-qualified buyers or renters. Two commenters suggested that these high standards will result in fewer FHA and USDA constructed properties and limit the supply of housing in a way that contradicts HUD's mission.

HUD–USDA Response. The agencies appreciate the concerns raised by the commenters but do not agree that the higher standards will result in fewer FHA- and USDA-financed properties. HUD and USDA conducted thorough and extensive analyses on the impact of the 2021 IECC on affordability and availability, using established cost and savings methodologies that have been developed by DOE for multiple code cycles. The agencies determined that the codes will not negatively impact the affordability or availability of the covered housing. HUD and USDA recognize that, as of December 2023, only five states have adopted a code that meets or exceeds the 2021 IECC. Nevertheless, in those states, affordability and availability will, by default, not be impacted by HUD and USDA's adoption of the 2021 IECC because no additional requirements would be put in place above those already adopted by the state. In addition, while the number of states that have already adopted the codes is currently limited, the number is growing rapidly, with more than 20 states actively considering adoption of the 2021 IECC. State adoption of ASHRAE 90.1–2019 is more advanced than the IECC: ten states and the District of Columbia have adopted a code that meets or exceeds this standard, and a similar number of states (twenty or more) are currently considering its adoption. Additionally, many local jurisdictions have gone beyond the statewide residential or commercial code by adopting the 2021 IECC or ASHRAE 90.1–2019.[41]

Nevertheless, the agencies recognize that it will be necessary for builders who are accustomed to the requirements of the 2009 IECC and ASHRAE 90.1–2007—the current HUD and USDA standards—to familiarize themselves with the verification methods incorporated into the subsequent versions of the code (including blower door and duct testing). HUD and USDA will provide technical assistance and training resources to aid in the implementation of these new standards, as described in more detail in section A.2. above. These resources will address elements of the verification requirements for the 2021 IECC that could be unfamiliar to some builders. As these builders become familiar with these requirements and construction practices, the energy improvements required by the more current codes will strengthen the quality of the built product and will benefit consumers in the long term as a result of high-quality construction.

8. Affordability and Availability Impacts in Rural Communities

Three commenters expressed concern regarding the specific impact that the proposed code requirements would have on rural areas. One commenter suggested that challenges related to adoption or implementation of the 2021 IECC and ASHRAE 90.1–2019 standards would be more significant for rural areas ''because materials or workers may need to be transported from elsewhere, [and] [r]ural residents may not have easy access to specialized materials or specific worker skills when energy-efficient construction requires them. That is particularly likely in remote rural areas.'' One commenter, from the Umatilla Indian Reservation, stated that the reservation's rural location makes it particularly difficult to find contractors and access green products.

Another commenter, a trade association of rural housing organizations, also stated that rural areas would have a higher cost differential for a mortgage between the 2009 IECC and 2021 IECC than the $5,500 increase indicated in the preliminary determination due to construction costs that might be higher in rural areas. Factors that contribute to this higher cost include difficulty sourcing materials and limited access to an appropriately trained workforce for energy efficient construction projects. In addition, the commenter noted that the cost to the homeowner may be higher under USDA's Section 502 direct loan program, since the PNNL cash flow projections assumed a downpayment of 10–12 percent whereas Section 502 typically requires no downpayment and will therefore yield a higher mortgage amount.

Two commenters suggested that few contractors have the knowledge and resources to meet the proposed standards, and that it will be difficult to find a contractor to build to the proposed standards in states that have not or will not adopt the 2021 IECC.

One commenter pointed to specific challenges likely to be encountered by non-profit affordable housing developers: they suggested that affordable nonprofit housing developers will have trouble producing new rental and homeownership housing units in Appalachian communities with the proposed standards due to the ''increased costs to construct homes, the unique nature of [these] housing markets, and the difficulty in implementing the standard.'' As a result, the commenter argued that there

[41] Department of Energy, Municipal Building Codes and Ordinances. Updated December 2023. *https://www.energycodes.gov/infographics#Municipal.*

will be very few (if any) affordable new homes on the market that can be acquired by low to moderate income homebuyers or developers. The commenter urged HUD and USDA to consider the ability of their nonprofit partners to ''produce the same quantity of housing after increased costs in without any increase in funding support.''

HUD–USDA Response: The concerns noted by the commenters fall into three broad areas: the increased costs to build homes to the proposed standard in rural areas; the ''nature of rural economies and housing markets;'' and operational, technical, and other difficulties in implementing the standard.

In response to the comment about the potential impact of HUD and USDA energy code adoption on housing on Indian reservations, with the exception of the Section 248 program, which has a small loan volume (only eight outstanding loans, no new endorsements since 2008), HUD and USDA note that Indian housing programs are excluded from this notice because they are not covered under the requirements of the governing statute: they neither constitute ''assisted housing'' nor are authorized under the National Housing Act (12 U.S.C. 1701 *et seq.*) as specified in EISA. For example, the Section 184 guaranteed loan program is authorized under Section 184 of the Housing and Community Development Act of 1992 (42 U.S.C. 1715z–13a).

Increased Costs in Rural Areas

HUD and USDA agree that there are increased first costs associated with building to the higher energy standards outlined in the preliminary determination but conclude that the initial investment will benefit both Appalachian and all rural communities across the U.S. through energy cost savings to residents and as well as health, comfort, and durability of higher-performance housing. Rural communities will especially benefit from more energy efficient homes in that rural households are typically overburdened with higher energy costs as a percentage of household income. Nationally, the median rural household energy burden is 4.4 percent, almost one-third higher than the national rate of 3.3 percent and about 42 percent above the median metropolitan energy burden of 3.1 percent.[42] One commenter cited a Virginia Tech report on Appalachian housing costs that concluded that ''utility costs contribute to housing costs substantially'' in Eastern Kentucky, Southern West Virginia and the western section of Appalachian Alabama, where both owners and renters saw the highest costs relative to metropolitan areas.[43] For some low- or very-low income households, the energy bill may be greater than the cost of the mortgage. Energy bills fluctuate and are only billed post-usage, often leading to unexpected increases in these bills, which can create serious financial stresses on lower income households.

At the same time there are good examples in rural America of how better performing homes can alleviate the impact of higher energy costs experienced by lower income households. One such example is a USDA Rural Community Development Initiative (RCDI) grantee, Mountain T.O.P., a faith-based organization in Grundy County, Tennessee. Based in one of Appalachia's persistent poverty counties where a significant share of the housing stock is dilapidated, the organization worked closely with the Rural Studio Front Porch Initiative to build Mountain T.O.P.'s capacity to replace homes with new, high-performance homes to address the high energy burden in their community.

Despite the long-term affordability benefits of building high performance, energy efficient homes, rural areas may face first cost (and other) constraints in adopting construction standards or codes above prevailing local codes. HUD and USDA do not, however, agree that there is a broad and consistent impact for all rural areas across the nation. Geographic distance may play a role in creating challenges for construction projects in rural areas when there are not locally available skilled workers, but this is true of all building construction, regardless of the specific codes that are in place.

While both HUD and USDA programs serve rural areas, USDA is especially focused on rural housing through its Rural Housing Service programs. USDA's Single Family Direct Loan program is the only direct mortgage product offered by the federal government; USDA can and does work intensively through its underwriting process to assist rural, low-income borrowers to become and to remain homeowners. This program offers 100 percent financing, zero downpayment and the ability to amortize beyond 30 years in addition to having an interest rate that is below market. It is also able to offer additional subsidies based on need. Borrowers of this program, of all the single family borrowers impacted by this notice, are likely to benefit the most from the proposed adoption of the 2021 IECC, and the addition of homes built to higher performance quality will generate long-term benefits to rural locations where housing quality has lagged behind.

One commenter raised a concern that Direct Loan borrowers would see higher costs since downpayment requirements can be as low as zero, and to the extent that the additional costs would need to be financed, this would make these loans less affordable. USDA believes that this concern is misplaced since, by eliminating the downpayment requirement, the Section 502 loan in fact removes a significant potential barrier to financing the added first costs of the IECC, and, given the very low interest rates associated with this product, this seems like an optimal financing vehicle available to rural borrowers for energy efficient housing.

The commenter also raised concerns regarding appraisals, and the ''appraisal gap'' in rural areas. These concerns are addressed in the larger appraisal discussion in section A.3 of this notice. The limitations of the current appraisal process are broadly applicable, but the gap may be higher in rural areas due to fewer available sales comparisons in these areas, as well as fewer appraisers qualified to assess energy efficient or other green features of a home, *e.g.,* solar. The agencies acknowledge that the current appraisal system in the U.S. for single family homes is not generally set up to fully account for energy efficiency or renewable energy but have proposed potential actions that can help close the gap for FHA and USDA borrowers, as discussed in-depth in section A.3 above.

Technical Capacity Issues in Rural Areas

Other difficulties besides the added cost noted by commenters included limited technical capacity and the need for workforce training in rural areas. HUD and USDA believe that contractors have or are capable of obtaining the knowledge and resources to meet the proposed standards before commencement of the applicable compliance period. The commenter does not provide evidence as to the basis of this proposition. As discussed elsewhere in response to similar comments, the agencies recognize that there will be places where builders may

[42] Lauren Ross et al, the High Cost of Energy in Rural America, ACEEE, 2018. *https://www.aceee.org/press/2018/07/rural-households-spend-much-more.*

[43] Virginia Center for Housing Research at Virginia Tech, *Housing Needs and Trends in Central Appalachia and Appalachian Alabama,* 2018.

not be familiar with energy code requirements, but these are likely to be more the exception than the rule, especially with regard to larger home builders who build a significant portion of homes, and unequivocally with regard to multifamily housing.

HUD and USDA agree that remote rural areas may not always have the proper skilled professionals to execute certain types of construction and that training may be needed. Training and support are planned by the two agencies to assist rural America in achieving homeowner financial sustainability through building to the most current energy codes. Trainings on standards that exceed energy codes (Energy Star New Homes, Zero Energy Ready Homes) are also available from EPA and DOE, while additional tax credits for affordable multifamily housing as well as electrification rebates are also becoming available to build energy efficient housing, discussed in more detail in section A.3 above.

HUD and USDA also agree that building codes that require on-site inspection are more challenging in rural areas than where building sites are located in close proximity to HERS rater, building inspector or verifier, but given that HUD and USDA already require the 2009 IECC these issues will not materially change with the adoption of an updated code. The increase in energy codes from the 2009 IECC to the 2021 edition will indeed require learning and implementation of new skills and project delivery methods, but these are relatively modest and likely limited to energy modeling, blower door testing, and duct leak testing. Note that these testing methods have been in place at least since the 2012 edition of the IECC.

As discussed in response to other comments in this notice, HUD will partner with USDA in implementing a training and technical assistance program to facilitate implementation of the energy codes requirements, including trainings on these blower door and duct testing skills. Additionally, USDA is exploring the feasibility of and potential for remote-hybrid inspections with RESNET and others, in which third-party verification may be completed remotely with the on-site assistance of individuals who have received minimum training to perform testing tasks such as blower door testing, duct leakage testing and infrared camera techniques but who may not yet be fully certified home raters.[44]

Finally, in recognition of the specific capacity constraints identified in Appalachia and other high needs rural areas to adopting these standards, HUD and USDA will provide a longer lead time for adoption of the IECC and ASHRAE 90.1 standards in these areas, as outlined in the Implementation section of the Final Determination, section VI. An additional year of compliance will be provided in persistent poverty rural areas, as defined by USDA's Economic Research Service, including persistent poverty census tracts located in rural (non-metro) counties.[45]

9. Limited Cost Effectiveness of Individual Code Measures

One commenter suggested that HUD and USDA should evaluate the cost effectiveness of individual measures in the 2021 IECC and amend those measures that do not provide value to the consumer. Relying on the overall cost-effectiveness ''masks the extremely low-cost effectiveness of some of the individual measures by averaging the results with the measures that are more cost effective.'' The commenter identified two specific measures as not meeting any reasonable cost effectiveness test: ceiling insulation requirements of R–60 in Climate Zones 3–8 and R–49 in Climate Zones 1–2; and wall insulation requirements of R–20+5 or R–13+10 in Climate Zones 4–5. The commenter indicated that on their own these measures do not meet ''any reasonable cost-effectiveness test'' and provided data showing paybacks of 63–150 years on these items.

The commenter noted that these two problematic measures were considered by the 2024 IECC consensus committee. These were realigned to their 2018 levels in the draft 2024 IECC or were provided an opt-out provision in exchange for an additional three credits in Section R408 (Additional Efficiency Requirements). The commenter recommended that in lieu of evaluating all individual measures in the 2021 IECC, the agencies should allow similar amendments to the 2021 IECC as has been approved for the 2024 IECC. Another commenter suggested that HUD and USDA review the determinations made on both codes and identify provisions that do not increase energy efficiency and exclude them as requirements.

HUD–USDA Response. The statutory requirement (Section 109(d) of the Cranston Gonzalez Act of 1990) for this notice requires HUD and USDA to make a determination on the latest ASHRAE 90.1 or IECC code editions as published. It does not allow for selecting only the most cost-effective measures in the code. The overall efficiency of the code relies on a package of measures considered and adopted by consensus during the code development process, with the more cost-effective measures essentially supporting less cost-effective measures. Therefore, HUD and USDA do not have the ability to pick and choose between specific amendments to the code. In addition, the conventional practice by DOE has been to consider the combined costs and savings for the entire code, rather than for each amendment separately. HUD and USDA believe that it is sound policy to align with DOE practice and cost-benefit methodologies for the purpose of this notice.

Even if allowed under the statutory constraints of this notice, unpacking the code to consider each amendment individually contradicts standard practice when implementing energy efficiency measures. Energy codes typically consider a bundle of measures that enable longer-payback measures to balance out shorter-term measures and enable the savings of the shorter payback items to pay for those that on their own may be less cost-effective. For example, codes combine shorter payback lower-cost lighting measures with more efficient windows that typically have longer paybacks when installed in isolation from other measures. In addition, the agencies believe that the combination of mandatory and optional measures as well as two performance paths provide builders with a great deal of flexibility in complying with the 2021 IECC.

HUD and USDA are aware that the two insulation amendments to the 2021 IECC cited by the commenter have been incorporated in the draft 2024 IECC, which is currently scheduled for publication in early 2024. As noted above, these amendments would roll back ceiling and wall insulation requirements for certain climate zones to the 2018 level, or provide for an opt-out, in exchange for an additional three energy efficiency credits. While HUD and USDA are not able to accept

[44] Third-party verification is an increasingly common mechanism for enforcing building codes in localities with a limited number of code officials capable of doing so. A third-party code verification program utilizes private sector organizations to verify energy code compliance by providing plan review and analysis, performance testing, and field inspections. More information on third-party verification is available at *https://www.eepartnership.org/wp-content/uploads/2015/07/Third-Party-Verification_Best-Practices_10-15-14-final.pdf.*

[45] USDA, Economic Research Service, Poverty Area Measures, Descriptions and Maps, *https://www.ers.usda.gov/webdocs/charts/105111/persistentcountytracts.png?v=7741.2.* See also USDA ERS definition of rural (non-metro) counties at *https://www.ers.usda.gov/topics/rural-economy-population/rural-classifications/.*

individual amendments such as this one to the 2021 IECC, if, after publication of the 2024 IECC, DOE determines that the revised code is more energy efficient than the 2021 IECC, housing built to comply with the 2024 IECC in its entirety will meet the requirements of the 2021 IECC.

HUD and USDA note that PNNL has conducted a preliminary analysis of the savings associated with the proposed 2024 IECC, and that DOE's preliminary cost-benefit analysis indicates that the 2024 IECC will exceed the energy efficiency of the 2021 IECC by approximately 6.7 percent. Energy cost savings are estimated to increase by approximately 6.4 percent.[46]

The savings result from the following measures: Additional energy efficiency credits (10 energy credits); Fenestration Table—Improved Window and Skylight U-factors in Climate Zones 4C—8; Ceiling Insulation changes in Climate Zones 4–8 from R–60 to R–49; Climate Zones 6–8 to 2.5 ACH50; Pipe Insulation Requirements update (1 inch thickness = R7); Heat Recovery Ventilator required in Climate Zone 6.

10. Understated Impact on Low-Rise Multifamily

One commenter suggested that the Regulatory Impact Analysis (RIA) is ''seriously flawed'' because it inadequately considers the impact of the 2021 IECC on low-rise multifamily construction and fails to give appropriate regard to the potential impact on the availability of affordable housing for low-to-moderate income renters. Another commenter questioned the use of a 30-year period of analysis, which the commenter says ignores investment and construction cost considerations for rental apartment investors that work on shorter investment horizons of a 10-year maximum.

HUD–USDA Response: As stated in the preliminary determination, the 2021 IECC may impact an estimated 170,000 housing units of HUD- and USDA-financed or -insured housing, which includes single family and low-rise multifamily housing. The majority of impacted units will be single family (86 percent); additionally, single family housing faces a greater estimated incremental cost when compared to low-rise or high-rise multifamily. As such, it is reasonable for the bulk of the analysis to center on the most significantly impacted housing type; however, HUD and USDA recognize the need to provide additional detail on availability impacts to low-rise multifamily housing. HUD estimates approximately 27,000 low-rise multifamily units may be impacted by this notice; all are HUD-financed since USDA multifamily programs are not covered by this notice.

When considering impacts on the availability of affordable housing, the economic rationale remains consistent when considering impacts for each housing type; the percentage change in the quantity of housing depends on the price elasticity of demand, price elasticity of supply, and incremental cost. The 1.5 percent reduction cited in the Regulatory Impact Analysis (p.80) applies broadly to housing, meaning that this rate holds for both single family and low-rise multifamily. As such, the maximum number of negatively impacted units is 405 units out of the 27,000 units of low-rise multifamily housing that are estimated to be impacted by this notice.

Existing energy efficiency programs make building to a higher standard more accessible for subsidized housing compared to market-rate housing. A report from DOE's Office of Scientific and Technical Information found that low-rise multifamily buildings were often designed to higher standards in order to qualify for additional energy efficiency certification programs.[47] The Low Income Housing Tax Credit program often requires above-code energy efficiency measures through state Qualified Allocation Plans, resulting in many affordable low-rise multifamily projects that are already being built to higher above-code standards, *e.g.,* Energy Star for New Construction or Passive House.

As far as impacts on renters, the energy efficiency improvements required by the most recent energy codes will provide health benefits in addition to reductions in energy expenditures for families living in rental housing, circumventing the split-incentive issue of landlords being unwilling or uninterested in improving the quality of rental housing for their tenants.

A 30-year period is used in HUD and USDA's affordability analysis following the well-established methodology developed by DOE for assessing the cost effectiveness of the IECC.[48] HUD's Regulatory Impact Analysis provides additional detail (p. 25). In response to the comments that investors in rental apartments typically rely on a 10-year timeline, HUD and USDA added Tables 17 and 18 to the final determination. These show the cash flow for single family and low-rise multifamily housing, respectively. For each building type, the cash flow is positive by the end of the second year, and the simple payback for the national average occurs after 7.7 years in both cases.

Additionally, it should be noted that this is only applicable to low-rise multifamily; mid-rise and high-rise multifamily buildings are required to meet the ASHRAE 90.1–2019 standard, which shows national average cost increases of only $208 per dwelling unit and negative cost increases for certain states and climate zones (meaning adopting the new standard saves money). Nationally, the simple payback is immediate with 40 states receiving immediate payback and South Dakota having the longest payback period of 1.6 years.

B. Current Status and Anticipated Timetable for State and Local Adoption of the Next Revision of the IECC and/or ASHRAE Codes

HUD and USDA requested comments from code officials on the current status of code adoption in their states, and the anticipated timetable for adopting the next revision of the IECC and/or ASHRAE 90.1 codes. No comments were submitted on the specific question of proposed timetables for state and local adoption of subject codes. However, multiple comments were received that expressed concerns regarding the interaction or alignment between the HUD and USDA proposal and state and local adoption of prior codes. These are discussed below.

1. Alignment of HUD and USDA Standards With State and Local Codes

Several commenters shared concerns regarding the transition that would be required to implement the 2021 IECC and ASHRAE 90.1–2019. Commenters cited the lack of alignment with state or local home rule adoption of these codes. One commenter suggested that the proposed standards would conflict with local building codes, causing delays in construction and significant cost impacts. One commenter suggested that HUD and USDA align implementation of the 2021 IECC with state and local government efforts for updating their energy codes to avoid placing major challenges on builders and local code enforcement officers. One commenter suggested that HUD and USDA accept

[46] PNNL for DOE, Energy Savings Analysis 2024 Residential IECC Interim Progress Indicator.

[47] DOE, Office of Scientific and Technical Information, Residential Building Energy Efficiency Field Studies: Low-Rise Multifamily (Technical Report), *https://www.osti.gov/biblio/1656655/.*

[48] PNNL, Methodology for Evaluating Cost-Effectiveness of Residential Energy Code Changes, prepared for DOE, *https://www.energycodes.gov/sites/default/files/2021-07/residential_methodology_2015.pdf.*

the two most recent versions of the IECC and ASHRAE 90.1 standards to help alleviate compliance issues for states and localities with code requirements below the proposed standards.

HUD–USDA Response: The statutory framework for this notice requires HUD and USDA to align their codes with the latest editions of the specified codes, *i.e.,* the 2021 IECC and ASHRAE 90.1–2019. The statutory requirement at Cranston Gonzalez Section 109(d) does not provide for substituting state-adopted codes (or previous editions as suggested by one commenter) for this cohort of HUD- and USDA-financed new buildings. The intent of the statute is for HUD and USDA to adopt the latest edition of the codes independent of the codes that states have adopted, provided that these do not negatively impact the affordability and availability of the subject homes.

HUD and USDA recognize that this above-code requirement (in states or localities that have not yet adopted the latest editions of the codes) will require builders, developers, and designers to familiarize themselves with the requirements of the new codes. However, the agencies note that it is *not* expected that local code officials will be required to ensure compliance with or enforce the proposed standard. The agencies will not rely on local code officials to certify compliance with the HUD and USDA requirements, and therefore local building inspectors will not be expected to familiarize themselves with the HUD and USDA requirements should they differ from the prevailing state or local code. Rather, HUD and USDA will rely on existing builder self-certification requirements and will also put in place a technical assistance and training program to educate and inform builders, architects, engineers, and developers about the requirements of the standard.

Additionally, there are some jurisdictions that do not adopt building codes at all, and federal agencies must provide prudent guidance and protection of consumers, taxpayers, and housing assets by requiring an industry-accepted code as a standard for all types of project development.

As noted, HUD and USDA's statutory requirement to consider adoption of the latest editions of the code does not allow acceptance of the previous 2018 IECC and ASHRAE 90.1–2016 editions as a compliance pathway, as suggested by one commenter, since these editions have been determined by DOE to be less efficient than the current standards. However, as has been standard practice, all subsequent versions of the IECC and ASHRAE 90.1 that have been determined by DOE to meet or exceed the energy efficiency of the 2021 IECC and ASHRAE 90.1–2019, are sufficient to meet the requirements that will go into effect as a result of this notice. Additionally, there are now significant federal incentives and encouragement from federal agencies for builders to achieve even higher energy performance through, for example, the Department of the Treasury's section 45L tax credit of up to $2,500 for homes that are certified as meeting the requirements of the EPA's Energy Star Single Family Homes or the Energy Star Multifamily Homes National Program (but do not meet the ZERH standards) and up to $5,000 for homes that are certified as meeting the requirements of DOE's ZERH program. Both the EPA's Energy Star Programs and DOE's ZERH's programs require minimum compliance with the most current energy code (2021 IECC) and energy performance of at least 10 percent better. It is anticipated that many builders will take advantage of these tax incentives—as well as rebates that will become available in 2025 or earlier for electric heat pumps and other building electrification measures—and in the process achieve energy efficiencies that are well above the 2021 IECC. Additionally, 45L tax credits of up to $2,500 per unit for Energy Star Multifamily New Construction and up to $5,000 per unit for DOE Zero Energy Ready Homes for multifamily homes are available for multifamily builders that meet prevailing wage requirements.

2. Adoption of Earlier Versions of the Energy Codes

One commenter stated that requiring the IECC 2021 breaks with the precedent established by HUD and USDA in 2015 of selecting an attainable code standard for states rather than the most recently published version. The commenter pointed out that in 2015, HUD established the baseline requirement of 2009 IECC despite newer versions having been published by that time; the commenter recommended that HUD and USDA delay this update until more states adopt the most recent versions of the codes or opt for the 2018 IECC as the requirement.

HUD–USDA Response. The authorizing statute for this notice requires HUD and USDA to adopt the most recent edition of the IECC and does not provide for consideration of prior editions; the delayed adoption of the 2009 IECC by HUD and USDA in 2015 was a function of the length of time the regulatory process took to publish a final determination on the 2009 IECC, not to establish a precedent for future adoption.

Further, the statute does not allow HUD and USDA to tie adoption by HUD and USDA of the most recent edition of the code to the number of states that have adopted that code. Specifically, section 109(d) of Cranston-Gonzalez (42 U.S.C. 12709) provides that revisions to the IECC or ASHRAE 90.1 codes will apply to the housing specified in the statute if: (1) either agency ''make(s) a determination that the revised codes do not negatively affect the availability or affordability'' of such housing. HUD and USDA therefore do not have the statutory authority to delay adoption of the most recent code until ''more states'' have adopted the code. The agencies note, however, that the number of states considering or adopting the revised standards is growing and is expected to grow further as a result of newly available IRA or BIL funding from DOE to support state adoption of the 2021 IECC or higher energy standards. As of December 2023, while only five states have already adopted the 2021 IECC, more than 20 additional states are actively considering its adoption.

HUD and USDA recognize that this presents challenges for developers and builders with regard to adopting a standard that may be above the prevailing locally adopted state or local code, but the governing statute for this notice limits the factors to be considered by HUD and USDA to ''affordability'' and ''availability;'' it does not provide for accepting alternative state or local codes as a compliance path. If HUD and USDA were to wait until more states had adopted the 2021 IECC, this would undermine the purpose of the governing legislation, which is to strengthen the standards for HUD- and USDA-financed new construction separately from state adoption provided that these were found to meet the affordability and availability standards.

3. IECC and ASHRAE 90.1 Alignment With State and Local Code Amendments

One commenter noted that the adoption of the 2021 IECC and ASHRAE 90.1–2019 creates ''hurdles in states that have not yet adopted these versions of the codes or have amended the codes so they are not deemed equivalent.'' The commenter suggested that HUD and USDA should ''conduct further due diligence on these issues'' to better understand the practical impact of updating the code requirements.

One commenter suggested that HUD and USDA postpone issuing the final determination until a critical mass of states adopt the 2021 IECC and ASHRAE 90.1–2019 standards. The commenter stated that prematurely enforcing these new standards will lead

to jurisdictions being unprepared to review or verify compliance; construction trades being untrained in implementing the new energy efficiency measures; builders, developers, and designers not being ready to transition to the new standards; third-party verification organizations being unprepared to certify compliance; appraisers not being able to recognize the added costs in valuations; and coordination with other code requirements at the jurisdictional level having limited time, leading to non-compliance and performance issues.

HUD–USDA Response. As noted in the above response, HUD and USDA recognize the potential challenges regarding compliance with the statutory requirement to adopt the most recent edition of the codes that may exceed the standards adopted by a state or locality. The preliminary determination provided an extensive discussion and analysis of the impact that adoption of the 2021 IECC would have on the availability of agency-financed housing. In places which have a significant share of FHA-insured or HUD-financed housing, including California (7,977 total units), Florida (22,607 total units), Georgia (9,736 total units), North Carolina (8,432 total units) and Texas (41,230 total units), HUD and USDA have determined that builders are more likely to build to the standards covered under this notice.

HUD and USDA also note that state adoption is an ongoing process: as of December 2023, only five states have adopted a code that meets or exceeds the 2021 IECC; however, five additional states have adopted the 2021 IECC, although with weakening amendments. Additionally, a significant number of states are currently actively considering the adoption of this standard (with or without amendments). Some 20 states are currently considering adoption of the 2021 IECC; when combined with the 10 states that have already adopted the 2021 IECC, or codes that meet or exceed the 2021 IECC, these states represent approximately 50 percent (an estimated 80,000 units) of HUD and USDA financed units projected to be impacted by this determination.

In summary, while the statute specifically limits HUD and USDA's ability to tie code requirements to the level or extent of state adoption of these requirements, from a practical point of view the pipeline of states currently considering or projected to adopt the 2021 IECC discussed above indicates that by the time the HUD and USDA 2021 IECC requirement takes effect, many more states will in fact have adopted the 2021 IECC or its equivalent, thereby aligning the HUD and USDA standard more directly with state or local code adoption. Additionally, HUD and USDA will put in place a technical assistance and training program to better enable builders, architects, and engineers to meet the 2021 IECC and ASHRAE 90.1–2019 standards.

C. Cost-Benefit Methodology Utilized by Pacific Northwest National Laboratory (PNNL) as Described in the Preliminary Determination

HUD and USDA requested comments on the methodology developed by PNNL and used by the agencies for their affordability analysis. Most comments received in response to this question were in support of the PNNL cost-benefit analysis. One commenter presented their own analysis, conducted by ICF, which aligns with the PNNL analysis and found that the 2021 IECC is cost effective when compared to the 2018 IECC across all climate zones.

However, some commenters shared concerns regarding the methodology used in the cost-benefit analysis. Among these concerns, two commenters expressed that the PNNL study overestimated the value of future savings, particularly for low-income buyers. Others raised concerns with the incremental costs, as well as the economic factors used to estimate cash flow and life cycle savings. One commenter presented an analysis prepared by Home Innovation Research Labs (Home Innovation) disputing PNNL's analysis, showing significantly higher cost estimates than the PNNL costs used by HUD and USDA for their analysis.

HUD–USDA Response: HUD and USDA acknowledge the many supportive comments on the cost-benefit analysis included in the preliminary determination. This analysis accurately reflected the economic landscape at the time of development in 2020. In addition, HUD and USDA reviewed the independent cost-benefit studies referenced in the public comments, one of which, by ICF, affirms PNNL's analysis and one of which (Home Innovation) disputes PNNL's analysis.

In general, HUD and USDA affirm the original analysis and methodology conducted by PNNL used by the agencies in the preliminary determination; however the agencies recognize that significant time has elapsed since the analysis was conducted in 2020 and have accordingly revised their analysis to include updated economic factors that better reflect current market conditions, including a significant increase in construction costs to reflect the supply-chain and other factors that have impacted construction costs from 2020–23. The appropriate tables have been revised in the final determination.[49]

1. Construction Cost Estimates

One commenter stated that the construction costs used in the PNNL analysis are substantially lower than the current market costs. The commenter included a summary of alternative cost estimates based on Home Innovation's analysis which demonstrates a much more significant (negative) impact on affordability.[50] The commenter also stated that the cost effectiveness analysis should consider the amount paid by the consumer as well as the builder, *i.e.,* should include builder gross profit margins as a cost factor.

[49] The final determination uses the same cost effectiveness methodology as the RIA, which HUD developed based on PNNL's incremental cost and energy cost savings figures. A key difference between the methodologies is that PNNL includes residual value and replacement costs in their calculation. Page 25 of the RIA explains why these factors are not included in this alternative methodology.

[50] Home Innovation Research Labs, 2021 IECC Residential Cost Effectiveness Analysis, June 2021, *https://www.homeinnovation.com/-/media/Files/Reports/2021-IECC-Residential-Cost-Effectiveness-Analysis.pdf.*

HUD–USDA Response: The analysis produced by PNNL was developed with a methodology that underwent a rigorous public comment and peer review process, has been used for cost-benefit analysis of the revised editions of the IECC and ASHRAE since the 2006 IECC. The Home Innovation report and a response report developed by ICF are independent, third-party studies that include additional data and analysis but are not peer reviewed nor do they follow a federally approved methodology. HUD carefully reviewed the cost estimates provided in the Home Innovation report. The agency recognizes that the incremental cost estimates in the Home Innovation report are two to three times higher than those estimated by PNNL, but ultimately determined that the current analysis' approach and findings most accurately represent accepted means of assessing building energy code impacts, including anticipated cost impacts. Additionally, there are other entities (ICF) that estimate lower cost increases than those calculated by DOE/PNNL.

It is important to note that both independent studies show consensus with the PNNL energy savings estimates used by HUD and USDA in their determination. Home Innovation concluded that energy savings from adopting the code would range from 6.4 percent to 11.6 percent depending upon the additional option chosen. For the basic package plus the water heater option, Home Innovation found a reduction of 9.7 percent of energy expenditures. This range is similar to the estimate reported by PNNL of 8 percent for single family homes (see RIA Figure 11).[51] However, the cost-effectiveness analysis conducted by Home Innovation estimates significantly higher incremental costs for the 2021 IECC over the 2018 IECC, ranging from $6,548 to $9,301 per house on average, compared to the government estimate of $2,372 per home; while the Home Innovation savings estimates are the same as those estimated by DOE, the higher estimated cost in the Home Innovation report result in significant differences in estimated simple payback periods for the initial investment.[52]

With regard to construction cost estimates, the agencies would expect there to be slight differences in the cost estimates given the variety of building types, methods of compliance, costs of materials, and quantity of materials. However, the differences between these the PNNL and Home Innovation estimates are unusually large: HUD and USDA attribute such a large difference to two factors: Home Innovation's assumption of a high profit margin and differences between the configuration of the model homes used by PNNL and Home Innovation respectively.

The representativeness of the Home Innovation and PNNL data are not equivalent. The set of prototypes PNNL uses in its analysis are designed to represent the majority of the new residential building construction stock in the United States using a combination of U.S. Census, RECS, and Home Innovation data. DOE's established methodology uses a suite of representative residential prototype buildings, including a single family and a low-rise multifamily residential building, each with four different foundation types (*i.e.,* slab-on-grade, vented crawlspace, heated basement, unheated basement) and four heating system types (*i.e.,* gas furnace, electric resistance, heat pump, fuel oil furnace). The Standard Reference House by Home Innovation is primarily based on the results of the 2008–2009 Annual Builder Practices Survey (ABPS). The ABPS is an annual national survey of builders that gauges national and regional building practices and material use. This survey represents a comprehensive source of general housing characteristics in the United States and contains information on building square footage, wall square footage, climate-based foundation type, climate-based wall construction type, and other residential construction characteristics. The parameters represent the average (mean) values from the survey for building areas and features not dictated by the 2006 IECC.

The Home Innovation study calculates the unit cost of any change and adds to that an overhead and profit premium of approximately 27 percent. For example, the incremental cost to the builder of installing a square foot of ceiling insulation is 59 cents per square foot, which is derived by inflating the 46-cent incremental cost by the overhead premium. The total incremental cost to the producer is given by the inflated unit cost of 59 cents and the quantity (1,875 square feet of ceiling insulation) to settle on an estimate of $1,106. The cost paid by the consumer is assumed to be the cost to the producer plus a return of 23.5 percent on the change in costs. The cost to the consumer of requiring thicker ceiling insulation would then be $1,366 ($1.235 \times \$1{,}106$).[53] Adding these markups on incremental costs would inflate the cost estimate by 57 percent (1.27×1.235).

The design of the home plays a role by determining the quantity of insulation. The model single family homes of PNNL are similar in terms of living space (floor area). The Home Innovation model is less dense, however, and has more of its floor area in the first floor than the second floor. A low-density design leads to larger areas exposed to the exterior and in need of insulation. For example, although the floor area of the Home Innovation home is only 5 percent greater, the ceiling area requiring insulation is 56 percent greater.

The profit assumption combined with the design of the home would lead to cost estimates approximately 2.2 times larger than the PNNL analysis. (The PNNL cost estimates include a 15 percent overhead and profit.)

While HUD and USDA continue to rely on PNNL construction cost estimates, the agencies recognize that construction costs have increased since the original analysis was conducted of the 2021 IECC. Accordingly, a supply chain cost increase factor of 37 percent has been applied to the incremental cost of adopting the new code to account for the increase in inputs for residential construction over the 2020–23 period. The 37 percent increase is derived by from the Bureau for Labor Statistics' Producer Price Index for inputs to residential construction less energy and cited by the NAHB in their monthly Eye on Housing blog.[54] Tables 13–15 in the Final Determination have been updated to reflect this cost increase.

2. Builder vs. Consumer Costs

One commenter asserted that the PNNL analysis relied on by HUD and USDA is based on costs experienced by the builder and does not account for the full costs experienced by the homeowner, including mark-ups such as builder profit margin.

HUD–USDA Response: Profit margin is already included in the DOE/PNNL Methodology. The PNNL methodology for evaluating the impacts of building energy codes defines first cost as the marginal retail cost of implementing a

[51] *https://www.energycodes.gov/sites/default/files/2021-07/2021_IECC_Final_Determination_AnalysisTSD.pdf.*

[52] *https://www.nahb.org/-/media/NAHB/advocacy/docs/top-priorities/codes/code-adoption/2021-iecc-cost-effectiveness-analysis-hirl.pdf.*

[53] HUD expects that builder profits would diminish rather than increase from this regulation. The NAHB implies the reverse: that the increase in revenue is greater will be greater than the cost. It is more likely that profit rates will fall.

[54] Producer Price Index Report, *https://www.bls.gov/news.release/ppi.nr0.htm.* See NAHB, Eye on Housing, Building Materials Prices Fall for Second Month Straight, *https://eyeonhousing.org/2023/06/building-materials-prices-fall-for-second-month-straight/.*

code change. This includes the price experienced by the home buyer, including materials, labor, equipment, overhead, and profit. A factor of 15 percent is included for overhead and profit.

3. Reliance on Simple Payback vs. Life Cycle Cost Savings

Another commenter cited an independent cost analysis by ICF of the Home Innovation report. The ICF analysis concluded that the Home Innovation analysis only evaluates cost effectiveness with a simple payback metric, which ignores many longer-term factors in the economic performance of an energy efficiency investment.

HUD–USDA Response: Beyond the specific figures cited by the commenter, the Home Innovation cost analysis is based solely on a simple payback metric which divides an incremental cost by the associated consumer cost savings to identify the time, typically in number of years, required to ''pay back'' the initial investment. While being a straightforward metric and relatively simple to calculate, it is not deemed sufficient to capture the full range of costs and benefits experienced by the home buyer. A life-cycle cost analysis is preferred as the widely accepted means of evaluating incremental costs of construction, including updated building energy efficiency standards, against expected consumer cost savings. The life-cycle approach accounts for the incremental costs of construction and consumer cost savings, as well as other costs and impacts experienced by the homeowner, including maintenance and replacement costs associated with a given measure. The Congressionally-recognized energy code development and consensus bodies, the International Code Council (ICC) and ASHRAE 90.1, both rely upon a life-cycle based approach for evaluating the cost impacts of their updated codes. As the Home Innovation analysis relies solely on simple payback, it is not directly comparable to the life-cycle cost analysis developed by PNNL and used in this notice by HUD and USDA. That said, USDA and HUD do include simple paybacks in their analysis, but provide it as a supplemental rather than primary measure of affordability.

4. Financing and Economic Factors Do Not Reflect Current Market Conditions

Several commenters raised concerns about certain economic factors used for the cash flow and Life Cycle Cost savings analysis in the preliminary determination and the RIA. The main concerns were with savings estimates, interest rates, down payments, discount rates, payback period, and applicability for typical FHA and USDA borrowers.

One commenter suggested that HUD and USDA should conduct additional analysis on the costs of compliance for their federal programs. Commenters stated that the PNNL analysis assumed an inflation rate of 1.4 percent and a mortgage rate of 3 percent while, as of July 2023, the inflation rate is 3.0 percent and mortgage rates are 6.97 percent. They also stated that the PNNL use of a 12 percent downpayment does not reflect the average downpayment for an FHA or USDA borrower, which are stated as 4.5 percent and zero percent respectively.

One commenter also suggested the cost effectiveness analysis used in the preliminary determination does not reflect the typical FHA and USDA borrowers for single family homes. The commenter suggested that ''HUD and USDA should conduct an independent analysis of the cost impact on the typical lending profiles for the borrowers that use their programs and customize the analysis to represent their clients more accurately.''

HUD–USDA Response: Regarding comments received on the economic factors used in the analysis, HUD and USDA address the effect of the relationship between the mortgage interest rate and the consumer's discount rate on mortgage affordability on page 31 of the RIA. Additionally, HUD and USDA did consider the differences in monthly mortgage payments and insurance premiums between HUD and USDA borrowers and the average borrower in PNNL's analysis. See pages 33–43 of the RIA for cash flow impacts to FHA and USDA borrowers.

At the same time, the agencies understand the significance of COVID–19 and global supply chain issues on factors such as inflation, interest rates, and energy prices. This issue is not unique to this final determination, as the ICC and DOE have also updated the economic factors proposed for determining the cost effectiveness of the 2024 IECC, as outlined below in Table 7.[55] These factors were agreed to by all stakeholders in the consensus process, including the home building industry.

Table 7. ICC Economic Factors for 2024 IECC Analysis

Parameter	Value	Source
Mortgage Interest Rate	3.84% nominal	Freddie Mac 5-year average
Loan Term	30 years	DOE 2021 Cost Effectiveness Analysis
Down Payment Rate	12%	DOE 2021 Cost Effectiveness Analysis
Points and Loan Fees	1%	DOE 2021 Cost Effectiveness Analysis
Discount Rates	3.84% nominal 7% real 3% real	30-year mortgage rate 2003 OMB Circular A-4 2003 OMB Circular A-4
Period of Analysis	30 years	
Inflation Rate	2.3%	EIA AEO 2021
Fuel price escalators	Electricity: -0.1% Gas: 0.5% Propane: 1.4%	EIA Annual Energy Outlook 2021 reference case, residential by fuel, national

[55] 2024 IECC Residential Cost Effectiveness Analysis Proposal, *https://www.iccsafe.org/wp-content/uploads/IECC_res_cost_effectiveness_proposal_final.pdf.*

HUD and USDA have used similar or equivalent sources, updated to reflect 2023 costs and fuel price escalators and mortgage interest rates to revise the economic factors used in the preliminary determination's affordability analysis to reflect current market conditions (Tables 13–16). This acknowledges the unusual circumstances of the recent four-year 2020–23 period, both with regard to increased mortgage interest rates as well as COVID-related supply chain shortages and associated cost increases. With these revisions, HUD and USDA have adopted a modified DOE methodology for the analysis. The analysis is based on the original cost effectiveness results from PNNL; however, it has been updated as described in response to several public comments. The economic parameters that have been revised are listed below in Table 8.

Table 8. Revised Economic Parameters for Final Determination

Parameter	Value	Source
Mortgage Interest Rate	Real: 3% Nominal: 5.3%	
Discount Rate	Real: 3% Nominal: 5.3%	Equal to Mortgage Interest Rate
Supply Chain Cost Increase Factor	37%	BLS Producer Price Increase
Energy Price Increase Factor	32%	EIA Natural Gas Prices, Electricity Prices, Heating Oil Prices
Fuel price escalator	1.9%	EIA Annual Energy Outlook 2023, Table 3. Energy Prices by Sector and Source. Prices in Nominal Dollars
FHA Savings Reduction Factor	3%	HUD Estimate
FHA Cost Reduction Factor	5%	HUD Estimate
Down payment	5%	Downpayment Factor (FHA and USDA borrowers)
Inflation	2.24%	First Quarter 2024, Survey of Professional Forecasters

These revisions better reflect impacts on HUD and USDA borrowers and also account for the higher cost of construction materials and labor, as well as increased energy prices over the past three years, as follows:

Economic Factors:

• *Construction cost increase (2020–23).* A supply chain cost increase factor of 37 percent has been applied to the incremental cost of adopting the new code to account for the increase in residential construction costs 2020–23. The 37 percent increase utilizes Bureau of Labor Statistics' Producer Price Index for inputs to residential construction less energy as reported by the National Association of Home Builders.[56]

• *Energy price increase (2020–22).* An energy price increase factor was developed by averaging price for electricity, natural gas, and heating oil for 2020 through 2022. The three-year averages were used to establish the rate of increase based on PNNL's original energy prices for each source. Finally, these rates were averaged based on the residential energy mix for 2022. Data for calculating the energy price increase factor was sourced from the U.S. Energy Information Administration.[57]

• *Energy price escalator.* A new fuel price escalator is used, based on the estimated 30-year trends in the Energy Information Administration's (EIA) 2023 Annual Energy Outlook.[58] While the energy price increase reflects historical increase in energy prices from 2020–23 and is used to estimate first year energy savings, the energy price escalator estimates future changes to energy prices over the full period of the analysis, changing the price for future years to align with the expected movement in energy prices over the 30-year mortgage. The escalator is set based on the projections with prices in nominal dollars.

Cash Flow and Financing Factors:

• *Mortgage interest rate.* A 5.3 percent nominal mortgage interest rate has been adopted, using DOE's established cost effectiveness methodology. HUD and USDA have based their analysis and the economic parameters on DOE's methodology wherever possible, despite incorporating some modifications to reflect the current economic landscape.

• *Discount rate.*[59] A 5.3 percent nominal discount rate (3 percent real discount rate) has been adopted for the purpose of this Notice. The discount rate reflects the time value of money. Following established DOE methodology, the discount rate has been set equal to the mortgage interest rate in nominal terms. Mortgage payment is an

[56] ''Building Materials Prices Fall for Second Month Straight,''| Eye On Housing, *https://eyeonhousing.org/2023/06/building-materials-prices-fall-for-second-month-straight.*

[57] EIA, Natural Gas Prices: Average Residential Price, *https://www.eia.gov/dnav/ng/ng_pri_sum_a_EPG0_PRS_DMcf_a.htm;* Heating Oil Prices: *https://www.eia.gov/dnav/pet/hist/LeafHandler.ashx?n=PET&s=M_EPD2F_PRS_NUS_DPG&f=M*; Electricity Prices: Electricity data browser—Average retail price of electricity, *https://www.eia.gov/electricity/data/browser/#/topic/7?agg=0,1&geo=vvvvvvvvvvvvo&endsec=vg&linechart=~ELEC.PRICE.US-RES.A&columnchart=ELEC.PRICE.US-ALL.A&map=ELEC.PRICE.US-ALL.A&freq=A&start=2001&end=2022&ctype=linechart&ltype=pin&rtype=s&pin=&rse=0&maptype=0.*

[58] EIA, U.S. Energy Information Administration—EIA—Independent Statistics and Analysis, *https://www.eia.gov/outlooks/aeo/data/browser/#/?id=3-AEO2023&region=1-0&cases=ref2023&start=2021&end=2050&f=A&linechart=ref2023-d020623a.3-3-AEO2023.1-0~ref2023-d020623a.5-3-AEO2023.1-0&map=ref2023-d020623a.3-3-AEO2023.1-0&ctype=linechart&sourcekey=0.*

[59] Methodology for Evaluating Cost-Effectiveness of Residential Energy Code Changes, U.S. Department of Energy, *https://www.energycodes.gov/sites/default/files/2021-07/residential_methodology_2015.pdf.*

investment available to consumers who purchase homes using financing, which makes the mortgage interest rate a reasonable estimate for a consumer's alternative investment rate.

- *Down payment.* Down payment has been revised from 12 percent used by PNNL to 5 percent to better reflect the HUD and USDA borrower. Note that this is somewhat higher than the minimum down payment required for FHA-insured mortgages of 3.5 percent, but the average down payment for new construction loans is somewhat higher than the minimum.
- *Other closing costs.* A 1.75 percent upfront mortgage insurance premium (MIP) to reflect current FHA requirements, a 0.55 percent annual MIP, and one percent variable closing costs are also included in the analysis.
- *FHA Typical Home Adjustment Factor.* An FHA cost adjustment factor and an FHA savings adjustment factor of 5 percent and 3 percent respectively were added to adjust the PNNL analysis to better reflect the smaller home size of a typical FHA or USDA property (2,000 sf) compared to a conventionally financed house modeled by PNNL (2,774 sf).

The relevant tables in the final determination have been updated to reflect these revised economic factors. Nationally, the updated economic factors have a minor adverse impact on the affordability of adopting the 2021 IECC. By way of illustration, Table 9 presents the new analysis included in the Final Determination using the revised economic factors (Table 13).

Table 9. National Costs and Benefits – 2021 IECC vs. 2009 IECC (Single Family)

Climate Zone	LCC Savings ($)	30 Year PV Benefits ($)	Incremental cost ($)	Annual energy savings ($)	Annual Mortgage Increase ($)	Down payment and other up-front costs ($)	Net annual cashflow for year one ($)	Years to positive cashflow	Simple payback (years)
National Average	15,071	25,124	7,229	963	439	550	377	1.5	7.7
CZ 1	10,774	15,866	3,662	608	222	279	311	0.9	6.2
CZ 2	8,313	15,871	5,436	608	330	414	168	2.5	9.2
CZ 3	13,917	25,093	8,037	961	488	612	311	2.0	8.6
CZ 4	19,989	31,965	8,613	1,225	523	656	527	1.2	7.2
CZ 5	17,691	28,467	7,750	1,091	471	590	463	1.3	7.3
CZ 6	29,834	39,409	6,886	1,510	418	524	952	0.6	4.7
CZ 7	39,308	51,604	8,843	1,977	537	673	1,261	0.5	4.6
CZ 8	52,078	64,377	8,845	2,467	537	673	1,750	0.4	3.7

The revised economic factors provide a revised estimate of average costs and benefits as outlined in the preliminary determination, both nationally and for individual climate zones. The average per-unit incremental cost increases to $7,229 (compared to $5,555 in the preliminary determination) due to the supply chain cost increase factor of 37 percent; however, the increase is moderated by the inclusion of the 5 percent FHA cost reduction factor to reflect the smaller FHA-sized house relative to the larger market as described above. Estimated annual energy savings increases to $963 (compared to $751 in the preliminary determination) due to the energy price increase factor of 32 percent. Net life cycle cost savings become $15,071. With these revisions, simple payback period increases slightly from 7.6 years shown in the preliminary determination to 7.7 years in the final determination. Due to the revised down payment rate of 5 percent reflecting the average FHA borrower's downpayment, years to positive cashflow is reduced to 1.5 years (compared to 2 years in the preliminary determination). Accordingly, HUD and USDA's analysis still demonstrates the affordability of the 2021 IECC.

5. Timeframe of Analysis

One commenter recommended calculating energy cost savings over the economic lifespan of a building, which is 75 years, instead of over a typical 30-year mortgage period, which would show greater energy cost savings.

HUD–USDA Response: HUD and USDA based the lifetime of the investment for the preliminary determination on the typical length of a mortgage, which is 30 years. This is the well-established cost estimate methodology established by DOE in consultation with the ICC and associated stakeholder input. The commenter is correct, and HUD and USDA agree, that these improvements will yield improved home quality and energy efficiency well beyond the 30 years, potentially for the life of the building, but there are no established estimates for accurately or reliably estimating these longer-term benefits. It is also likely that homeowners will upgrade their homes with more efficient equipment or improved building measures such as higher performance windows. While DOE's analysis includes replacement costs over the period of a typical mortgage, estimates of efficiency gains beyond that period are not included in the modeling here.

D. Impact of Manually Operated Bathroom Fans Allowed Under the IECC on Indoor Air Quality and the Health of Occupants

HUD and USDA requested comments on anecdotal reports that because manually operated bathroom fans allowed under the IECC to meet ventilation requirements rely on occupant action to operate them, these may impact indoor air quality and the health of occupants.

There were no comments, supportive or otherwise, that directly addressed the possible health concern caused by the use of manually operated bathroom fans to meet IECC ventilation requirements.

However, several comments were received on moisture management, and ventilation issues. One commenter reiterated the importance of moisture management in energy efficient buildings and recommended the use of energy recovery ventilation (ERV) or heat recovery ventilation (HRV) equipment. Another commenter indicated that ''HUD must ensure that that the benefits of the proposed standards do not come at the expense of resident health,'' noting that updated energy codes require more tightly sealed envelopes that, if not accompanied by appropriate and well-maintained ventilation, may create the risk of moisture retention and mold, accumulation of indoor air pollutants, and other causes of building related illness. The commenter proposed that HUD should ''fully fund and vigorously implement'' time-of-construction inspections to enforce ventilation requirements such as ASHRAE 62.1 and 62.2, as well as on-going NSPIRE inspections.

HUD–USDA Response: HUD and USDA share the commenter's commitment to resident health in energy efficient buildings. The 2021 IECC sets maximum air leakage of 5.0 ACH50 (5 air changes per hour) or 0.28 CFM/sf as measured by a blower door test, or 3.0ACH50 when following prescriptive requirements (allows for 0.30 CFM/sf enclosure area for attached dwelling units and buildings that are 1,500 sf or smaller). The IECC requires compliance with Section M1505 of the International Residential Code (IRC), which sets minimum ventilation rates for whole house ventilation systems as well as local exhaust rates. ASHRAE 90.1 for multifamily buildings references ASHRAE 62.2, Ventilation and Acceptable Indoor Air Quality in residential buildings.

Regarding energy or heat recovery systems, the 2021 IECC requires such systems for Climate Zones 7 and 8 (colder climate zones), but these are optional in other climate zones. Heat Recovery Systems (HRVs) supply continuous fresh air from outside the home and recover between 60–95 percent of heat in exhaust air, thereby contributing significantly to the energy efficiency of a building. Energy Recovery Systems (ERVs) can exchange both heat and moisture, thereby keeping humidity levels relatively stable.

E. Potential Fire Code Issues Associated With Air-Sealing Requirements for Attached Single Family Homes or Low-Rise Multifamily Properties

HUD and USDA asked for comments on potential challenges to meeting both the more stringent air sealing requirements introduced in the 2012 IECC (3 ACH 50 in certain climate zones) as well as fire code specifications in attached row-house, town home or multifamily settings. This had been identified as a possible barrier when 3ACH 50 was originally proposed in the 2012 IECC.

Several commenters indicated that the 2021 IECC air leakage requirements of 3 air changes per hour or 5 air changes per hour at 50 pascals depending on the climate zone should not present fire code issues for single family attached homes or low-rise multifamily properties. Commenters experienced on the issue indicated that they have no knowledge of any challenges meeting the 2021 IECC air leakage requirements and fully complying with the fire code. One commenter included that 28 states and more localities have implemented the code without any fire code issues. Another commenter stated that technologies exist to comply with air leakage and fire code requirements without challenges.

HUD–USDA Response: Air sealing of area separation wall assemblies in multifamily buildings had been identified by DOE and others as a barrier that limits the ability of builders to cost effectively achieve higher energy efficiency and quality levels in multifamily housing.[60]

Air leakage through these assemblies could also be a barrier to achieving air leakage limits mandated by the IRC and IECC. More specifically, fire blocking sealants approved for use to seal framing penetrations within a dwelling are not allowed to be used to seal the perimeter of ¾ inch air space required in UL 263 (also ASTM E119) area separation walls. This unsealed perimeter condition makes these walls porous to airflow coming from the exterior or from attached garages.

Training materials from the Energy Efficient Building Association (EEBA) also indicate that the 3 ACH 50 air sealing requirement may be a challenging target for townhomes or where there are common walls between units, and that there is a lack of clarity in how to air seal the wall between these units without violating the fire-rated assembly.[61] EEBA indicated that there have been some breakthroughs recently with retesting fire-rated wall assemblies with specific foams and sealants to show that they will perform, and several options are now listed in the UL database. Based on the comments received, this issue seems to have been resolved.

F. Time Required for Builders and Building Designers To Familiarize Themselves With the New Codes and Training or Technical Support That May Be Required

HUD and USDA requested comments on the time required for builders and building designers to familiarize themselves with the new codes, the training or technical support that may be required by building professionals and local code officials on the new requirements of the 2021 IECC and ASHRAE 90.1–2019 standards, workforce training needs, and any other issues related to implementation of these standards. Comments on particular challenges or issues facing rural areas in adoption and/or implementation of these codes were also requested.

1. Implementation Timeline

Several commenters indicated that HUD and USDA should implement the new 2021 IECC and ASHRAE 90.1–2019 standards in a way that accommodates time requirements, training and technical support requirements, and other issues necessary for builders and building designers to meet the new codes.

One commenter noted that implementation of these standards has already begun in certain states and localities. One commenter suggested that the implementation timeline should align with state activities and federal incentives to best ensure the intended benefits are achieved. Another commenter suggested that an implementation timeline of at least two years be adopted to enable builders and code enforcement officials to become familiar with the new standards.

Some of the commenters suggested approaches to most easily support the implementation of the 2021 IECC and ASHRAE 90.1–2019 standards. Several commenters advised HUD and USDA to recognize and consider key market dynamics, including supply chain issues and contractor education and training in the development of an implementation timeline. One commenter suggested that HUD and USDA should clarify compliance requirements for builders and conduct training for builders, developers, designers, and construction workers on the new codes.

[60] Department of Energy, *Building America Expert Meeting: Code Challenges with Multifamily Area Separation Walls, 2015.*

[61] Energy Efficient Building Association (EEBA), Air Sealing Requirements for IECC 2021 with Building Code Expert Joe Nebbia; Excerpts from Module 6 of an 8-Part IECC 2021 Code Series, *https://www.eeba.org/air-sealing-requirements-for-iecc-2021-with-building-code-expert-joe-nebbia.*

One commenter suggested that extending the implementation timeline, particularly for FHA-insured and USDA-guaranteed loans, would improve the implementation process of the new requirements. The commenter stated that such an extension may be necessary to align the proposed HUD and USDA requirements with the Inflation Reduction Act section 50131 funding, which serves to assist jurisdictions in the adoption and effective implementation of energy codes that meet or exceed the 2021 IECC.

HUD–USDA Response: HUD and USDA agree that the implementation time period for new editions of the codes needs to have some flexibility to allow for proper training and education of builders on the requirements of the most recent editions of the IECC and ASHRAE 90.1. Note, however, such training is already offered by, for example, the Regional Energy Efficiency Organizations (REEOs), such as SPEER in Texas and Oklahoma, and there are already builders that are using these codes. Some states have also already required them or exceeded them. In addition, DOE is offering new funding for energy codes training for the building industry, states, and local municipalities.

HUD and USDA also agree that alignment with existing or new sources of funding that can assist in the effective implementation of the energy codes will be useful. This transition will have some learning curves. The agencies anticipate gradual adoption beginning for some programs at the publication of this notice and full implementation within all programs covered by this final notice by the date of January 1, 2025, or later for certain programs.

HUD and USDA also agree that there is a need to align federal incentives that can assist builders to become trained in these codes. HUD and USDA are working with DOE and the states to leverage the unprecedented levels of funding through the Bipartisan Infrastructure Law (BIL) and Inflation Reduction Act (IRA) to support builders and developers in complying with the 2021 IECC and ASHRAE 90.1–2019 standards proposed in this notice. This funding includes $225 million in BIL funding for state agencies to partner with key stakeholders, such as local building code agencies, codes and standards developers, and associations of builders and design and construction professionals to update their building codes. In addition, another $1 billion in IRA funds is available to support states, territories, and jurisdictions with the authority to adopt energy codes in adopting and implementing the latest energy codes and zero energy codes.

DOE has already released funding in advance of this notice to support the training of builders in these codes. As part of the $225 million in BIL funding, DOE announced $90 million as Resilient and Efficient Codes Implementation (RECI) competitive grant awards in July 2023 to help states and partnering organizations implement updated building energy codes. This funding is the first installment of a 5-year program established to support building energy code adoption, training, and technical assistance at the state and local levels. Twenty-seven awards were made in 26 states.[62] In addition, in September 2023 DOE announced another $400 million in IRA formula funds to the states to implement energy codes; $240 million will be available to adopt and implement the latest building energy code, the 2021 IECC for residential buildings and ANSI/ASHRAE/IES Standard 90.1–2019 for commercial buildings, or other codes that achieve equivalent or greater energy savings.[63] HUD and USDA will work with DOE and its grant recipients to leverage technical assistance and training for builders, developers, and others involved in building HUD- and USDA-financed housing.

In addition to the BIL and IRA funds awarded to states to advance adoption of more current energy codes, including the 2021 IECC and zero energy codes, HUD and USDA anticipate a significant increase in the number of new homes certifying to Energy Star New Home or ZERH standards as builders take advantage of the Section 45L tax credits of up to $2,500 and $5,000 that are now available to build to these standards. Building to these standards will automatically comply with 2021 IECC requirements. For multifamily, tax credits of up to $2,500 per unit for Energy Star Multifamily New Construction and up to $5,000 per unit for DOE Zero Energy Ready Homes for multifamily homes are now available as well, when builders comply with prevailing wage requirements.

Some affordable housing builders of rental housing are already building to higher energy standards as required by state, federal, or local affordable housing funding streams. A significant driver of affordable housing is the Low-Income Housing Tax Credit, administered by the states. Some states set their energy requirements to exceed prevailing state codes in their Qualified Allocation Plans (QAPs); housing developers who take advantage of such funding are already well versed in meeting higher level energy codes than the baseline.

Regarding comments that HUD and USDA should align its implementation timeline requirements with state code adoption timetables, states follow a wide range of schedules and procedures when considering adoption of the new editions of the codes. States adopt building codes on their own timelines, with some achieving or exceeding the code levels of energy efficiency and others not adopting any code at all. The statutory requirement governing this notice does not provide for HUD and USDA adoption of prevailing state standards but sets the 2021 IECC and ASHRAE 90.1–2019 as published by the relevant code bodies as the required standard for the covered programs.

2. Need for Training and Technical Assistance

Several commenters stated the need for training on the 2021 IECC and ASHRAE 90.1–2019 standards to limit the potential gap between the efficiency levels required in the standards and the efficiency levels achieved in the field. One commenter stated that a lack of training can result in poor implementation of the code and cause unintended building performance and compliance issues.

One commenter referenced a DOE study that found proper training for code officials and the construction community can reduce energy costs by an average of 45 percent due to varying levels of compliance with the codes. Another commenter suggested that HUD and USDA provide free code books and workbooks as part of the training and technical assistance for builders and building designers to alleviate the cost concerns related to training materials and resources. One commenter suggested that HUD and USDA should offer a comprehensive, no-cost training program to ensure equal access to the material necessary to comply with the new standards. The commenter also suggested that the Federal government should cover the cost of any technical training or equipment necessary for nonprofit housing developers to meet the new standards.

HUD–USDA Response: As with any code update, training is indeed an important issue, particularly for changes that include fundamental changes in technology, materials, or practices. In

[62] *https://www.energy.gov/articles/biden-harris-administration-announces-90-million-support-resilient-and-efficient-building.*

[63] $160 million will be available to adopt and implement the zero energy provisions in the 2021 IECC, or other codes with equivalent or greater energy savings. *https://www.energy.gov/articles/biden-harris-administration-announces-400-million-states-improve-building-energy.*

updating to the 2021 standard, the primary focal points will be wall insulation, mechanical systems, and envelope air tightness. Due to the outdated nature of the 2009 IECC, many of these transitions and practices are already happening across the country. Recent energy code field studies, including those conducted by DOE in the 2014 through 2023 timeframe, indicate that higher insulation values, better windows, more advanced mechanicals, and tighter envelopes are already commonplace due to natural market forces and advancements in building products.

Even with this being the case, HUD and USDA will develop training materials and offer training to builders, developers, and lenders through guidance materials and webinars to support the implementation of these new standards, as described in detail in section A.2. above.

3. Enforcement and Compliance

Several commenters emphasized the need to prioritize enforcement of the standards upon enacting the new requirement to ensure the new requirements are being met. One commenter suggested allowing builders to demonstrate compliance through DOE's REScheck code compliance tool. One commenter suggested that HUD and USDA should ensure ventilation maintenance meets the higher standard required in tightly sealed buildings. One commenter suggested that HUD and USDA provide technical assistance to state and local officials to support enforcement. One commenter suggested that HUD and USDA should conduct a post-implementation study to assess compliance and enforcement over the first one to two years of the new requirements.

HUD–USDA Response: HUD and USDA agree that enforcement of the standards will be important in ensuring compliance with the standard. The agencies are anticipated to rely on self-certification that builders and developers will comply with the code requirements specified in this notice. For single family FHA-insured properties, FHA employs self-certification requirements for many of their policies and program requirements and may pursue enforcement for any false claims or false statements made. Enforcement can include criminal penalties, civil penalties, or both.

For FHA single family new construction, in HUD–92541, HUD already requires the builder to certify that the new construction meets or exceeds the 2009 IECC; this certification will be updated for the 2021 IECC.[64] HUD will update the Minimum Property Standards referenced in HUD–92544 with a conforming amendment to align with the requirements of this notice; HUD is the final adjudicator of whether a defect exists and whether the remedy is required.[65]

Certainly, REScheck is a tool that can be used to demonstrate compliance; it is a DOE-supported tool for builders, designers, and contractors to quickly and easily determine whether new homes, additions, and alterations meet the requirements of the IECC or a number of state energy codes. REScheck also simplifies compliance determinations for building officials, plan checkers, and inspectors by allowing them to quickly determine if a low-rise residence meets the code.

Note that REScheck is set up for building envelope-related insulation and window trade-off calculations in residential single family and low-rise multifamily buildings only; it is not used for the IECC performance path, which relies on other energy modeling tools, *e.g.,* HERS or IC3. REScheck works by performing a simple U-factor x Area (UA) calculation for each building assembly to determine the overall UA of a building. The UA that would result from a building conforming to the code requirements is compared to the UA for the building constructed. If the total heat loss (represented as a UA) through the envelope of a building does not exceed the total heat loss from the same building conforming to the code, the software generates a report that declares the building is compliant with the code.

G. Impact and Duration of COVID-Related Supply Chain Challenges for Certain Products and Materials, Particularly But Not Exclusively for Lumber Products

HUD and USDA's preliminary determination acknowledged the construction industry's experience with COVID-related supply chain challenges for certain products and materials, particularly but not exclusively for lumber products, leading to significant price increases in such products as framing lumber, plywood, and oriented strand board (OSB). The agencies solicited comments on the duration, persistence and intensity of these price increases, the extent to which they may impact the cost of energy related products or materials covered by the IECC or ASHRAE 90.1 energy codes addressed in this notice, and to what extent these supply chain issues may impact implementation of the codes addressed by this notice.

One commenter affirmed the insulation industry's ability to meet any increase in demand as a result of requiring the 2021 IECC and ASHRAE 90.1–2019 standards.

Two commenters expressed concern for the construction industry's ability to meet the additional demand caused by HUD and USDA's requirement of the 2021 IECC and ASHRAE 90.1–2019 standards. A commenter stated that additional code requirements will exacerbate the existing stresses for homebuyers and developers, which include market scarcity, rising prices, high interest rates, increased construction costs, labor shortages, and limited subsidies.

One commenter stated their concern with construction costs continuing to rise which impacts affordability on top of supply shortages for required materials such as windows, insulation, and other components. The commenter highlighted the fact that HUD's National Housing Market Summary for the first quarter of 2023 indicated that rising construction costs are expected to have an ongoing impact on the affordability of rental housing. Another commenter suggested that the agencies create a right of review on a case-by-case basis for builders unable to source required building materials.

HUD–USDA Response: HUD and USDA recognize that there were significant cost increases in certain construction materials resulting from specific COVID-related supply chain shortages, as well as inflation. The agencies have included a construction cost increase using the Bureau of Labor Statistics Producer Price Index (PPI) of 37 percent, as cited by the NAHB.[66] [67] This reflects cost increases for residential construction during the 2020–23 period. While this additional cost increase adds to the initial first cost of complying with the 2021 IECC, this does not impact the overall affordability of the investment, as shown in Tables 13–16 of this final determination.

With regard to material shortages including windows and insulation and

[64] HUD Builder Certification, *https://www.hud.gov/sites/dfiles/OCHCO/documents/92541.pdf.*

[65] *https://www.hud.gov/sites/dfiles/OCHCO/documents/92544.pdf.*

[66] BLS, Producer Price Index Commodity Data, One-Screen Data Search, *https://data.bls.gov/PDQWeb/wp.* [Under Select a Group, select ''IP Inputs to industries''; under Select one or more Items, select ''IP23110013 Inputs to residential construction, goods less foods and energy.''

[67] Building Materials Prices Fall for Second Month Straight, Eye On Housing, *https://eyeonhousing.org/2023/06/building-materials-prices-fall-for-second-month-straight/.*

their potential impact on builders' ability to comply with the latest editions of the codes, HUD and USDA recognize that some materials may be in short supply and may cause construction delays, but have been unable to determine the scale and scope of such shortages nationwide. In addition, the 2021 IECC and ASHRAE 90.1–2019 do not require specialized materials that are not already required for previous editions. According to one recent report, the hardest insulation material to procure has been polyiso insulation, a closed-cell, rigid foam board typically used for roofing—as a result of 2021's winter storm Uri that disrupted the supply chain of MDI, one of the raw materials that goes into polyiso insulation material.[68] That resulted in a shortage of insulation materials starting in February 2021. In other parts of the country, COVID–19 and transportation issues strained supply. However, the report cites industry sources report that lead times for items like fiberglass insulation and spray foam insulation have improved in recent months.

HUD and USDA recognize that shortages may arise as a result of COVID–19 supply chain issues. If shortages arise that prevent builders from meeting the IECC 2021 and ASHRAE 90.1–2019 requirements, builders should contact HUD or USDA with information on the product shortage. HUD and USDA will consider alternate materials based on the agencies' review of available materials. In addition, HUD and USDA will publish a list of possible material shortages and provide options for builders to comply with the codes.

H. Alignment With Green Building Standards and Alternate Compliance Paths

The preliminary determination noted that HUD and USDA currently provide incentives or require green building standards for some programs and their interest in maximizing alignment between the 2021 IECC and ASHRAE 90.1–2019 and these green building standards. Recognizing that there might be a lag time between the publication of the current editions of the IECC and ASHRAE 90.1 and their incorporation in these green building standards, the agencies requested comments on the current minimum IECC and ASHRAE 90.1 requirements in these standards, and/or the timetable for adopting the 2021 IECC and ASHRAE 90.1–2019 as baseline requirements.

One comment was received on the specific question of the baseline energy code established in third-party green building standards but several comments were submitted as to how these or other standards could be used as alternative compliance paths for the 2021 IECC and ASHRAE 90.1–2019 requirements of this notice. Several commenters who expressed their support for the preliminary determination provided suggestions for certification alternatives to meet the 2021 IECC and ASHRAE 90.1–2019 standards. One commenter emphasized that any alternative compliance pathways must enforce equivalent building envelope standards to those required by the 2021 IECC and ASHRAE 90.1–2019. One commenter stated that third-party certifications are an essential part of expanding access to HUD and USDA financing in markets where there may be a lack of certified inspectors or inspectors who are trained on an amended energy code that does not meet the program requirements.

1. Alternative Compliance Pathways

One commenter stated that third-party certifications are an essential part of expanding access to HUD and USDA financing in markets where there may be a lack of certified inspectors or inspectors who are trained on an amended energy code that does not meet the program requirements. Several commenters proposed that HUD and USDA accept specific green building or energy code standards. One commenter proposed an alternative compliance pathway of ENERGY STAR v3.1.

One commenter suggested HUD and USDA accept the following as alternative compliance pathways: ENERGY STAR Certified Homes, DOE Zero Energy Ready Homes, ANSI/RESNET/ICC standard 301, Enterprise Green Communities, ENERGY STAR Indoor Air Plus, LEED, Living Building Challenge, and Passive House. Multiple commenters proposed an alternative compliance pathway of the National Green Building Standards.

One commenter suggested HUD and USDA recognize the Home Energy Rating System (HERS) Index as an alternative compliance pathway. The commenter suggested adopting a threshold of a HERS Index Score of either 60, as used by Freddie Mac for their Single Family Green Mortgage-Backed Securities program, or 57 as the equivalent index to IECC 2021. Another commenter proposed an alternative compliance pathway of a HERS Index Score of 57 or lower.

One commenter suggested that HUD and USDA accept third-party energy and green building certifications as alternative energy compliance methods. Two commenters suggested that HUD and USDA move towards the adoption of an all-electric new construction standard to achieve zero carbon new homes for low- and moderate-income communities. The commenter suggested the adoption of the optional zero-emissions and zero-energy appendices of the 2024 IECC and adapt the appendixes for ASHRAE 90.1–2022.

One commenter suggested that HUD and USDA offer the ASHRAE 90.2–2018 standard as an alternative compliance pathway to the 2021 IECC standard as it provides more flexibility to satisfy local conditions and costs while delivering residential building energy performance that is approximately 50 percent less consumptive than the 2006 IECC standard and approximately 20 percent more energy efficient than the 2021 IECC standard.

HUD–USDA Response: HUD and USDA appreciate the range of recommendations for alternative compliance pathways suggested by the commenters. Most of these pathways conform to the requirements of meeting and exceeding the 2021 IECC and ASHRAE 90.1–2019. These are discussed below:

• *HERS Ratings.* With regard to the proposal to accept the HERS rating as an acceptable alternative, HUD and USDA recognize the important role that the HERS Index plays in rating new homes in the U.S. A recent RESNET report shows that 330,000 homes received a HERS rating in 2022. The commenter recommending adoption of the HERS Index pointed to two states, Massachusetts and Texas, that have adopted the HERS Index as an alternate compliance path. Texas has adopted a sliding scale for the HERS Index with graduated increases in efficiency from 2022 to 2028, with a HERS Index of 55–59 required after 2028 for Climate Zones 2,3,4. These scores are above (*i.e.,* less efficient than) the 2021 IECC ERI scores of 51–54 for these zones. Massachusetts, on the other hand, set the required HERS rating at 52, the same as the 2021 IECC.

These alternative HERS ratings do not include the mandatory requirements of the 2021 IECC; accordingly, HUD and USDA are not in a position to accept a HERS rating as an alternative to the 2021 IECC but do recognize the growing importance of this rating as a means to communicate energy performance better to homebuyers and encourage its use by builders. The HERS rating is also an integral part of the two federal above-

[68] Construction Dive, Construction's supply chain outlook: more shortages, price hikes ahead, November 2022 *https://www.constructiondive.com/news/supply-chain-construction-building-materials-price-2023/636442/.*

code standards of EPA's Energy Star for Homes and DOE's Zero Energy Ready Homes, which can earn the 45L tax credit of $2,500 and $5,000 respectively.

• *Zero Energy or Zero Energy Ready standards:* HUD and USDA are aware of the voluntary IECC zero emission appendix and the new zero energy appendix to ASHRAE 90.1–2022. While the statute that governs this notice does not allow the agencies to require an above-code zero energy standard or zero energy ready standard without an affordability or availability determination, the agencies encourage builders to consider building to the standards outlined in these appendices as published by the ICC and ASHRAE respectively. Adoption of the appendices is at the builder or developer's discretion.

Additionally, there are IRA funds that support solar and renewable energy installations including the Greenhouse Gas Reduction Fund and solar and renewable energy tax credits, which are refundable and offer greater incentives for low-income communities. HUD and USDA encourage builders to explore ways to utilize this financing to build zero energy homes that will, by lowering energy expenditures, assist homebuyers in achieving long-term homeowner financial sustainability.

• *Energy Star for New Construction.* Energy Star Version 3.1, the prevailing version of the standard that is nationally required by EPA as of January 2023, has been modeled to exceed the 2015–2018 IECC by approximately 10 percent, which on an overall performance basis is likely to be equivalent or equal to the 2021 IECC. However, the absence of specific thermal backstop requirements specified in the 2021 IECC excludes Version 3.1 from serving as a compliance pathway for the 2021 ICC. Version 3.2, however, takes effect January 2025, and will be accepted by HUD and USDA as an alternate compliance path. Similarly, Energy Star for Multifamily New Construction Version 1.2 will be accepted as an alternate compliance path.

• *DOE Zero Energy Ready Homes Program.* The DOE Zero Energy Ready Homes Program sets rigorous efficiency and performance criteria, with certified homes capable of offsetting most or all of the home's annual energy use through a renewable energy system. Single family homes must achieve Single Family Version 2 certification to be accepted as an alternate compliance path. Multifamily homes must achieve Multifamily Version 2 certification, which will be released on January 1, 2025, to be accepted as an alternate compliance path.

• *Green Building Standards.* As noted in the preliminary determination, HUD specifies a range of green building certifications through a range of programs, either as an incentive (the Green Mortgage Insurance Premium) or as a requirement (CDBG–DR). HUD and USDA will accept a Green Building Certification as a compliance pathway upon submission and approval by the agencies of evidence that the 2021 IECC and ASHRAE 90.1–2019; Energy Star Single Family New Construction Version 3.2 certification or Version 1.2 for Multifamily New Construction certification; or DOE Zero Energy Ready Homes Single Family Version 2 or, once released, Multifamily Version 2 have been established as minimum requirements.

2. Promoting Unvented Attic Spaces

Several commenters suggested HUD and USDA allow for the use of unvented attics, which provide builders with additional flexibility by enabling insulation with lower R-values and eliminating thermal losses from ductwork in unconditioned attic spaces. Two of these commenters suggested that HUD and USDA adopt the International Residential Building Code (IRC), which would replace existing references to the 1994 CABO Code and enable the use of unvented attics.

One commenter suggested that to promote the use of unvented attics, HUD and USDA adopt an alternative compliance pathway for insulating attics. The commenter suggested an alternative standard for unvented attics and enclosed rafter assemblies. This included lowering R values for ceiling insulation in Climate Zones 1–3 to R–22 and in Climate Zones 4–8 to R–26, requiring blower door tests results of less than 3.0 ACH50 for all climate zones, and other measures.

HUD–USDA Response: While significant efficiency gains can be achieved by locating all heating and cooling equipment in a property's conditioned space and providing for unvented attic space, the specific proposal recommended by the commenter would lower ceiling/roof insulation levels below those specified in the 2021 IECC and therefore cannot be accepted as part of the HUD and USDA determination. The agencies are not able to adopt amendments to the 2021 IECC and must establish the standard in full as is required by the statute.

Note that the reference by the commenter to the 1994 CABO is assumed to reference outdated code citations that have not been updated in HUD regulations; HUD anticipates removing any references to outdated codes in its regulations as part of its implementation of this standard.

3. Alignment With Existing State or Local Codes

One commenter suggested that HUD and USDA take local and state requirements into consideration when finalizing code requirements at the national level. Two comments were received on how the HUD and USDA requirements would align with adoption by states of the 2021 IECC with amendments. One commenter suggested that HUD and USDA accept the IECC code version adopted by the state where a project is located instead of requiring the 2021 IECC. Another commenter stated their concern that implementation of this proposed rule would leave many jurisdictions out of HUD and USDA programs, including three states that have adopted the 2021 IECC with amendments and would not be in compliance with this requirement.

HUD–USDA Response: HUD and USDA recognize that states considering IECC adoption may do so with either weakening or strengthening amendments. DOE's State Portal analyzes the impact of any amendments to the site energy index for the energy code adopted by each state. For example, Idaho adopted the 2018 IECC with amendments and DOE found these amendments to reduce the efficiency of the 2018 IECC to more closely resemble the 2009 IECC.

As of December 2023, 42 states and the District of Columbia have adopted some version of the IECC. Of these states, 33 have adopted the IECC with amendments. According to DOE's analysis, 24 of these amendments weaken the efficiency of the code, five do not substantially alter the efficiency of the code, and four improve the efficiency of the code.[69]

Of the 22 states that are shown by DOE to have adopted the 2009 IECC or its equivalent due to weakening amendments, two states have adopted the 2012 IECC with weakening amendments, six states have adopted the 2015 IECC with weakening amendments, nine states have adopted the 2018 IECC with weakening amendments, and one state have adopted the 2021 IECC with amendments that have been determined by DOE to be equivalent to a weaker code. The governing EISA-amended Cranston Gonzalez statute does not provide for the flexibility of amending

[69] State Portal, Building Energy Codes Program, *https://www.energycodes.gov/state-portal.* Based on update from 09/29/2023.

either code; the statute requires that all housing specified in the statute ''meet the requirements of the revised code or standard''. (42 U.S.C. 12709(d)). HUD and USDA recognize that many states adopted the codes with amendments; however, these amendments often impact the energy efficiency of the code. To comply with the final determination, all impacted HUD and USDA housing must meet or exceed the energy efficiency of the 2021 IECC or ASHRAE 90.1–2019 regardless of any amendments adopted to the code at the state level.

HUD and USDA acknowledge that the code adoption landscape has changed and will continue to change ahead of the final determination going into effect. Since the drafting of the preliminary determination, two states, Connecticut and New Jersey, have adopted the 2021 IECC as the state requirement. With this in mind, the estimated 150,000 single family homes and low-rise multifamily units and 16,550 high-rise multifamily units affected by this notice represents the approximate number of impacted homes based on average annual production from 2019 to 2021.

4. Proposed Alternative Prescriptive and Performance Compliance Pathways

One commenter proposed an alternative prescriptive compliance path framework. This alternative compliance path involves integrating the expected 2024 IECC ceiling insulation and wall insulation requirements into the 2021 IECC, as well as a credit system for prescriptive measures similar to that proposed for the 2024 IECC. The same commenter also proposed an alternative performance compliance framework for energy modeling software developers.

HUD–USDA Response: The commenter is proposing an approach that is not applicable for including in a federal determination. These amendments are more relevant to the code development process, which has been discussed in the 2021 and 2024 energy code update cycle, rather than the code adoption process.

The EISA statute requires HUD and USDA to adopt the code in full, meaning that the preliminary determination is not an opportunity to reevaluate the code package itself. HUD and USDA cannot specify an alternative code that deviates from the published and consensus-based model energy code, which has gone through a rigorous affordability and availability analysis in preparation for its proposed adoption. Both the proposed prescriptive and performance compliance path frameworks envision modifications to the 2021 IECC that have been proposed or adopted for the 2024 IECC, *e.g.,* realignment of ceiling and wall insulation requirements (Prescriptive Framework proposal 2), establishing requirements for energy modeling software for envelope backstops (Performance Framework proposal 3).

Once the 2024 IECC is published, it can serve as a viable alternative to the 2021 IECC for states who choose to adopt the new code as has been the case for states that have adopted versions beyond the 2009 IECC over the past decade. The proposed changes would require modifying the 2021 IECC in a manner that is inappropriate for this technical review of the 2021 IECC and ASHRAE 90.1–2019 standards. In addition, changes resulting from these proposed modifications to the modeling software would likely result in modifications to the requirements of the 2021 IECC; modifications to the 2021 IECC are beyond the scope of the statutory requirements that govern this notice. HUD has provided DOE with the performance modeling framework proposals for consideration in future code modeling.

I. Additional Comments

1. Veterans Administration Enhanced Loan Underwriting Methods

One commenter suggested that HUD and USDA add a provision for the recently enacted Department of Veterans Affairs (VA) enhanced loan underwriting methods to FHA and USDA mortgages.

HUD–USDA Response: This comment references recently enacted legislation requiring the VA to incorporate energy expenditures when underwriting VA loans (Consolidated Appropriations Act of 2023, Section 203. Enhanced Underwriting Methods (Pub. L. 117–238). While the legislation does not specify methodology for addressing energy efficiency, it will incorporate household energy expenditures into the Principal Interest Taxes Insurance (PITI) calculation. This is beyond the scope of this notice, which does not address underwriting methods. The agencies will track the VA initiative for lessons learned and applicability to HUD and USDA programs.

2. Incorrect Montana Data

One commenter suggested that the data utilized in the preliminary determination to produce the energy cost savings and financial impacts incorrectly utilized the 2009 IECC for the State of Montana instead of the 2021 IECC, which Montana adopted with exceptions for cost-prohibitive requirements based on state-specific variables and climate requirements in June 2022.

HUD–USDA Response: As noted in the preliminary determination, HUD and USDA use DOE–PNNL assessments of the effective or equivalent code adopted by a state after weakening amendments. In Montana's case, the state adopted the 2021 IECC with amendments that reduce the overall energy efficiency of the code by 10.4 percent. As such, DOE has determined that Montana's code functionally resembles the 2009 IECC.[70]

3. Inclusion of Greenhouse Gas Emissions

One commenter suggested that the RIA and the final determination should not consider the external social value of reducing emissions of greenhouse gases because the statute does not require its consideration. In contrast, another commenter suggested that the preliminary determination may understate the benefits associated with updating minimum efficiency requirements by not quantifying the non-energy benefits from improved efficiency as well as the total emissions reductions.

HUD–USDA Response. Pursuant to OMB requirements, the RIA includes estimated reduction of carbon emissions and associated savings in the social cost of carbon. However, HUD and USDA agree that the social impact of reducing carbon emissions is not relevant to the consumer affordability analysis required by the statute. The inclusion of these costs in the RIA is used to determine the larger benefits of this regulatory action, but they are not taken into account when considering the affordability and availability of the impacted housing.

4. Covered Housing vs. Existing Housing Stock

One commenter stated that the statute specifically requires HUD and USDA to make a determination that the revised codes do not negatively affect the availability or affordability of new construction, indicating that the availability of new construction specifically needs to be the point of analysis instead of the overall availability of the existing housing stock. This commenter stated that this is particularly important due to the outsized role new homes play in the current market, making up 31 percent of the housing stock.

HUD–USDA Response: With regard to considering the ''overall availability'' of the existing housing stock, it is not clear

[70] State Portal, Building Energy Codes Program, *https://www.energycodes.gov/state-portal.*

what item in the RIA or preliminary determination the commenter is referring to; both the RIA and the preliminary determination focused on the impact that this notice would have on the supply/production of new USDA–HUD financed housing, not on the availability of housing outside this stock.

The RIA does acknowledge purchase of an existing home as an alternative option; however, the availability analysis focuses on impacts to new construction as per the statute. As part of the analysis, it takes into account the broader economic impacts of the proposed standards. This perspective is included to demonstrate the substitutes available to buyers in the real world; however, existing homes are not considered as a central part of the availability analysis. HUD and USDA have modified the RIA.

5. Impact on Increased Sprawl

One commenter suggested that the preliminary determination does not accurately account for the potential increase in urban sprawl, which would increase travel-associated greenhouse gas emissions.

HUD–USDA Response: The commenter raises an important point regarding carbon emissions and the built environment: siting and location of housing will impact transportation carbon emissions, as discussed in the National Transportation Decarbonization Blueprint. Siting housing near transportation options or adjacent to schools, employment, services, and amenities will significantly lower Vehicle Miles Traveled (VMTs) and associated carbon emissions. However, this is outside the scope of this notice.

III. Final Determination—2021 IECC

A. Overview

The IECC is a model energy code developed by the International Code Council (ICC) through a public hearing process involving national experts for single family and low-rise residential buildings as well as commercial buildings.[71] The code contains minimum energy efficiency provisions for residential buildings, defined as single family homes and low-rise multifamily buildings (up to three stories). The code offers both prescriptive and performance-based approaches. The efficiency standards associated with the IECC set benchmarks for a structure's walls, floors, ceilings, lighting, windows, doors, duct leakage, and air leakage.

Revised editions of the IECC are typically published every three years. Full editions of its predecessor, the Model Energy Code, were first published in 1989, and new editions of the IECC were published every three years beginning in 1998. The residential portion of the IECC was heavily revised in 2004: the Climate Zones were completely revised (reduced from 17 Zones to the current eight primary Zones) and the building envelope requirements were restructured into a different format.[72] The post-2004 code became much more concise and simpler to use, but these changes complicate comparisons of State codes based on pre-2004 versions of the IECC to the more recent editions.

For single family housing, the IECC is one component of the larger International Residential Code (IRC). Each version of the IRC, beginning with the 2015 edition, has the corresponding version of the IECC embedded directly into that code (Chapter 11). A majority of states have adopted some version of the IRC. For other building types, including multifamily housing, the equivalent building code is the International Building Code (IBC), which also refers to other codes such as the International Plumbing Code, the International Electrical Code or, in this case, the IECC. Those codes also then embody or refer to other codes in the industry, such as ASHRAE 90.1. In this hub and spoke model, there is even more differentiation between states regarding which versions of which codes are adopted as a suite of codes at any given point in time. Even with the adoption of the IRC, the all-in-one code that is focused on single family housing, states and local areas sometimes make adjustments to the code, removing and in some cases adding requirements for some building elements.

1. Current HUD–USDA Standard and Subsequent Revisions

In May 2015, HUD and USDA published a Final Determination that established the 2009 IECC as the minimum standard for both new single family housing built with HUD and USDA assistance and new HUD-assisted or FHA-insured low-rise multifamily housing.[73] HUD and USDA estimated that 3,200 multifamily units and 15,000 single family units per year could potentially be impacted in the 16 states that had not yet adopted either of these codes. The average incremental cost of the higher standard was estimated to be $1,019 per unit, with average annual savings of $215, for a 5-year payback and a 1.3-year net positive cash flow. HUD and USDA determined that adoption of the 2009 IECC would not negatively impact the affordability and availability of the covered housing. The 2009 IECC represented a significant increase in energy efficiency of 7.9 percent and a 10.8 percent cost savings over the previous (2006) code.

Since HUD and USDA's adoption of the 2009 IECC, there have been four revisions to the IECC.[74] No action was taken by the prior Administration to comply with the statutory requirements to consider or adopt these updated codes.

The figure below shows the average national energy cost savings estimated with each version of the IECC. The greatest incremental savings come from the 2012 IECC (23.9 percent), followed by the 2009 IECC (10.8 percent over the 2006 IECC), followed by the 2021 IECC (8.7 percent). PNNL provided HUD with cost and benefit estimates for adopting the 2021 IECC from a baseline of the 2009 IECC and has made publicly available estimates for adopting the 2021 IECC from a 2018 IECC baseline. For states that have adopted standards equivalent to the 2012 or 2015 IECC, HUD and USDA use the estimates for the adoption from the 2018 to the 2021 IECC, as the 2012 and 2015 IECC both are closer to the 2018 IECC than the 2009 IECC.

[71] The IECC covers both residential and commercial buildings. States that adopt the IECC (or portions thereof) may choose to adopt the IECC for residential buildings only or may extend the code to commercial buildings (which include multifamily residential buildings of four or more stories). Chapter 4 of the IECC Commercial Code allows compliance with ASHRAE 90.1 as an optional compliance path.

[72] In the early 2000s, researchers at the U.S. Department of Energy's Pacific Northwest National Laboratory prepared a simplified map of U.S. climate zones. The map was based on analysis of the 4,775 U.S. weather sites identified by the National Oceanic and Atmospheric Administration, as well as widely accepted classifications of world climates that have been applied in a variety of different disciplines. This PNNL-developed map divided the United States into eight temperature-oriented climate zones. See *https://www1.eere.energy.gov/buildings/publications/pdfs/building_america/4_3a_ba_innov_buildingscienceclimatemaps_011713.pdf.*

[73] 80 FR 25901 (May 6, 2015).

[74] IECC 2012, 2015, 2018, and 2021.

Table 10. Incremental Energy Savings Associated with Each IECC Version – 2006 to 2021[75]

Year of code	Comparison year	National weighted energy cost savings (%)
2009	2006	10.8
2012	2009	23.9
2015	2012	0.7
2018	2015	2.0
2021	2018	8.7

Each successor edition since the 2009 IECC has increased energy efficiency and offered cost savings to consumers in varying degrees:

(1) The 2012 IECC was published in May 2011, representing a significant increase of 23.9 percent in energy cost savings over the 2009 IECC.[76] [77] Key changes in the 2012 edition included: increased stringency for opaque thermal envelope components; clarification that sun rooms enclosing conditioned spaces must meet the thermal envelope provisions; requirements for a blower door test to determine the air leakage rate and limits for the number of prescribed air changes per hour (ACH) per climate zone; insulation to at least R–3 for hot water piping; and an increase in the minimum number of high-efficacy electrical lighting sources from 50 percent to 75 percent of permanent fixtures or lamps in permanent fixtures.[78] [79] This translated into an estimated $500 or 32.1 percent annual cost savings per unit over the 2006 IECC.[80]

(2) The 2015 IECC was substantially the same as the 2012 edition, with a modest increase in energy efficiency of just 0.87 percent over the 2012 IECC.[81] Revisions in this edition included: revised provisions for existing buildings; removal of exemption for historic buildings; revised requirements for building envelope and duct leakage testing and hot water distribution efficiency. The most notable innovation was the introduction of a new Energy Rating Index (ERI) performance path that utilizes the Home Energy Rating System (HERS) Index.

(3) The 2018 IECC also saw limited changes to the prior edition. In its efficiency determination for the 2018 IECC, DOE found site energy savings over the prior code of just 1.68 percent; 1.91 percent source energy savings; and 1.97 percent annual energy cost savings.[82] Of the 47 changes in this edition, most were expected to have a neutral impact on energy efficiency, with two changes making up most of the energy savings associated with the updated code: (1) lower fenestration U-factors in Climate Zones 3 through 8, and (2) an increase in high-efficacy lighting from 75 percent to 90 percent of permanently installed fixtures in all climate zones.

2. 2021 IECC—Overview

As required by statute, this notice addresses the most recent edition of the IECC, the 2021 IECC.[83] In its efficiency determination for this standard, DOE determined that this edition would result in significant savings relative to the 2018 IECC: 9.4 percent savings in annual site energy use intensity (EUI); 8.8 percent in annual source EUI; 8.7 percent in annual energy cost savings; and 8.7 percent reduction in carbon emissions.[84] The 2021 standard will yield a national weighted energy cost savings of 34.4 percent over the current USDA–HUD baseline 2009 standard.

In their qualitative assessment of the code, PNNL identified a total of 114 approved code changes or addenda in this edition of the code over the prior edition, of which 35 will have a direct impact on energy use in residential buildings. Of these, 29 are expected to reduce energy use, while six are expected to increase energy use.[85]

The following are the primary technical changes in the 2021 IECC over the previous edition:

• *Building Envelope.* Building envelope revisions include increased insulation requirements; more efficient U factors and Solar Heat Gain Coefficients (SHGCs) for windows and fenestration; maximum air leakage rate of 5 Air Changes per Hour (ACH) at 50 pascals for all compliance paths, with 3 ACH for Climate Zones 3–8 following the prescriptive path. Testing alternatives are provided for smaller homes and attached single family and multifamily buildings.[86]

[75] Sources: DOE, 2012: *https://www.pnnl.gov/main/publications/external/technical_reports/PNNL-22068.pdf;* 2015: *https://www.energycodes.gov/sites/default/files/2021-07/2015_IECC_FinalDeterminationAnalysis.pdf;* 2018: *https://www.energycodes.gov/sites/default/files/2021-07/EERE-2018-BT-DET-0014-0008.pdf,* 2021: *https://www.regulations.gov/document/EERE-2021-BT-DET-0010-0006.*

[76] U.S. Department of Energy, ''*Updating State Residential Building Energy Efficiency Codes: notice of Final Determination.*'' 77 FR 29322 (May 17, 2012). *http://www.gpo.gov/fdsys/pkg/FR-2012-05-17/pdf/2012-12000.pdf.*

[77] Pacific Northwest National Laboratory, *Cost-Effectiveness Analysis of the 2009 and 2012 IECC Residential Provisions—Technical Support Document,* U.S. Department of Energy, PNNL–22068, April 2013. *https://www.pnnl.gov/main/publications/external/technical_reports/PNNL-22068.pdf.*

[78] Pacific Northwest National Laboratory, *Guide to the Changes between the 2009 and 2012 International Energy Conservation Code,* U.S. Department of Energy, PNNL–21435, May 2012. *http://www.pnnl.gov/main/publications/external/technical_reports/PNNL-21435.pdf.*

[79] Pacific Northwest National Laboratory, *Energy savings for a Typical New Residential Dwelling Unit Based on the 2009 and 2012 IECC as Compared to the 2006 IECC,* Letter Report, PNNL–88603, April 2013, Table 1.

[80] Pacific Northwest National Laboratory, *Cost-Effectiveness Analysis of the 2009 and 2012 IECC Residential Provisions—Technical Support Document,* U.S. Department of Energy, PNNL–22068, Tables 8.1 and 8.4, April 2013.

[81] U.S. Department of Energy, *Determination Regarding Energy Efficiency Improvements in the 2015 International Energy Conservation Code,* 80 FR 33250 (June 11, 2015), *https://www.federalregister.gov/documents/2015/06/11/2015-14297/determination-regarding-energy-efficiency-improvements-in-the-2015-international-energy-conservation.*

[82] DOE, ''*Final Determination Regarding energy efficiency Improvements in the 2018 International Energy Conservation Code,*'' 84 FR 67435 (Dec. 10, 2019), *https://www.federalregister.gov/documents/2019/12/10/2019-26550/final-determination-regarding-energy-efficiency-improvements-in-the-2018-international-energy;* also PNNL for DOE, *Energy Savings Analysis: 2018 IECC for Residential Buildings,* November 2019, *https://www.energycodes.gov/sites/default/files/2021-07/EERE-2018-BT-DET-0014-0008.pdf.*

[83] International Code Council, *2021 International Energy Conservation Code,* January 29, 2021. *https://codes.iccsafe.org/content/IECC2021P1.*

[84] 86 FR 40529 (July 28, 2021), *Analysis Regarding Energy Efficiency Improvements in the 2021 International Energy Conservation Code (IECC) https://www.federalregister.gov/documents/2021/07/28/2021-15969/analysis-regarding-energy-efficiency-improvements-in-the-2021-international-energy-conservation-code;* also PNNL, *Preliminary Energy Savings Analysis: 2021 IECC for Residential Buildings,* April 2021, *https://www.energycodes.gov/sites/default/files/2021-07/2021_IECC_PreliminaryDetermination_TSD.pdf.*

[85] 79 additional changes were determined to be administrative or impact non-energy portions of the code.

[86] AMCA International, *International Energy Conservation Code: 2021 Changes, Getting Involved in the 2024 Process,* May 5, 2021, *https://*

Continued

• *Heating, Ventilation and Air Condition (HVAC).* Mechanical ventilation in Climate Zones 7 and 8 provided by a Heat Recovery Ventilator (HRV) or Energy Recovery Ventilator (ERV) is required for the prescriptive compliance path.[87]

• *Additional Efficiency Options.* Additional efficiency options in the 2021 IECC include an enhanced envelope performance option—a 5 percent improvement in proposed home UA value (R408.2.1); a more efficient HVAC equipment option (highlighted above); a reduced energy use in service water heating option 0.82 EF for fossil fuel, 2.0 EF for electric fuels or 0.4 solar fraction water heater (R405.2.3); a more efficient duct thermal distribution system option—100 percent of ducts in conditioned space or ductless systems (R405.2.4); and an improved air sealing and efficient ventilation option—air leakage at 3.0 ACH50 with ERV or HRV with 75 percent Sensible Recovery Efficiency (SRE) (R405.2.5).

• *Lighting Changes.* The efficacy value of high-efficacy lamps increases to 70 lumens/watt (100 percent of lighting), a 10 percent increase over the 2018 standard.

• *Renewables.* The 2021 IECC revises the definition for ''on-site renewables'' for consistency with other national standards; adds a definition for biogas and biomass; and requires that Renewable Energy Certificates (RECS) be retired with the homeowner when using the ERI compliance approach.[88]

• *Zero Energy Appendix.* In addition to these technical changes, the 2021 IECC includes, for the first time, a Zero Energy Appendix that requires compliance with an ERI score without renewables and then achieving an ERI score of ''0'' with renewables. This provides jurisdictions with an opportunity to adopt a base or stretch code that achieves zero energy in homes and low-rise multifamily buildings.[89]

• *Building Electrification.* While the 2021 IECC did not include building electrification provisions in the final version of the code, provisions are available for adoption by states as amendments to the 2021 IECC: RE147–19, Electrification-Ready; RE126–19, Energy Efficient Water Heating; RE107–19, Eliminate Continuous Burning Pilot Light.

• *Compliance Pathways.* There are three compliance pathways in the 2021 IECC: Prescriptive, Performance, and Energy Rating Index or ERI, which reverted to IECC 2015 levels. The prescriptive paths can follow the R-value minimum table, the U-Factor equivalent table, or the UA equivalent alternative. All compliance pathways now have required Additional Efficiency Options (AEOs) to achieve five percent greater energy efficiency than base levels. The 2021 IECC lowers the performance path ERI scores compared to the 2018 IECC.

3. Current State Adoption of the 2021 IECC

There is typically a lag time between the publication of a new edition of the IECC and state adoption of the code: Table 11 and Figure 1 show that, as of December 2023, while all but eight states have adopted a version of the IECC, only five states (California, Washington, Vermont, New Jersey, and Connecticut) have adopted the 2021 IECC or its equivalent.[90]

Overall, 41 states plus the District of Columbia have adopted a version of the code that is equivalent to or higher than the current HUD and USDA standard of the 2009 IECC. Of these, only 18 states plus the District of Columbia have adopted a code above the 2009 IECC (the 2018 IECC, the 2015 IECC, or equivalent to the 2021 IECC),[91] while 23 states have set their codes at the 2009 IECC or its equivalent. The remaining 9 states have either adopted standards that pre-date the 2009 IECC (1 state) or have no state-wide codes (8 states).

Based on historical experience and the continued consideration or adoption of the 2021 IECC by states, it is anticipated that over time additional states are likely to adopt the 2021 IECC, either as published by the ICC or with amendments.

www.amca.org/assets/resources/public/assets/uploads/FINAL-_ICC_Webinar-_presentation_May_5__2021.pdf.

[87] Northeast Energy Efficiency Partnerships, *Key Changes in the 2021 IECC for the Northeast and Mid-Atlantic, https://neep.org/sites/default/files/media-files/2021_iecc_one-pager_.pdf.*

[88] New Buildings Institute, *2021 IECC National Model Energy Code (Base Codes). https://newbuildings.org/code_policy/2021-iecc-base-codes/.*

[89] Ibid.

[90] California's Title 24 2019 Building Energy Efficiency standard, Washington's 2018 State Energy Code, and Vermont's amendments to the 2018 IECC were determined to meet or exceed the 2021 IECC.

[91] PNNL, *State Level Residential Codes Energy Use Index, FY 2023Q2,* Excel File at *https://www.energycodes.gov/state-portal.*

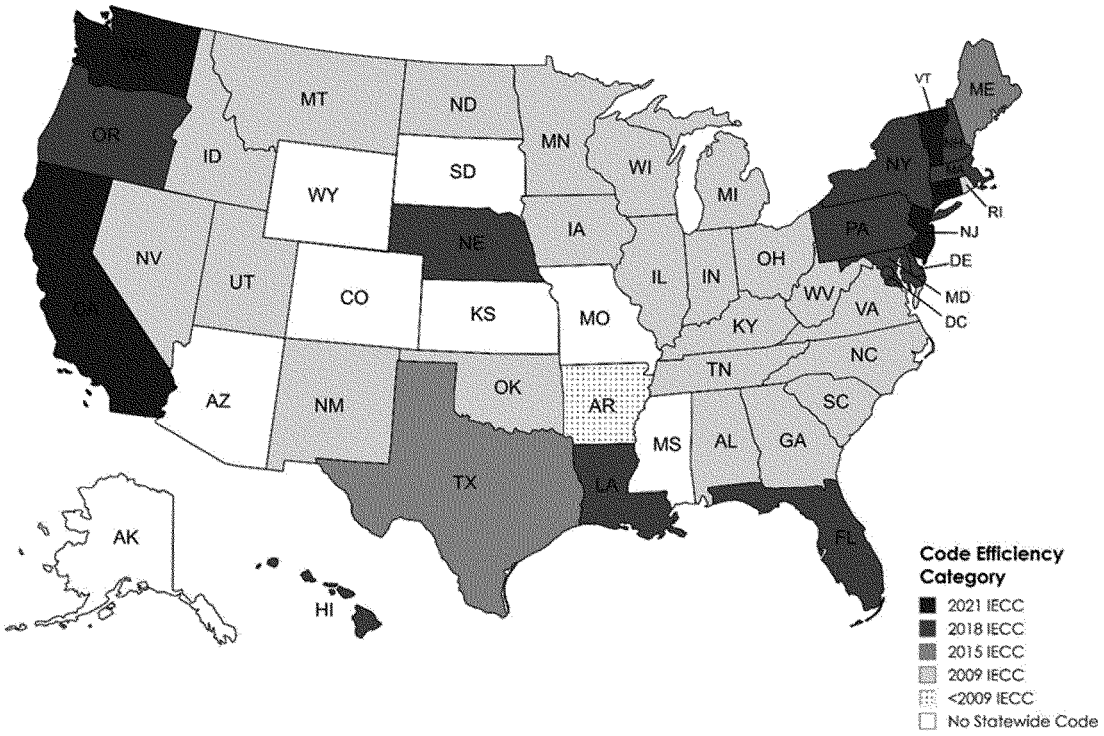
Table 11. Current State Adoption of the IECC (As of December 2023)

Above Current HUD and USDA Standard (18 states + DC)	
2021 IECC or Equivalent (5)	
California	Vermont
Connecticut	Washington
New Jersey	
2018 IECC or Equivalent (11 states + DC)	
Delaware	Massachusetts
District of Columbia	Nebraska
Florida	New Hampshire
Hawaii*	New York
Louisiana	Oregon
Maryland	Pennsylvania
2015 IECC or Equivalent (2)	
Maine	Texas
Current HUD and USDA Standard (23 States)	
2009 IECC or Equivalent	
Alabama	North Carolina
Georgia	North Dakota
Idaho	Ohio
Illinois	Oklahoma
Indiana	Rhode Island
Iowa	South Carolina
Kentucky	Tennessee
Michigan	Utah
Minnesota	Virginia
Montana	West Virginia
Nevada	Wisconsin
New Mexico	
Older than 2009 IECC Or No Statewide Codes (9 States)	
Equivalent to Less Than 2009 IECC (1)	
Arkansas	
Home Rule/No statewide code (8)	
Alaska	Mississippi
Arizona*	Missouri
Colorado	South Dakota
Kansas	Wyoming
U.S. Territories	
American Samoa – No Code	N. Mariana Islands (2003 IECC equivalent)
Guam – 2009 IECC	Puerto Rico (2011 PR Building Standard)
U.S. Virgin Islands – 2009 IECC	

*A review of the codes in place across the state indicates that 86 percent (Hawaii) and 82 percent (Arizona) of the population is covered by codes at this level.

This tabulation is drawn from DOE's tracking of state adoptions of the IECC, available at DOE's state portal at *https://www.energycodes.gov/state-portal.* For the purpose of this notice, HUD and USDA rely on the December 2023 update of the status map maintained by DOE at this site. Figure 1 displays the state IECC adoption status shown in Table 11.

Figure 1. IECC Adoption Map (Residential)
Status as of December 2023



Note that states often adopt amendments to the code as published by the ICC. In some cases, these amendments will sufficiently alter the IECC code as published, such that the energy performance of buildings meeting the amended code provisions may be equivalent to that of a prior code.

The DOE code adoption map and the adopted codes listed in Table 11 reflect DOE/PNNL's analysis of state adopted codes (including amendments) and associated assessment of their IECC code equivalent. Accordingly, 18 states have adopted the 2012, 2015, 2018, or 2021 IECC with amendments and were determined by PNNL to be equivalent to the 2009 IECC. These are therefore shown in Table 11 and Figure 1 as at the 2009 IECC level.[92] Additionally, DOE provides an analysis of the energy use index of each state-adopted code on their state portal.[93]

Ohio, for example, adopted the 2018 IECC with amendments to basement and crawl space wall R-values, air leakage rates and the allowance to utilize framing cavities as return ducts.[94] DOE/PNNL determined that the Ohio code as adopted with amendments is equivalent to the 2009 IECC.[95] New Mexico adopted the New Mexico Energy Conservation Code, based on the 2018 IECC, with state-specific amendments which were determined by DOE/PNNL to yield a performance standard equivalent to the 2009 IECC. On the other hand, if the new code is less than one percent more efficient than the prior code then DOE counts the newer code as equivalent to the previous code. California has adopted its own standard, Title 24, which DOE has determined meets or exceeds the 2021 IECC.

In certain cases, home rule cities or counties within a State may adopt a different code from the rest of the State. For example, Austin, Texas has adopted the 2021 IECC energy code, thereby exceeding the minimum Texas statewide code of the 2015 IECC.[96] In instances where a local entity has a more stringent standard, the affordability impacts within a State will differ.[97]

4. Estimated Impacts

Table 12 provides an estimate of the average number of units that may be impacted annually by adoption of the 2021 IECC. HUD and USDA used prior-year production for these programs in order to estimate future annual production for these programs.[98] Based on average annual production for the three year 2019–21 period, the agencies estimate that a total of approximately 161,700 units of HUD- and USDA-financed or insured housing may be impacted by the 2021 IECC, of which 150,227 are in the 45 states plus DC and U.S. territories that have not yet adopted this standard.

[92] The 23 states deemed equivalent to the 2009 IECC are: AL, GA, ID, IL, IN, IA, KY, MI, MN, MT, NV, NM, NC, ND, OH, OK, RI, SC, TN, UT, VA, WV, WI. See Table for a listing of these code equivalents at *https://www.energycodes.gov/state-portal* and ''Reidential State Level Results'' Excel file at ''Available Data'' for detailed DOE/PNNL analysis.

[93] DOE, *State Portal, https://www.energycodes.gov/state-portal.*

[94] ACEEE, State Scorecard Ranking, *https://database.aceee.org/state/ohio.*

[95] See ''Residential State Level Results'' at *https://www.energycodes.gov/state-portal.*

[96] City of Austin, Building Technical Codes. *https://www.austintexas.gov/department/building-technical-codes.*

[97] HUD and USDA do not maintain a list of local communities that may have adopted a different code than their state code. See ACEEE, State and Local Policy Database for codes adopted by individual cities. *https://database.aceee.org/city/energy-code-stringency.*

[98] Three-year averages were used (2019–21) for all programs, except for public housing which used four-year 2016–2020 averages since limited data were available for the three-year period. Prior-year production data provided by program offices using internal tracking or reporting systems.

Table 12. Estimated Number of Units Impacted Annually by 2021 IECC[99]

State or Territory	FHA Single Family	USDA Guaranteed Loan Program	USDA Direct Loan Program	FHA Single Family – Condos	Public Housing	HOME	Housing Trust Fund	RAD	Low-Rise Multi-family	Total
AK	42	27	19	3	0	35	19	25	0	170
AL	1,975	611	27	0	52	60	0	0	321	3,046
AR	1,024	453	52	0	0	145	12	16	164	1,866
AZ	4,595	391	90	54	0	97	0	38	432	5,697
CA (2021)	5,629	136	339	803	12	880	0	12	166	7,977
CO	2,701	151	42	65	13	199	1	10	682	3,864
CT (2021)	70	9	0	7	23	42	0	0	125	276
DC	17	0	0	8	12	0	0	0	137	174
DE	584	179	25	20	0	5	0	48	0	860.5
FL	19,178	1,119	189	24	146	366	87	21	1,477	22,607
GA	7,977	731	45	17	32	139	0	0	795	9,736
HI	77	61	39	40	3	33	0	0	0	253
IA	224	44	5	0	0	16	5	0	0	294
ID	812	134	13	0	0	56	29	73	11	1,128
IL	750	10	2	4	35	96	0	0	404	1,301
IN	1,890	205	137	1	0	121	0	0	49	2,403
KS	161	29	1	0	0	39	30	0	55	315
KY	798	277	66	13	0	71	0	2	188	1,415
LA	2,181	1,036	42	0	12	189	2	3	124	3,589
MA	174	7	7	11	0	20	0	35	491	745
MD	2,073	171	5	150	0	143	0	0	849	3,391
ME	116	48	16	0	0	40	30	24	15	288.5
MI	227	73	32	234	16	93	0	0	102	777
MN	542	99	16	1	3	120	0	5	607	1,393
MO	896	306	6	2	0	236	2	0	444	1,892
MS	1,048	304	43	2	1	0	0	0	0	1,398
MT	120	50	22	0	0	35	3	21	68	318.5
NC	4,977	1,211	165	2	7	724	25	0	1,321	8,432
ND	112	14	1	0	0	27	13	0	0	167
NE	177	9	1	0	0	17	0	0	297	501
NH	69	5	1	2	0	50	6	46	106	285
NJ (2021)	477	8	3	43	42	151	0	0	50	774
NM	751	21	26	0	0	11	15	12	115	950.5
NV	1,642	52	6	101	4	408	3	1	92	2,309

State or Territory	FHA Single Family	USDA Guaranteed Loan Program	USDA Direct Loan Program	FHA Single Family – Condos	Public Housing	HOME	Housing Trust Fund	RAD	Low-Rise Multi-family	Total
NY	233	5	6	3	15	262	0	27	1,445	1,996
OH	1,339	51	17	25	10	229	0	0	105	1,776
OK	1,464	288	41	0	0	34	13	10	81	1,931
OR	703	127	31	22	0	142	12	30	38	1,105
PA	697	78	13	4	43	90	0	0	85	1,010
RI	64	0	3	1	0	3	23	2	35	130.5
SC	4,169	992	87	3	0	44	0	0	236	5,531
SD	148	49	16	1	0	124	75	37	12	461.5
TN	3,355	644	55	9	2	39	30	103	751	4,988
TX	32,070	1,670	98	325	83	243	57	0	6,684	41,230
UT	1,679	417	127	103	0	7	0	17	476	2,826
VA	2,119	416	71	178	12	85	45	0	924	3,850
VT (2021)	10	4	2	0	0	59	24	0	9	108
WA (2021)	1,529	128	81	45	15	107	6	31	413	2,355
WI	168	24	7	0	5	85	0	0	173	462
WV	298	221	3	0	0	12	10	5	71	620
WY	55	32	3	0	0	16	1	0	18	125
Territories										
Guam			8			18				26
Mariana Isl.			9			3				12
Puerto Rico	186	284	53		53	5				581
Total	**114,372**	**13,411**	**2,214**	**2,326**	**651**	**6,271**	**578**	**645**	**21,243**	**161,711**
45 states	106,657	13,126	1,789	1,478	559	5,032	548	611	20,480	150,227

Table 12 includes both single family and low-rise multifamily housing. Of the total, in the 45 states and the U.S. territories that have not yet adopted the 2021 IECC, approximately 106,650 units are estimated to be FHA-insured new single family homes; approximately 13,100 units are USDA Section 502 direct loans, and 1,800 units are Section 502 guaranteed loans. The remaining single family units are financed through the HOME program (5,000 units), HUD's Public and Indian Housing (PIH) programs (approximately 600 units through the Choice Neighborhoods and Capital Fund Financing Programs), and 500 units through the Housing Trust Fund program. Also included in Table 12 are some 20,200 FHA-insured multifamily housing units financed with FHA multifamily insurance that are estimated to be low-rise multifamily and therefore covered under the 2021 IECC.[100] When adjusted to exclude units in states that have already adopted codes equivalent to the 2021 IECC (California, Connecticut, New Jersey, Vermont, Washington), the total potential number of estimated units potentially impacted decreases to around 150,000 units.

Note that the volume of estimated production is not evenly distributed across the states but reflects historic demand for FHA and USDA financing for one or more of the agencies' programs: two states, Texas (24 percent) and Florida (14 percent), account for almost 40 percent of potentially impacted units based on prior-year production. As noted above, Austin, Texas, has already adopted the 2021 IECC, as have 86 other Texas home-rule jurisdictions albeit often with amendments. Given Texas and Florida have passed more current iterations of the IECC since 2009, and one or more areas of Texas is IECC 2021 compliant, it is possible builders will be more adaptable to constructing in accordance with the 2021 IECC. Along with Georgia (6 percent), North Carolina (6 percent) and California (5 percent), five states account for more than half of all potentially impacted units (56 percent). Note that historical production is used as a guide to future production; actual state by state unit counts in the future may vary from these estimates, based on actual supply and demand.

[99] Estimated count of impacted units does not include the Project-Based Voucher program. There is insufficient data on the annual use of this program for new construction. Additionally, it is likely that, in most cases, Project-Based Vouchers are used for new construction projects that also rely on one or more of the other programs included in this table.

[100] In order to derive the number of low-rise multifamily units, the following assumptions were made: for FHA units, 50 percent of all multifamily units are assumed to be low-rise; for public housing units, all units coded as ''multifamily/walkup apartments'' are assumed to be low-rise; and for HOME units, all units in multifamily developments with less than 100 units are assumed to be low-rise, as well as 50 percent of all units in developments with more than 100 units.

B. 2021 IECC Affordability Analysis

In this notice, HUD and USDA address two aspects of housing affordability in assessing the impact that the revised code will have on housing affordability. As described further below, the primary affordability test is a life-cycle cost savings (LCC) test, *i.e.,* the extent to which the additional, or incremental, investments required to comply with the revised code are cost effective inasmuch as the additional measures pay for themselves with energy cost savings over a typical 30-year mortgage period. A second test is whether the incremental cost of complying with the code as a share of total construction costs—regardless of the energy savings associated with the investment—is affordable to the borrower or renter of the home.

Note that there may be other benefits associated with energy efficient building codes in addition to energy cost savings. These include increased resilience against extreme temperature events, the potential for lowering mortgage defaults, and lowering the disproportionate energy burden for low-moderate income households. In addition, studies show that added energy efficiency may also yield improved health outcomes.[101]

A 2023 study from PNNL found that energy efficiency measures improve the habitability of single family buildings during extreme cold and extreme heat events by up to 120 percent and 140 percent, respectively.[102] With the frequency and intensity of extreme weather events, particularly heatwaves, expected to increase, the improved resilience of energy efficient buildings will save lives. In 2020, 34 million U.S. households, or 27 percent of all households, reported difficulty paying their energy bills or kept their homes at an unsafe temperature because of energy cost concerns, according to the Energy Information Administration.[103] In some cases, homes perform so poorly that the energy bills impact spending choices about allocating financial resources for other necessities, like food, clothing, transportation, and medical care.[104] Excessive energy bills can create a snowball effect, leading to mortgage defaults, missed opportunities to participate in job training and educational opportunities, and family separations, ultimately increasing wealth inequality. Poor-performing homes can even cause physical harm and death in extreme heat and cold events during power outages.[105]

Another benefit may be the potential for lower mortgage defaults associated with improved energy efficiency. A study by the University of North Carolina (UNC) Center for Community Capital and the Institute for Market Transformation (IMT) shows a correlation between greater energy efficiency and lower mortgage default risk for new homes. The UNC study surveyed 71,000 Energy Star-rated homes and found that mortgage default risks are 32 percent lower for these more energy efficient homes than homes without Energy Star ratings.[106]

1. Cost Benefit Analysis and Results

The baseline analysis used for this Determination is the PNNL study prepared for DOE, *National Cost Effectiveness of the Residential Provisions of the 2021 IECC,* published in June 2021. This analysis estimates annual energy and cost savings as well as life-cycle cost (LCC) savings that assume initial costs are mortgaged over 30 years.[107] The study provides an assessment of both the initial costs as well as the long-term estimated savings and cost-benefits associated with complying with the 2021 IECC.

HUD and USDA have adopted a modified version of the DOE methodology. These modifications include adding a supply chain cost increase factor and energy price increase factor to adjusted for inflation from 2020 to 2023 as well as cost and savings adjustment factors that reflect the smaller FHA home relative to the prototypes used in the PNNL model. Additionally, one difference in this approach is that it does not take into account replacement costs or residual value, which are factored in for the PNNL model. The RIA explains the reasoning for this difference on page 25. The modifications to the DOE methodology have been included to respond to public comments that the HUD-USDA analysis take into account current market and economic conditions as well as the specific features of HUD-USDA financing and characteristics of the FHA-USDA borrower.

The LCC method used by DOE And adapted by HUD and USDA for this final determination is a ''robust cost-benefit metric that sums the costs and benefits of a code change over a specified time frame. LCC is a well-known approach to assessing cost-effectiveness'' [108] and reflects extensive prior public comment and input. In September 2011, DOE solicited input on their proposed cost-benefit methodology [109] and this input was incorporated into the final methodology posted on DOE's website in April 2012 and further updated in August 2015.[110] [111]

For this analysis, DOE calculates energy use for new homes using EnergyPlusT energy modeling software, Version 9.4.[112] Two buildings are simulated: (1) a two-story single family home, with 2,376 square feet of conditioned floor area, excluding the conditioned basement (if any), and a window area equal to 15 percent of the conditioned floor area; and (2) a low-rise apartment building (a three-story multifamily prototype with six 1,200 square-foot dwelling units per floor) with a window area of approximately 23 percent of the exterior wall area. DOE combines the results into a composite average dwelling unit based on Census building permit data for each state and for eight Climate Zones. Single family home construction is more common than low-rise multifamily construction;

[101] See, for example, DOE, Jonathan Wilson et al, Home Rx: *The Health Benefits of Home Performance,* December 2016; HUD, *BRIGHT Study Finds Improved Health at Boston Housing Authority's Old Colony Homes, https://www.huduser.gov/portal/casestudies/study-05042017.html.*

[102] Franconi, E, E Hotchkiss, T Hong, M Reiner et al. 2023. *Enhancing Resilience in Buildings through Energy Efficiency.* Richland, WA: Pacific Northwest National Laboratory. PNNL–32737, Rev 1.

[103] Energy Information Administration, *https://www.eia.gov/todayinenergy/detail.php?id=51979.*

[104] *https://fahe.org/wp-content/uploads/Summary-of-Issues-Facing-Rural-Housing-V1.2.pdf.*

[105] National Institutes of Health, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10249403/.*

[106] UNC Center for Community Capital, Institute for Market Transformation, ''Home Energy Efficiency and Mortgage Risks,'' March 2013, Available at: *http://www.imt.org/uploads/resources/files/IMT_UNC_HomeEEMortgageRisksfinal.pdf.*

[107] PNNL, Salcido et al, *National Cost Effectiveness of the Residential Provisions of the 2021 IECC,* June 2021. *https://www.energycodes.gov/sites/default/files/2021-07/2021IECC_CostEffectiveness_Final_Residential.pdf.*

[108] Department of Energy, *National Energy and Cost Savings for new Single- and Multifamily Homes: A Comparison of the 2006, 2009 and 2012 Editions of the IECC.* April 2012, p. A–1, *https://www.energycodes.gov/sites/default/files/2020-06/NationalResidentialCostEffectiveness_2009_2012.pdf.*

[109] 76 FR 56413 (Sep. 13, 2011).

[110] Pacific Northwest National Laboratory for the Department of Energy (Z. Taylor, R. Lucas, N. Fernandez) *Methodology for Evaluating Cost-Effectiveness of Residential Energy Code Changes.* April 2012. Available at: *http://www.energy.sc.gov/files/view/Taylor%202012.pdf.*

[111] Pacific Northwest National Laboratory for the Department of Energy (V. Mendon, R. Lucas, S. Goel), *Cost-Effectiveness Analysis of the 2009 and 2012 IECC Residential Provisions—Technical Support Document. April 2013,* Available at *https://www.pnnl.gov/main/publications/external/technical_reports/PNNL-22068.pdf.*

[112] Pacific Northwest National Laboratory for the Department of Energy (Z. Taylor, V. Mendon, N. Fernandez), *Methodology for Evaluating Cost-Effectiveness of Residential Energy Code Changes,* August 2015, *https://www.energycodes.gov/sites/default/files/2021-07/residential_methodology_2015.pdf.*

the results are weighted accordingly to reflect this for each Climate Zone as well as each state.

Four heating systems are considered for modeling the energy savings in these building prototypes: natural gas furnaces, oil furnaces, electric heat pumps, and electric resistance furnaces. The market share of heating system types is obtained from the U.S. Department of Energy Residential Energy Consumption Survey (2015). Domestic water heating systems are assumed to use the same fuel as the space heating system.

2. Limitations of Cost Savings Models

HUD and USDA are aware of studies that discuss limitations associated with cost-savings models such as those developed by PNNL for DOE. For example, Allcott and Greenstone suggest that ''it is difficult to take at face value the quantitative conclusions of the engineering analyses'' associated with these models, as they suffer from several empirical problems. The authors cite two problems in particular. First, engineering costs typically incorporate upfront capital costs only and omit opportunity costs or other unobserved factors. For example, one study found that nearly half of the investments that engineering assessments showed in energy audits for medium-size businesses that would have short payback periods were not adopted due to unaccounted physical costs, risks, or opportunity costs. Second, engineering estimates of energy savings can overstate true field returns, sometimes by a large amount, and some engineering simulation models have still not been fully calibrated to approximate actual returns.[113] HUD and USDA nevertheless believe that the PNNL-DOE model used to estimate the savings shown in this notice represents the current state-of-the art for such modeling, is the product of significant public comment and input, is now the standard for all of DOE's energy code simulations and models, and presents a reliable and validated methodology for estimating energy code costs and benefits.

3. Estimated Costs and Savings

For all 50 states and the District of Columbia, DOE estimates that for a weighted average of both single family and low-rise multifamily housing, the 2021 IECC saves 9.38 percent of energy costs for heating, cooling, water heating, and lighting over the 2018 IECC.[114] For the purposes of this notice, DOE provided HUD and USDA with a special tabulation that disaggregates this analysis into each building type (single family and low-rise multifamily). The disaggregated data are shown in Tables 13 (single family) and 14 (low-rise multifamily) for the following data points: LCC savings, incremental cost, annual mortgage increase, down-payment and other up-front costs, net first year annual cash flow, years to positive cash flow, and simple payback for the 2021 IECC in relation to the current HUD and USDA baseline of the 2009 IECC. Tables 13 and 14 provide both national average costs and benefits, as well as for each climate zone.

The United States has eight Climate Zones, further subdivided to represent moist, dry, or marine climates, that are listed here: 1A Very hot humid; 2A Hot Humid; 2B Hot Dry; 3A Warm Humid; 3B Warm Dry; 3C Warm Marine; 4A Mixed Humid; 4B Mixed Dry; 4C Mixed Marine; 5A Cool Humid; 5B Cool Dry; 6A Cold Humid; 6B Cold Dry; 7 Very Cold; and 8 Subarctic/Arctic. Zone 1 includes Hawaii, Guam, Puerto Rico, and the Virgin Islands. Almost all of Alaska is in Zone 7.[115]

Tables 13 and 14 show the economics of adopting the 2021 IECC nationally and in each Climate Zone, relative to the 2009 IECC baseline. Table 15 shows costs and savings against the 2018 IECC baseline. Data points provided include, incremental or first costs, annual energy savings, increased debt service on a thirty-year mortgage, estimated down payment and closing costs, net annual cash flow in the first year, and simple payback on the initial investment.[116]

4. Analysis of Adopted State Energy Codes for Residential Buildings

The Department of Energy assesses the energy code adopted by each state, considering the impact of any included amendments to the original IECC code. This analysis can be found in the ''residential state-level results'' available for download at *https://www.energycodes.gov/state-portal.* The analysis shows the energy index, which is the modeled energy use based on the adopted energy code, for the adopted code of each state as well as multiple versions of the IECC. A comparison of the energy index for the IECC code and any state-adopted version with amendments demonstrates the impact of amendments to the code on energy efficiency.

5. Incremental or Added Costs

Tables 13 shows the average per-unit incremental cost of adopting the 2021 IECC over the current HUD and USDA 2009 IECC baseline for single family homes, both nationally and for each Climate Zone: a national average of an estimated $7,229 per unit for single family housing,[117] ranging from a low of $3,662 in Climate Zone 1, to a high of $8,845 in Climate Zone 8. Cost data sources used to derive these costs include: Building Component Cost Community (BC3) data repository; construction cost data collected by Faithful+Gould under contract with PNNL; RS Means Residential Cost Data; National Residential Efficiency Measures Database; and price data from nationally recognized home supply stores.[118]

[113] Hunt Allcott and Michael Greenstone, ''Is there an energy efficiency gap?'' Journal of Economic Perspectives, Volume 26, Number 1,Winter 2012, pp. 3–28.

[114] PNNL, Salcido et al., 2021.

[115] DOE, *IECC climate zone map, https://basc.pnnl.gov/images/iecc-climate-zone-map.*

[116] The 2009 standard is used as the primary baseline for this analysis since, as shown in Table 11, 23 states still require a standard equivalent to the 2009 baseline, which is also the most recent baseline established by HUD and USDA, while eleven states and the District of Columbia have adopted the 2018 standard. However, Tables 19 and 20 below shows baseline data for individual states per data provided by DOE/PNNL based on the state adoption status in 2021, which has seven states and the District of Columbia at the 2018 IECC.

[117] Source: Data provided by DOE to HUD and USDA showing disaggregated LCC Savings, Incremental Cost, and Annual Energy Savings for single family and low-rise multifamily homes.

[118] See for example, PNNL, *Alaska Cost Effectiveness Analysis, https://www.energycodes.gov/sites/default/files/2021-06/AlaskaResidentialCostEffectiveness_2018.pdf.*

Table 13. National Costs and Benefits – 2021 IECC vs. 2009 IECC (Single Family) (2023 dollars)

Climate Zone	LCC Savings ($)	30 Year PV Benefits ($)	Incremental cost ($)	Annual energy savings ($)	Annual Mortgage Increase ($)	Down payment and other up-front costs ($)	Net annual cashflow for year one ($)	Years to positive cashflow	Simple Payback (Yrs)
National Average	15,071	25,124	7,229	963	439	550	377	1.5	7.7
CZ 1	10,774	15,866	3,662	608	222	279	311	0.9	6.2
CZ 2	8,313	15,871	5,436	608	330	414	168	2.5	9.2
CZ 3	13,917	25,093	8,037	961	488	612	311	2.0	8.6
CZ 4	19,989	31,965	8,613	1,225	523	656	527	1.2	7.2
CZ 5	17,691	28,467	7,750	1,091	471	590	463	1.3	7.3
CZ 6	29,834	39,409	6,886	1,510	418	524	952	0.6	4.7
CZ 7	39,308	51,604	8,843	1,977	537	673	1,261	0.5	4.6
CZ 8	52,078	64,377	8,845	2,467	537	673	1,750	0.4	3.7

6. Annual Cost Savings

Table 13 summarizes the first-year annual energy cost savings per single family dwelling unit for the 2021 IECC compared to the 2009 IECC, aggregated over 16 single family residential prototype buildings modeled by DOE/PNNL.[119] Modeled energy savings are converted to cost savings using the most recent residential fuel prices from DOE's Energy Information Administration (EIA).[120] Cost savings stated are time zero dollars not adjusted for inflation or fuel price escalation. The per-unit annual energy cost savings for single family homes is estimated to be $963 per unit, ranging from $608/unit in Climate Zones 1 and 2, to a high of $2,467 in Climate Zone 8.

7. Simple Payback

Simple payback is a commonly used measure of cost effectiveness, defined as the number of years required for the sum of the annual returns on an investment to equal the original investment. The simple payback for adoption of the 2021 IECC code is an estimated 7.7 years for single family homes, ranging from 3.7 years in Climate Zone 8 to 9.2 years in Climate Zone 2.

8. Total Life Cycle Cost Savings

LCC analysis computes overall cost savings per dwelling unit resulting from implementing efficiency improvements. LCC savings are based on the net change in overall cash flows (energy savings minus additional costs) resulting from implementing the new code. LCC savings are a sum over an analysis period of 30 years: future cash flows vary from year to year and are discounted to present values using a discount rate that accounts for the changing value of money over time. LCC is the primary metric used by DOE to determine the cost effectiveness of the code or specific code changes. The economic analysis assumes that initial costs are mortgaged, and that homeowners do not take advantage of the mortgage interest deduction since most FHA/USDA borrowers are likely to take the standard, non-itemized tax deduction.[121]

Net life cycle cost savings shown in Table 13 average $15,071 per housing unit for adoption of the latest 2021 IECC. LCC savings vary considerably by Climate Zone, from as low as $8,313 in Climate Zone 2 to a high of $52,078 in Climate Zone 8.

9. Consumer Cash Flows

Converting first costs and annual savings to Consumer Cash Flows is an important component of the affordability analysis. Consumer Cash Flow results are derived from the year-by-year calculations that underlie LCC savings and provide an assessment of how annual cost outlays are compensated by annual energy savings and the time required for cumulative energy savings to exceed cumulative costs, including both increased mortgage payments and down payment and other up-front costs.

The financial and economic parameters used by HUD in calculating LCC savings and annual cash flow are based on DOE's cost-effectiveness methodology. Based on public comments, HUD has revised the original DOE analysis to incorporate new economic parameters that better reflect current market and economic conditions. Figure 2 shows the original and revised parameters. These revised parameters account for significant changes in construction, labor, and energy costs as well as several adjustments to financing terms to better reflect HUD and USDA borrowers.

[119] For residential buildings, PNNL uses two base prototypes to simulate (1) a single family detached house and (2) a multifamily low-rise apartment building. These prototypes are modified to accommodate four different heating system types and four foundation types typically found in residential new construction. The result is an expended set of 32 models (16 for each building type) which is then simulated across 18 climate locations for each edition of the IECC. This results in a set of 3,552 energy models in EnergyPlus Version 9.5).

[120] U.S. Energy Information Administration, Washington, D.C. Natural Gas Prices, *https://www.eia.gov/dnav/ng/ng_pri_sum_a_EPG0_PRS_DMcf_m.htm*. Electric Power Monthly, *https://www.eia.gov/electricity/monthly/epm_table_grapher.php?t=epmt_5_06_b*. Petroleum and Other Liquids. *https://www.eia.gov/dnav/pet/PET_PRI_WFR_A_EPD2F_PRS_DPGAL_W.htm*..

[121] PNNL, Salcido et al., 2021.

Figure 2. Economic Parameters for Consumer Cash Flows

Parameter	Preliminary Determination[122]	Final Determination
Mortgage interest rate	3.0%	Real: 3.0% Nominal: 5.3%
Loan fees	1% of mortgage amount	1% of mortgage amount
Loan term	30 years	30 years
Down payment	12.0%	5.0%
Discount rate (equal to mortgage rate)	3.0%	Real: 3.0% Nominal: 5.3%
Inflation rate	1.4%	2.24%
Marginal Federal income tax	12%	-
Marginal State income tax	% Varies by State	-
Property tax	1.24%	1.5%
Supply Chain Cost Increase Factor	-	37.0%
Energy Price Increase Factor	-	32.0%
Fuel Price Escalator (Nominal)	-	1.9%
FHA Savings Reduction Factor	-	3.0%
FHA Cost Reduction Factor	-	5.0%

Annual cash flow is defined as the net difference between annual energy savings and annual cash outlays (mortgage payments, etc.), including all tax effects but excluding up-front costs (mortgage down payment, loan fees, etc.). Only first year net cash flow is reported: subsequent years' cash flow will differ due to the effects of inflation and fuel price escalation, changing income tax effects as the mortgage interest payments decline, etc. Assuming a 5 percent, 30-year fixed mortgage, and a 5 percent down payment, increased annual debt service is shown in Table 13 to be an average of $439/unit, or $36.58/month, with annual energy savings more than twice that amount: $963, or $80.25/month. This translates into a net annual positive cash flow in Year One of $377 or $31.42/month. Years to Positive Cash Flow, *i.e.,* the number of years needed to recoup the cost of the initial down payment and first-year debt service with annual savings, is just eighteen months on average.

10. Low-Rise Multifamily Buildings

Table 14 shows costs and savings for low-rise multifamily housing similar to those shown in Table 13 for single family homes. The costs and savings shown are aggregated over 16 low-rise multifamily residential prototype buildings modeled by DOE/PNNL.[123] The incremental costs for this housing type, as well as associated savings, are generally lower than for single family homes, as a result of both differences in unit size and building type. Incremental costs average $3,002/unit nationally, more than half of the $7,229 per unit cost for single family housing only. Net LCC savings of $6,345 for low-rise multifamily housing are also projected to be lower than for single family housing only ($15,071/unit).

First year increased debt service for low-rise multifamily housing is estimated to be $182/unit, while savings are nearly three times that amount: $403/year, for a net annual cash flow of $160/year. While costs and savings differ, Years to Positive Cash Flow are similar to that of single family homes (1.4 years), and the national Simple Payback average of 7.6 years is also comparable. Simple paybacks range from a low of 5.1 years in Climate Zone 8 to a high of 8.2 years in Climate Zones 2 and 3. Net LCC savings vary considerably from $5,218 in Climate Zone 2 to a high of $18,185 in Climate Zone 8. Higher incremental or added costs typically translate into higher annual savings, with net annual positive cash flows for year one ranging from $123 to $565.

[122] PNNL, Salcido et al., 2021.

[123] See Footnote 47 for methodology for prototype buildings.

Table 14. National Costs and Benefits – 2021 vs. 2009 IECC (Low-Rise Multifamily) (2023 dollars)

Climate Zone	LCC Savings ($)	30 Year PV Benefits ($)	Incremental cost ($)	Annual energy savings ($)	Annual Mortgage Increase ($)	Down payment and other up-front costs ($)	Net annual cashflow for year one ($)	Years to positive cashflow	Simple payback (years)
National Average	6,345	10,519	3,002	403	182	229	160	1.4	7.6
CZ 1	6,308	9,359	2,194	359	133	167	181	0.9	6.3
CZ 2	5,218	9,089	2,784	348	169	212	123	1.7	8.2
CZ 3	5,978	10,453	3,218	401	196	245	140	1.8	8.2
CZ 4	7,047	11,340	3,088	434	188	235	184	1.3	7.3
CZ 5	6,087	10,267	3,006	393	183	229	150	1.5	7.8
CZ 6	9,735	13,621	2,795	522	170	213	296	0.7	5.5
CZ 7	13,188	19,788	4,747	758	288	361	374	1.0	6.4
CZ 8	18,185	24,784	4,746	950	288	361	565	0.6	5.1

Table 15 shows the energy savings and incremental costs of construction for the average housing unit (average of single family and multifamily). First costs average $2,620 per unit, well below the average first cost of $7,229 against the 2009 baseline. As would be expected, annual savings are similarly lower, and the resulting national average payback is higher than the 2009 IECC—at 10.7 years vs. 7.7 years against the 2009 IECC. Simple paybacks vary considerably across Climate Zones, from 4.8 years in Climate Zone 1 to 16.8 years in Climate Zone 5.

Table 15. National Costs and Benefits – 2021 vs. 2018 IECC[124] (2023 dollars)

Area	Upfront Cost for Single Family ($)	Upfront Cost for Condo ($)	Upfront Cost for Average Unit ($)	First Year Energy Savings for Average Unit ($)	Simple Payback for Average Unit (years)
National Average	3,087	1,713	2,620	245	10.7
Climate Zone 1: Very Hot	1,218	1,214	1,217	256	4.8
Climate Zone 2: Hot	1,991	1,492	1,822	246	7.4
Climate Zone 3: Warm	2,419	1,551	2,124	256	8.3
Climate Zone 4: Mixed	4,799	1,995	3,847	262	14.7
Climate Zone 5: Cool	4,645	1,935	3,725	222	16.8
Climate Zone 6: Cold	1,922	1,434	1,757	157	11.2
Climate Zone 7: Very Cold	3,878	3,388	3,712	392	9.5
Climate Zone 8: Subarctic/Arctic	3,881	3,388	3,713	526	7.1

Notes: Single family cost and condo cost and average energy savings from PNNL. Upfront cost derived by HUD and simple payback calculated by HUD. HUD does not have disaggregated estimates for single family and multifamily units for the update from 2018, only the average across single family and low-rise multifamily

11. Additional analysis—6 Percent Mortgage Interest Rate and 3.5 Percent Down Payment

Table 16 provides cash flow analysis for single family housing using a 3.5 percent downpayment consistent with minimum FHA requirements, and a 6.5 percent nominal mortgage interest rate predicted to be in place at the end of 2024 (compared to 5% average downpayment and 5.3 percent mortgage interest rates used in Tables 13–15, above). The cash flows are similar to the prior analysis, with positive cash flows ranging from less than a year to 2.8 years and simple paybacks below 10 years.

[124] HUD does not have PNNL estimates of energy savings disaggregated by single family and multifamily for the 2021 IECC relative to the 2018 standard. HUD computed a weighted average of the incremental cost of construction. The weights used by PNNL in their analysis are 66 percent for single family units and 34 percent for low-rise multifamily units.

Table 16. National Costs and Benefits – 2021 IECC vs. 2009 IECC (Single Family) 6.5% mortgage rate; 3.5% down payment. (2023 dollars)

Climate Zone	LCC Savings ($)	30 Year PV Benefits ($)	Incremental cost ($)	Annual energy savings ($)	Annual Mortgage Increase ($)	Down payment and other up-front costs ($)	Net annual cashflow for year one ($)	Years to positive cashflow	Simple Payback (Yrs)
National Average	14,182	25,124	7,229	963	502	445	314	1.4	7.7
CZ 1	10,323	15,866	3,662	608	254	225	279	0.8	6.2
CZ 2	7,644	15,871	5,436	608	377	335	121	2.8	9.2
CZ 3	12,928	25,093	8,037	961	558	495	241	2.1	8.6
CZ 4	18,929	31,965	8,613	1,225	598	530	452	1.2	7.2
CZ 5	16,737	28,467	7,750	1,091	538	477	396	1.2	7.3
CZ 6	28,986	39,409	6,886	1,510	478	424	892	0.5	4.7
CZ 7	38,219	51,604	8,843	1,977	614	544	1,184	0.5	4.6
CZ 8	50,989	64,377	8,845	2,467	614	544	1,673	0.3	3.7

12. Cash Flows for Single Family and Low-Rise Multifamily

HUD and USDA rely on a 30-year term for the loan based on guidance from DOE. Tables 13 and 14 show net life-cycle costs of $15,071 (single family) and $6,345 (low-rise multifamily) for the 2021 IECC over the 2009 IECC. In both cases, positive cashflows occur by the end of the second year. Table 17 and 18 present the cumulative, present value cash flow for each building type at the one-, two-, five-, 10-, 20-, and 30-year marks as well as with no loan. The tables show cash flows for the national average as well as each climate zone.

LCC savings for periods of less than 30 years also show positive cash flows. At the 10-year mark, the national savings are estimated to be $2,515 over the 2009 IECC and $1,076 over the 2018 IECC.

Table 17. Cash Flow for Single Family –2021 IECC vs. 2009 IECC (2023 dollars)

Period	National	CZ 1	CZ 2	CZ 3	CZ 4	CZ 5	CZ 6	CZ 7	CZ 8
First Year (incl. upfront cost)	(173)	33	(246)	(301)	(128)	(127)	428	588	1,077
First Year (excl. upfront cost)	377	311	168	311	527	463	952	1,261	1,750
Second Year	407	329	188	342	565	497	993	1,314	1,813
5 Year	1,506	1,353	565	1,141	2,176	1,903	4,342	5,763	8,161
10 Year	**3,908**	**3,131**	**1,831**	**3,304**	**5,401**	**4,752**	**9,397**	**12,433**	**17,115**
20 Year	9,321	6,916	4,898	8,378	12,525	11,064	19,696	25,989	34,914
30 Year	15,071	10,774	8,313	13,917	19,989	17,691	29,834	39,308	52,078
PV No loan	17,380	11,943	10,048	16,483	22,739	20,166	32,033	42,131	54,902

Table 18. Cash Flow for Low-Rise Multifamily –2021 IECC vs. 2009 IECC (2023 dollars)

Period	National	CZ 1	CZ 2	CZ 3	CZ 4	CZ 5	CZ 6	CZ 7	CZ 8
First Year (incl. upfront cost)	(69)	14	(89)	(105)	(51)	(79)	83	12	204
First Year (excl. upfront cost)	160	181	123	140	184	150	296	374	565
Second Year	173	191	134	153	198	162	310	396	591
5 Year	642	783	470	533	758	592	1,316	1,607	2,546
10 Year	**1,654**	**1,822**	**1,290**	**1,471**	**1,893**	**1,559**	**2,944**	**3,773**	**5,605**
20 Year	3,931	4,041	3,180	3,638	4,407	3,750	6,335	8,421	11,914
30 Year	6,345	6,308	5,218	5,978	7,047	6,087	9,735	13,188	18,185
PV No loan	7,304	7,009	6,107	7,006	8,033	7,047	10,627	14,703	19,701

12. Appraisals of Energy Efficiency Improvements

In this section of the determination, we address the question of home appraisals, and the extent to which they fully value energy efficiency improvements. As noted in the response to public comments received on this topic, the residential appraisal system in the U.S. is not generally set up to fully assign a contributory value to increased energy efficiency of a home, particularly in the absence of sales comparisons, in part because of imperfect information—the level of energy efficiency is not typically disclosed at the time of home purchase, unless the home has a HERS rating, or it has an energy efficient certification such as Energy Star or Zero Energy Ready Homes. In addition to information availability necessary to identify and develop the contributory value of energy efficient measures in a residential appraisal, the valuation requires a market recognizable response, appraiser technical expertise and training, and underwriter recognition of the approaches, methods and techniques applied in support of the conclusions.

As discussed in the comments section of this notice, however, there are several mitigating factors, as well as emerging trends that indicate that tools are available to the appraiser that when properly applied allow for adjustments to as-is valuations. In addition, studies of sales prices in Washington, DC and other markets show that energy efficient homes command higher sales prices.[125] A review of sales prices of FHA homes for the past four years relative to appraised values show that a significant share—32 percent—are valued at more than $5,000 or more above the sales price, thereby allowing a significant margin for borrowers to accommodate the estimated increase in value associated with the 2021 IECC. There is also increasing use of the MLS that have ''green'' fields including energy certifications, HERS ratings, and in some cases utility costs associated with a home (existing homes), which provide both lenders and appraisers with the necessary information needed to incorporate in the home valuation. In addition, while still underutilized, tools such as the Green Addendum that is available to appraisers and can be filled out by HERS raters (or even the homeowner) are available to identify the energy features of a home. See Section A.5 in the Comments section of this notice for a discussion of these issues. HUD and USDA plan to implement a robust training and technical assistance program for both appraisers and lenders to maximize the use of accurate and reliable valuation methods and will work with the rosters of FHA- and USDA-approved appraisers to provide such training.

14. State-Level Results [126] [127]

Table 19 provides a state-by-state breakout of estimated costs and savings, for single family homes only. This table provides a more granular breakout of estimated costs and savings than the national and Climate Zone averages shown in Table 13 above, using the HUD and USDA 2009 IECC baseline for those states that have not yet adopted this standard or its equivalent as well as a 2018 IECC baseline for the 7 states plus the District of Columbia that have adopted the 2018 IECC or its equivalent.[128] [129] All states have positive LCC savings and meet the necessary affordability requirements.

DOE did not provide HUD and USDA with a cost effectiveness analysis for the U.S. territories—American Samoa, Guam, North Mariana Islands, Puerto Rico, and U.S. Virgin Islands. In situations without a state-or territory-specific cost effectiveness analysis, the cost effectiveness analysis for the climate zone is used to determine affordability. As shown in Table 13, climate zone 1, the climate zone for each of the U.S. territories, has LCC savings of $10,774, which meets the affordability requirements. The climate zone also has an incremental cost of $3,662, annual energy savings of $608, and a simple payback period of 6.2 years.

[125] Adomatis, Sandra, ''What is Green Worth? Unveiling High Performance Home Premiums in Washington DC,'' September 2015, *https://doee.dc.gov/sites/default/files/dc/sites/ddoe/service_content/attachments/2015_High Performance%20Home%20Valuation%20Report_FINAL.pdf.*

[126] State-level results are based on PNNL analyses on the cost-effectiveness of the 2021 IECC for residential buildings in each state. As such, Tables 19 and 20 present the cost-effectiveness of the 2021 IECC for each state based on their adopted energy code in July 2021. States that have revised their energy code requirements since July 2021 should look to other states in the same climate zone with the same energy code requirements for estimated costs and savings.

[127] State results use state-specific property tax rates provided in the PNNL analyses on the cost-effectiveness of the 2021 IECC for residential buildings in each state instead of the national property tax rate of 1.5 percent.

[128] Cost benefit data are not available for three states (California, Washington, and Oregon). According to DOE, these codes ≥deviate significantly from the model codes≥ and as a result DOE has historically not analyzed those states.

[129] The 2018 data shown in Tables 19 and 20 are aggregated single family and low-rise multifamily data adjusted for the weighted averages used by PNNL for the 2009 IECC.

Table 19. State by State Costs and Benefits – 2021 IECC vs. 2009 or 2018 IECC (Single Family)[130] (2023 dollars)

State	Current Code	Incremental Cost ($)	Increase Downpayment ($)	Annual Mortgage ($)	Annual Energy Savings ($)	LCC Savings ($)	30 Year PV Benefits ($)	Simple Payback (Years)
AK	2009	11,523	576	700	2,849	59,402	74,355	4.2
AL	2009	6,332	317	385	931	17,001	24,310	7.0
AR	2009	6,974	349	424	993	17,597	25,914	7.2
AZ	2009	5,418	271	329	639	10,003	16,683	8.7
CA	2021	-	-	-	-	-	-	-
CO	2009	7,534	377	458	704	9,257	18,363	11.0
CT	2021	-	-	-	-	-	-	-
DC	2018	3,231	162	196	508	9,453	13,268	6.5
DE	2018	4,409	220	268	381	4,766	9,944	11.9
FL	2009	4,385	219	266	564	9,092	14,720	8.0
GA	2009	6,804	340	413	969	16,740	25,281	7.2
HI	2009	3,046	152	185	1,354	31,865	35,338	2.3
IA	2009	7,410	371	450	1,278	23,370	33,359	6.0
ID	2009	6,887	344	418	631	8,013	16,463	11.2
IL	2009	8,443	422	513	870	10,570	22,702	10.0
IN	2009	8,079	404	491	891	13,083	23,256	9.3
KS	2009	7,604	380	462	1,184	20,656	30,906	6.6
KY	2009	8,295	415	504	1,227	21,808	32,036	7.0
LA	2009	5,147	257	313	574	9,202	14,987	9.2
MA	2018	1,274	64	77	145	2,132	3,786	9.0
MD	2018	3,232	162	196	414	6,730	10,813	8.0
ME	2009	6,420	321	390	1,478	30,190	38,586	4.5

MI	2009	7,558	378	459	1,198	20,576	31,269	6.5
MN	2009	7,583	379	461	1,461	28,277	38,132	5.3
MO	2009	8,721	436	530	1,058	16,538	27,626	8.5
MS	2009	6,332	317	385	856	14,790	22,342	7.6
MT	2009	6,423	321	390	720	10,729	18,791	9.2
NC	2009	6,753	338	410	959	16,630	25,038	7.2
ND	2009	6,667	333	405	1,249	23,449	32,611	5.5
NE	2018	4,376	219	266	270	732	7,046	16.7
NH	2009	7,213	380	425	1,274	22,686	33,239	5.8
NJ	2021	-	-	-	-	-	-	-
NM	2009	7,663	383	466	703	9,157	18,343	11.2
NV	2009	8,700	435	529	778	9,368	20,306	11.5
NY	2018	3,837	192	233	495	7,782	12,907	8.0
OH	2009	7,774	389	472	895	12,760	23,350	8.9
OK	2009	6,987	349	424	1,058	18,960	27,603	6.8
OR	2018	-	-	-	-	-	-	-
PA	2009	8,445	422	513	1,101	17,249	28,736	7.9
PR	2011 PR Building Code	-	-	-	-	-	-	-
RI	2009	8,293	415	504	1,396	25,160	36,440	6.1
SC	2009	6,357	318	386	937	16,911	24,467	7.0
SD	2009	5,847	292	355	1,244	24,587	32,457	4.8
TN	2009	7,238	362	440	957	16,120	24,986	7.8
TX	2018	2,016	101	122	276	4,286	7,215	7.5
UT	2009	6,817	341	414	664	9,092	17,332	10.6
VA	2009	7,675	384	466	1,158	20,726	30,220	6.8
VT	2021	-	-	-	-	-	-	-
WA	2021	-	-	-	-	-	-	-
WI	2009	7,578	379	460	1,104	17,875	28,810	7.1
WV	2009	8,360	418	508	1,208	21,597	31,517	7.1
WY	2009	6,394	320	388	912	16,095	23,798	7.2

Incremental costs for adoption of the 2021 IECC in those states currently at the 2009 IECC or its equivalent range from a low of $3,046 (Hawaii) to a high of $11,523 (Alaska), with most states typically in the $6,000 range. Annual energy savings exceed added debt service in all states with energy savings ranging from a low of $564 (Florida) to a high of $2,849 (Alaska).

Both incremental costs and savings for the 2021 IECC in the 11 states plus the District of Columbia that have adopted the 2018 IECC are typically lower than for those at the 2009 IECC baseline. New York, for example, shows an added cost of $3,837/unit for adoption of the 2021 IECC relative to its current 2018 baseline, $495 in annual estimated savings, yielding LCC savings of $7,782.

15. Total Costs and Benefits

Table 20 provide estimated up-front costs, annual energy cost savings, and life cycle cost savings for the 2021 IECC for all 50 states and the District of Columbia, weighted by the estimated share of single family and low-rise multifamily units potentially impacted by the adoption of the 2021 IECC. As previously shown in Table 12, an estimated 140,000 single family and low-rise multifamily units would be impacted annually by this code if adopted today. By multiplying the incremental cost/unit per state by the number of units estimated likely to be impacted, the total cost of implementing the 2021 IECC is estimated at $605.4 million, total savings are estimated at $2.1 billion, and net life-cycle cost savings of $1.3 billion.[131]

[130] Current code is set at the 2009 IECC, the current HUD requirement, for states at or below the 2009 IECC based on the standard adopted by each state as of July 2021, which was when PNNL conducted their state analysis for the 2021 IECC. States that have since adopted the 2021 IECC show no impact as they current require the proposed standard. As shown in Table 11, some states have adopted a state code that is below the current HUD/USDA standard (2009 IECC) or have not yet adopted any state code.

[131] Net LCC savings of $1.3 billion are based on life-cycle costs of $770 million and life-cycle savings of $2.1 billion over the 30-year period.

Table 20. Aggregate Estimated Costs and Savings for 2021 IECC (Single Family and Low-Rise Multifamily) (2023 dollars)

State	Current Code	Total Incremental Cost Per State ($)	Total Annual Energy Cost Savings Per State ($)	Life-Cycle Cost (LCC) Savings ($)	Simple Payback (Years)
AK	2009	1,467,302	362,749	7,563,877	4.0
AL	2009	15,751,159	2,322,686	42,441,810	6.8
AR	2009	10,787,851	1,539,224	27,308,371	7.0
AZ	2009	25,877,923	3,055,881	47,851,967	8.5
CA	2021	-	-	-	-
CO	2009	22,048,256	2,059,004	27,089,312	10.7
CT	2021	-	-	-	-
DC	2018	789,874	123,257	2,284,586	6.4
DE	2018	7,557,323	652,990	8,167,536	11.6
FL	2009	78,027,936	10,085,227	163,080,925	7.7
GA	2009	54,200,100	7,732,423	133,786,239	7.0
HI	2009	641,349	278,936	6,549,083	2.3
IA	2009	2,865,479	491,595	8,967,910	5.8
ID	2009	6,458,270	591,494	7,514,250	10.9
IL	2009	10,184,197	1,049,049	12,746,796	9.7
IN	2009	15,080,067	1,663,982	24,440,942	9.1
KS	2009	3,917,376	610,412	10,651,023	6.4
KY	2009	14,501,366	2,149,551	38,223,760	6.7
LA	2009	12,046,255	1,350,091	21,698,030	8.9
MA	2018	359,843	113,426	2,493,512	3.2
MD	2018	8,987,272	1,137,731	18,341,653	7.9
ME	2009	1,380,494	316,587	6,457,741	4.4
MI	2009	5,157,941	809,020	13,818,750	6.4
MN	2009	7,105,575	1,304,653	24,817,262	5.4
MO	2009	11,327,527	1,381,200	21,648,400	8.2
MS	2009	8,145,813	1,101,578	19,036,644	7.4
MT	2009	1,556,448	174,178	2,592,446	8.9
NC	2009	40,733,576	5,819,749	101,179,307	7.0
ND	2009	1,369,480	256,657	4,816,719	5.3

State	Current Code	Total Incremental Cost Per State ($)	Total Annual Energy Cost Savings Per State ($)	Life-Cycle Cost (LCC) Savings ($)	Simple Payback (Years)
NE	2018	1,330,406	79,978	167,721	16.6
NH	2009	1,347,422	234,827	4,157,578	5.7
NJ	2021	-	-	-	-
NM	2009	7,489,828	689,004	9,005,317	10.9
NV	2009	18,406,827	1,646,889	19,842,774	11.2
NY	2018	1,764,960	207,634	3,061,397	8.5
OH	2009	11,549,503	1,328,498	18,941,414	8.7
OK	2009	11,554,693	1,747,839	31,325,528	6.6
OR	2018	-	-	-	-
PA	2009	8,043,921	1,049,813	16,459,200	7.7
PR	2011 PR Building Code	-	-	-	-
RI	2009	674,452	112,658	2,023,038	6.0
SC	2009	30,174,298	4,459,928	80,540,750	6.8
SD	2009	1,571,406	331,691	6,542,036	4.7
TN	2009	29,623,159	3,934,188	66,397,370	7.5
TX	2018	66,546,268	8,937,478	136,575,571	7.4
UT	2009	16,672,620	1,627,949	22,336,566	10.2
VA	2009	23,199,372	3,534,206	63,545,340	6.6
VT	2021	-	-	-	-
WA	2021	-	-	-	-
WI	2006	1,807,146	261,252	4,211,113	6.9
WV	2009	4,583,037	661,985	11,839,942	6.9
WY	2009	730,032	103,282	1,816,195	7.1

This LCC figure covers a single year's cohort of HUD and USDA financed housing. Annual effects will increase as more cohorts are added to the stock of new HUD- and USDA-assisted, insured, or guaranteed energy-efficient housing. In the second year, with two cohorts in place, there could be a stream of almost $150 million (future value) of energy savings. The number of units affected every year will decline as states update their standards to the 2021 IECC, or industry adopts the prescribed above-code standards. Thus, we expect the aggregate annual incremental effects to taper off. The maximum annual effect of all cohorts is not likely to exceed somewhere between three or four times the annual effect of a single-year cohort. While a new code edition is typically published every three years, since HUD and USDA must consider the affordability and availability impacts of each edition when it is published, in this notice, LCC savings cover one year's cohort. See ''Aggregate Incremental Impacts of IECC Update'' in the Regulatory Impact Analysis (p.44) for further discussion.

The Regulatory Impact Analysis at *www.regulations.gov* provides an estimated first cost of $553 million, annual energy savings of $73 million, and net LCC savings that range from $972 million (7 percent real discount factor) to $1.48 billion (3 percent real discount factor). (See RIA Figures 20 and 21).

C. Final Affordability Determination—2021 IECC

Based on the analysis provided above, HUD and USDA have determined that adoption of the 2021 IECC will not negatively impact the affordability of homes covered by the statute. This conclusion recognizes the profile of FHA borrowers, who according to FHA's 2021 Annual Report are typically first-time home buyers (84 percent) who are more likely than repeat buyers to be especially price sensitive.

While the national average incremental cost shown in Table 13 of adopting this standard is $7,229, this represents a modest 2.2 percent increase in the median cost of $330,000 for a new FHA-insured home in 2023. In all cases this translates into an increase in the downpayment and other first costs, on average, of $445, which represents approximately 0.13 percent of the median FHA-insured new energy efficient home mortgage.[132]

Unlike other added costs associated with the home purchase transaction, these incremental costs yield significant cost savings to the borrower. As shown in Tables 13–15, cash flows are extremely favorable for all types of housing covered by the IECC (single family and low-rise multifamily), for the 2021 IECC against both the 2009 IECC and the 2018 IECC baselines, in all Climate Zones, and for both life cycle cost savings as well as first year savings to the consumer. In all cases, annual energy savings in Year One exceed increases in debt service. Using the national average for the 2021 IECC over the 2009 IECC as a base case, as shown in Table 13, debt service increases average just $36/month ($439/year) for net positive cash flows of $31/month ($377/year) after debt service. Consumers are expected to see energy savings of $963 annually, and a net positive cash flow of $377 in the first year. On a life cycle basis, consumers are projected to save $25,100 in energy bills over the life of a typical 30-year mortgage, and a net life cycle savings (after costs) of $15,071. Years to positive

[132] Average USDA Section 502 Direct Loan 2018–20 of $191,100, and of Section 502 Guaranteed Loan of $210,700. Incremental cost of $7,229 equals 3.0 percent and 2.8 percent respectively of these loans; down payment and other upfront costs are 0.28 percent and 0.26 percent. For average FHA new home mortgage of $363,000 (2023), added first cost equals 2.0 percent, average down payment and other upfront costs equals 0.15 percent.

cash flow range average 1.5 years and range from less than six months to 2.5 years depending on Climate Zone. The simple payback—the years required to recoup the full cost of the code update—averages 7.7 years and is less than 10 years in all Climate Zones, ranging from a low of 3.7 years to a high of 9.2 years.

While there is likely to be variability in actual cash flows depending on energy use associated with family size and behavior, the data shows that on average the adoption of these measures are likely to improve overall affordability in light of these positive cash flows.

While the cash flows and lifetime cost savings are positive, an additional affordability consideration is whether increased down payment costs due to the added or incremental cost will negatively impact home buyers with regard to qualifying for a mortgage, or to meet mortgage down payment requirements. This is especially important for first-time home buyers who typically have lower cash availability for down payments. As shown in Table 13, HUD estimates increased average down payment and other up-front costs of $550, ranging from $279 to $673 for FHA-insured mortgages (varying by Climate Zone).[133] This is based on an assumed average 5 percent down payment.

HUD and USDA do not view these additional downpayment requirements as a barrier to qualifying for financing: a borrower purchasing a median FHA new energy code-compliant home of $337,200 will need an additional downpayment of $360 (5 percent down) plus an additional $190 for variable closing costs, including $126 (1.75 percent) for the Upfront Mortgage Insurance Premium (MIP) for a total of $550. A cash-constrained borrower may be able to finance the Upfront MIP in the mortgage and in doing so would still be well above the minimum FHA down payment requirement of 3.5 percent. Amortizing this amount will add a nominal additional monthly mortgage payment, yet result in an average of $80 per month or $963 a year in energy savings from this investment. The borrower who is already contributing the minimum 3.5 percent downpayment required by FHA will need an average of an additional $252 down payment (3.5 percent of $7,229 added average cost) over the $11,550 downpayment required for a non-energy code compliant home. In the event that the borrower is not able to contribute this additional cash above the minimum 3.5 percent downpayment, we note the large number of down payment assistance programs that may be available to borrowers to close this gap.[134] For one program, the USDA Section 502 Direct Loan Program which serves low-income borrowers with 50–80 percent incomes, there is a zero down payment requirement; for these borrowers the incremental down payment will by default present no affordability challenges. Longer amortization schedules (up to 38 years for up to 60 percent AMI borrowers) can also be used to lower monthly payments for Direct Loan borrowers if needed.

Note that energy costs and savings are generally not factored into current underwriting practices for single family mortgages, *i.e.,* while positive cash flows related to improved energy efficiency will be realized, they are not specifically included in the Principal Interest, Taxes, and Insurance (PITI) debt-to-income ratios typically used by lenders to qualify borrowers. Multifamily underwriting, on the other hand, does take into account energy savings: FHA offers the Green Mortgage Insurance Premium to multifamily borrowers who build to a green building standard, which may include the most recent energy code as a mandatory element, or may offer additional points if the building meets or exceeds the latest IECC or ASHRAE 90.1 standard.

Equity Impacts

The Regulatory Impact Analysis (RIA) that accompanies this notice includes an extensive equity analysis, which discusses the disproportionate energy burden experience by low-income borrowers—and conversely the increased benefits likely to be realized by low-income borrowers from increased efficiency. See the Equity Impacts section of the RIA (p.98) at *www.regulations.gov.*

Lower-income households face disproportionately higher energy burdens; they spend a higher share of their gross household income on energy costs.[135] Two-thirds of low-income households earning up to 200 percent of the federal poverty level face high energy burdens, spending more than 6 percent of their income on energy bills. Black, Hispanic, Native American, and older adult households, as well as families residing in manufactured housing and low-income households with a person with a disability, experience disproportionately high energy burdens.[136]

Since increasing energy efficient codes will lower the energy burden for buyers of energy efficient homes, more efficient codes will at the same time be most beneficial to lower-income households. These codes typically require added first costs, but HUD and USDA single family insured or guaranteed programs include mitigating factors which may make this investment more affordable to eligible borrowers, *e.g.,* lower down payment requirements (3.5 percent for FHA-backed mortgages compared to 20 percent required for conventional financing without mortgage insurance), as well as more flexible underwriting requirements such as lower allowable credit scores. USDA's Direct Loan program serves an underserved market, very low or extremely low-income borrowers in rural areas, through no-or low-down payment requirements, as well as significant interest rate subsidies. FHA's low-rise multifamily housing serves a renter population that is not directly responsible for any additional first costs.

The overall conclusion provided in the RIA concerning the equity impacts of a minimum energy standard is that lower-income households will benefit more from the existence of energy-efficient housing but may be challenged in their ability to address first costs. Empirical work has shown that residential energy is a necessary good, but that reducing its cost through energy efficiency requires an additional investment that lower-income households may not have the disposable income to accommodate. If, however, the notice encourages the supply of energy efficiency in the affordable housing stock, then low-income households will gain. Precise impacts are likely to vary by housing market and climate zone.

[133] Average price in 2023 for all FHA-insured purchases, including existing homes, was $363,000.

[134] See, for example, *https://nwhomepartners.org/get-ready-help-for-homebuyers/down-payment-help/,* or *https://www.energy.gov/scep/slsc/low-income-community-energy-solutions.*

[135] *https://www.energy.gov/scep/slsc/low-income-community-energy-solutions.*

[136] Drehobl, A.L. Ross, and R. Ayala. 2020. How High Are Household Energy Burdens? Washington, DC: American Council for an Energy-Efficient Economy.

IV. Final Determination—ASHRAE 90.1–2019

Overview

EISA requires HUD to consider the adoption of revisions to ASHRAE 90.1 for HUD-assisted multifamily programs.[137] Published and revised every three years in coordination with the publication schedule of the IECC, the standard provides minimum requirements for the energy-efficient design of commercial buildings, including residential buildings with more than three stories.[138]

ASHRAE 90.1 includes several compliance pathways. The first is the prescriptive path, which establishes energy-related criteria for individual building components, including minimum insulation levels, maximum lighting power, and controls for lighting and heating, ventilation, air conditioning, and refrigeration systems. Some requirements are considered mandatory, even when one of the optional paths is utilized. ASHRAE 90.1 also includes two optional whole-building performance paths. The first is the Energy Cost Budget method, which allows the designer to trade off compliance among various code requirements, using established energy modeling protocols. A building is deemed in compliance when the annual energy cost of the proposed design is no greater than the annual energy cost of the reference building design (baseline). ASHRAE 90.1 also includes a second performance approach, the Performance Rating Method in Appendix G. Appendix G has been used to rate the performance of buildings that exceed the requirements of Standard 90.1 for above-code programs, such as LEED, Green Globes, ASHRAE Standard 189.1, the International Green Construction Code, the National Green Building Standard, and other above-code programs.

1. Current HUD and USDA Standard and Subsequent Revisions

In their May 2015 Final Determination, HUD and USDA established the 2007 edition of ASHRAE 90.1 (ASHRAE 90.1–2007) as the minimum standard for HUD-assisted multifamily properties. ASHRAE has revised the code four times since the publication of the 2007 edition. ASHRAE 90.1–2010 was published in October 2010. There were 56 changes to the 2007 edition code with a positive impact on energy efficiency, including revised requirements for the building envelope, HVAC systems, commissioning, lighting, and power.[139] DOE determined that the ASHRAE 90.1–2010 code would yield national energy cost savings of 7.72 percent in mid-rise apartment buildings and 6.99 percent in high-rise apartment buildings over the previous 2007 code.[140]

The next edition, ASHRAE 90.1–2013, published in October 2013, included 52 changes over the 2010 edition, most of which were determined by DOE to be relatively minor. Only six were applicable to residential buildings, including improved lighting controls and decreased lighting power densities, increased building envelope requirements for ''opaque assemblies and fenestration,'' and increased efficiency requirements for smaller air conditioners and heat pumps.[141] These amendments resulted in an average energy savings of 5.4 percent in mid-rise apartment buildings and 6.9 percent in high-rise multifamily buildings (site energy) over ASHRAE 90.1–2010.[142] Cost savings were estimated by DOE to be 5.0 percent for mid-rise apartments and 8.7 percent for high-rise apartments.

The following edition, ASHRAE 90.1–2016, yielded an additional 3.6 percent site energy savings for mid-rise apartment buildings, and 4.0 percent for high-rise apartment buildings.[143] Energy cost savings were estimated by DOE to be 3.9 percent and 5.1 percent respectively over the 2013 edition for these two building types.

DOE's quantitative analysis concluded that ASHRAE 90.1–2019 for mid-rise and high-rise multifamily buildings (representing 11.65 percent of all commercial buildings) would yield an additional site energy savings of 2.65 percent over the 2016 edition, and energy cost savings (Energy Cost Index (ECI)) of 2.5 percent.[144] [145] [146]

Tables 21 and 22 show the changes in incremental costs for each code cycle since the 2007 edition. Table 21 shows that per square foot costs increased for the first two cycles (2010 and 2013) in a prototype mid-rise apartment building modeled by PNNL in five representative climate zones. In 2013, for example, the incremental cost of complying with ASHRAE 90.1–2019 ranged from just $0.17/sf to $0.69/sf, or 0.14 to 0.59 percent of total building costs. In contrast, the last two code cycles (both 2016 and 2019) have seen incremental cost savings rather than cost increases as a result of complying with these codes. In all cases, the incremental cost, whether a cost increase or a cost savings, is a small fraction of the total per building first cost ($111/sf in 2010 to $218/sf in 2019).

[137] USDA multifamily programs are not covered by the Act.

[138] Standard 90.1 is published in October of the year two years before the year listed for the IECC, to allow the latest version of standard 90.1 to be submitted to the IECC for inclusion in the commercial chapter of the IECC.

[139] A ''positive change'' is defined as a change to the code that results in increased energy efficiency. Other changes might include items that are either savings-neutral, or, in rare cases, may lower energy efficiency.

[140] Pacific Northwest National Laboratory for the Department of Energy, *Cost-effectiveness of ASHRAE Standard 90.1–2010 Compared to ASHRAE Standard 90.1–2007*, May 2013, Tables C.2, *http://www.pnnl.gov/main/publications/external/technical_reports/PNNL-22043.pdf.*

[141] PNNL, National Cost-effectiveness of ANSI/ASHRAE/IES Standard 90.1-2013, January 2015, *https://www.pnnl.gov/main/publications/external/technical_reports/PNNL-23824.pdf.*

[142] U.S. Department of Energy, *Determination Regarding Energy Efficiency Improvements in ANSI/ASHRAE/IES Standard 90.1–2013: Energy Standard for Buildings, Except Low-Rise Residential Building,* Table IV.5, 79 FR 57900 (Sep. 26, 2014), *https://www.federalregister.gov/documents/2014/09/26/2014-22882/determination-regarding-energy-efficiency-improvements-in-ansiashraeies-standard-901-2013-energy.* For more detailed analysis, see PNNL, ANSI/ASHRAE/IES Standard 90.1–2013 Determination of Energy Savings: Quantitative Analysis, August 2014. Available at *https://www.pnnl.gov/main/publications/external/technical_reports/PNNL-23479.pdf.*

[143] PNNL/DOE *Preliminary Energy Savings Analysis, ANSI/ASHRAE/IES Standard 90.1–2016*, June 2017, *https://www.energy.gov/sites/default/files/2017/07/f35/Preliminary_90.1-2016_Energy_Savings_Analysis.pdf.*

[144] Op cit., PNNL, *Energy Savings Analysis*, July 2021.

[145] PNNL, Impacts of Model Building Energy Codes—Interim Update, July 21, 2021, *https://www.pnnl.gov/main/publications/external/technical_reports/PNNL-31437.pdf.* For all commercial buildings, DOE estimates national site energy savings of 4.7 percent and energy cost savings of approximately 4.3 percent.

[146] 86 FR 40543 (July 28, 2021), *Final Determination Regarding Energy Efficiency Improvements in ANSI/ASHRAE/IES Standard 90.1-2019, https://www.federalregister.gov/documents/2021/07/28/2021-15971/final-determination-regarding-energy-efficiency-improvements-in-ansiashraeies-standard-901-2019.*

Table 21. Incremental ASHRAE 90.1.-2019 Construction Costs ($/sf and %/sf)

Year	Building	2A	3A	3B	4A	5A
	First Cost	Tampa	Atlanta	El Paso	New York	Buffalo
	($/ft^2)	$/ft^2)	($/ft^2)	($/ft^2)	($/ft^2)	($/ft^2)
2019	$218	($0.36)	($0.37)	($0.40)	($0.30)	($0.29)
		-0.16%	-0.17%	-0.19%	-0.14%	-0.13%
2016	$194	($0.54)	($0.51)	($0.53)	($0.37)	($0.73)
		-0.28%	-0.27%	-0.27%	-0.19%	-0.38%
2013	$117	$0.17	$0.69	$0.69	$0.38	$0.58
		0.14%	0.59%	0.59%	0.33%	0.50%
2010	$111	$0.62	$0.62	$0.62	$0.62	$0.62
		0.56%	0.56%	0.56%	0.56%	0.56%

Table 22 shows building-level incremental cost or cost savings for each code cycle since 2007. In Climate Zone 2A (Tampa) for example, the incremental cost for the prototype mid-rise building was estimated to be $20,858 and $5,711 for the 2010 and 2013 editions respectively, followed by a combined savings of $30,167 in the following 2016 and 2019 codes.

Table 22. Incremental ASHRAE 90.1 Construction Costs ($/Prototype 32-Unit Building)

Code	Prototype Bldg First Cost	2A	3A	3B	4A	5A
		Tampa	Atlanta	El Paso	New York	Buffalo
	$/bldg	$/Bldg	$/Bldg	$/Bldg	$/Bldg	$/Bldg
2019	$7.36 million	($11,992)	($12,389)	($13,661)	($9,966)	($9,674)
2016	$6.55 million	($18,175)	($17,353)	($17,944)	($12,430)	($24,614)
2013	$3.95 million	$5,711	$23,214	$23,358	$12,891	$19,577
2010	$3.75 million	$20,858	$20,858	$20,858	$20,858	$20,858

2. ASHRAE 90.1–2019 Overview

This notice addresses ASHRAE 90.1–2019, which was the most recently published edition of ASHRAE 90.1 at the time of drafting the preliminary determination. In its qualitative analysis of the code, DOE identified a total of 88 changes, or addenda, to ASHRAE 90.1–2016.[147] [148] Twenty-nine changes were determined to have a positive impact on energy efficiency (*i.e.,* yield energy savings). These include: increased requirement for building vestibules, removal of data processing centers from exceptions to HVAC requirements, removal of hotel room exceptions to HVAC requirements, modification of demand-controlled ventilation requirements, modification of fan power limitations, modification of retail lighting requirements, modification of cooling tower testing requirements, modification of commercial boiler requirements, modification of part load fan requirements, modification of opaque envelope requirements, and modification of fenestration envelope requirements.

[147] Pacific Northwest National Laboratory for the U.S. Department of Energy, Energy Savings Analysis: *ANSI/ASHRAE/IES Standard 90.1–2019, July 21, 2021, https://www.energycodes.gov/sites/default/files/2021-07/Standard_90.1-2019_Final_Determination_TSD.pdf.*

[148] 148DOE determined that 59 of the 88 addenda will have a neutral impact on overall building efficiency; these included editorial changes, changes to reference standards, changes to alternative compliance paths, and other changes to the text of the standard that may improve the usability of the standard, but do not generally improve or degrade the energy efficiency of the building. Changes with impacts which do not become effective within three years from the publication of Standard 90.1–2019 (*i.e.,* until a cutoff date of December 31, 2022), are also considered as having no impact within the context of this analysis.

On March 6, 2024, DOE published an affirmative efficiency determination for ASHRAE 90.1–2022, which has additional energy savings.[149] The 2022 edition includes 89 addenda in total, of which 39 are expected to decrease energy use. With the publication of DOE's affirmative efficiency determination as required under the Energy Conservation and Policy Act, each state is now required to review the provisions of their commercial building code regarding energy efficiency, and, as necessary, update their codes to meet or exceed Standard 90.1–2022. This determination considered only ASHRAE 90.1–2019 because that was the most recent determination available to HUD and USDA at the time of developing the preliminary determination.[150]

3. Current State Adoption of ASHRAE 90.1–2019

Table 23 shows the current adoption status of ASHRAE 90.1 for mid-rise or high-rise multifamily buildings. As of December 2023, ten states and the District of Columbia have adopted ASHRAE 90.1–2019. A total of 33 states and the District of Columbia have adopted an ASHRAE 90.1 standard that is above the current HUD and USDA standard (one of the 2010, 2013, 2016, or 2019 editions), while 17 states have adopted codes that are currently equivalent to or below the current HUD and USDA standard or have no statewide codes.[151] Additionally, DOE provides an analysis of the energy use index of each state-adopted code on their state portal.[152]

[149] Energy Efficiency and Renewable Energy Office, *2024–03–06 Determination Regarding Energy Efficiency Improvements in ANSI/ASHRAE/IES Standard 90.1–2022; Notification of determination. https://www.regulations.gov/document/EERE-2023-BT-DET-0017-0001.*

[150] See ANSI/ASHRAE/IES Standard 90.1–2022 Changes for list of amendments. *www.ashrae.org/technical-resources/bookstore/ansi-ashrae-ies-standard-90-1-2022-changes.*

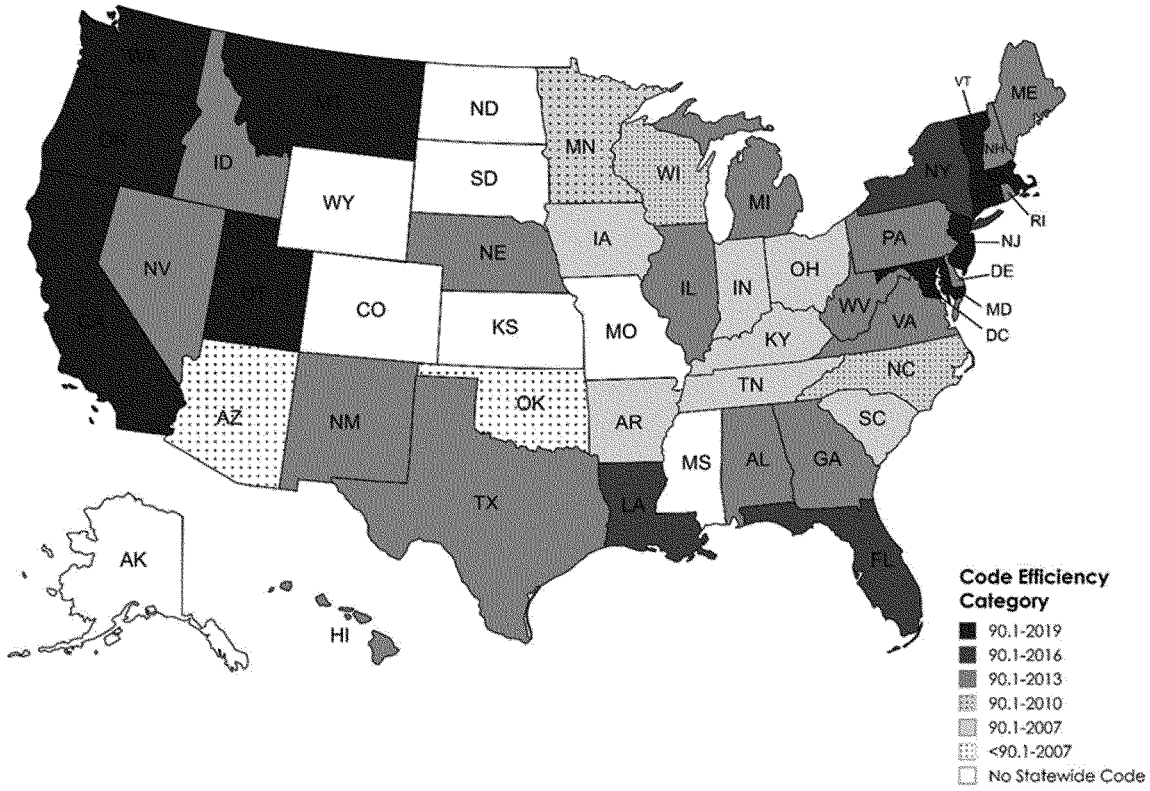
[151] DOE, *Status of State Energy Code Adoption—Commercial, https://www.energycodes.gov/status/commercial.* Note that the codes shown in Table 23 and Figure 3 represent DOE/PNNL's Determination of the standard that the state-adopted code is equivalent to, reflecting amendments that may have been adopted by each state.

[152] DOE, *State Portal, https://www.energycodes.gov/state-portal.*

Table 23. Current Adoption of ASHRAE 90.1 Multifamily Mid- and High-Rise Buildings (December 2023)

Above Current HUD and USDA Standard (33 states + DC)	
ASHRAE 90.1-2019 or Equivalent (10 states + DC)	
California	New Jersey
Connecticut	Oregon
District of Columbia	Utah
Maryland	Vermont
Massachusetts	Washington
Montana	
ASHRAE 90.1-2016 or Equivalent (3 states)	
Florida	New York
Louisiana	
ASHRAE 90.1-2013 or Equivalent (17)	
Alabama	Nevada
Delaware	New Hampshire
Georgia	New Mexico
Hawaii	Pennsylvania
Idaho	Rhode Island
Illinois	Texas
Maine	Virginia
Michigan	West Virginia
Nebraska	
ASHRAE 90.1-2010 or Equivalent (3)	
North Carolina	Minnesota
Wisconsin	
At or Below Current HUD and USDA Standard (17)	
ASHRAE 90.1-2007 or Equivalent (7)	
Arkansas	Ohio
Iowa	South Carolina
Indiana	Tennessee
Kentucky	
No Statewide Code (8)	
Alaska	Missouri (Home Rule)
Colorado (Home Rule)	North Dakota (Home Rule)
Kansas (Home Rule)	South Dakota (Home Rule)
Mississippi	Wyoming (Home Rule)
Equivalent to Less Than ASHRAE 90.1-2007 (2)	
Arizona (Home Rule)	Oklahoma
U.S Territories	
Guam 2018 IBC	N. Mariana Islands 2018 IBC
Puerto Rico IBC 2018 (amended)	American Samoa N/A
U.S. Virgin Islands 2018 IBC	

Figure 3. ASHRAE 90.1 Adoption Map Mid-Rise and High-Rise Multifamily (Status as of December 2023)



4. Analysis of Adopted State Energy Codes for Commercial Buildings

As with residential buildings, the Department of Energy assesses the energy code adopted by each state for commercial buildings. This analysis can be found in the ''commercial state-level results'' available for download at *https://www.energycodes.gov/state-portal.* The analysis presents the energy index for each state-adopted code, including any amendments, as well as each version of ASHRAE 90.1. A comparison of the energy index for the amended codes to that of their code efficiency category demonstrates the impact of each amendment on energy efficiency.

5. Impacted Multifamily Housing

Table 24 provides the estimated number of new mid-rise or high-rise multifamily units that are estimated to be impacted annually by the proposed Determination on ASHRAE 90.1–2019. Using a three-year average (2019 to 2021) annual production for each program, HUD preliminarily estimates that a total of approximately 15,000 new mid-or high-rise multifamily units (four or more stories) will be impacted annually in the 40 states that had not yet adopted ASHRAE 90.1–2019. This includes approximately 11,900 FHA-insured multifamily units, 300 public housing units, and 2,000 HOME- and 300 HTF-financed units. No USDA-guaranteed multifamily units are impacted since these are not covered under this notice.

Table 24. High-Rise Multifamily Units Potentially Impacted by ASHRAE 90.1-2019

State	PIH	HOME	Housing Trust Fund	RAD	FHA Multifamily	Total
AK	0	18	13	25	0	56
AL	34	29	0	0	207	270
AR	0	67	8	16	105	196
AZ	0	58	0	38	278	374
CA (2019)	8	378	0	12	107	505
CO	8	72	0	10	440	530
CT (2019)	15	22	0	0	81	118
DC (2019)	7	0	0	0	89	96
DE	0	2	0	48	0	50
FL	94	124	56	21	953	1248
GA	21	80	0	0	513	614
HI	2	0	0	0	0	2
IA	0	3	3	0	0	6
ID	0	25	17	73	7	122
IL	22	56	0	0	260	338
IN	0	60	0	0	32	92
KS	0	4	19	0	36	59
KY	0	34	0	2	122	158
LA	8	105	1	3	80	197
MA (2019)	0	9	0	35	316	360
MD (2019)	0	77	0	0	547	624
ME	0	21	19	24	10	74
MI	11	54	0	0	65	130
MN	2	73	0	5	391	471
MO	0	138	1	0	286	425
MS	0	0	0	0	0	0
MT (2019)	0	19	2	21	44	86
NC	4	79	0	0	852	935
ND	0	17	8	0	0	25
NE	0	0	0	0	191	191
NH	0	33	4	46	69	152

State	PIH	HOME	Housing Trust Fund	RAD	FHA Multifamily	Total
NJ (2019)	27	75	0	0	32	134
NM	0	5	9	12	74	100
NV	3	216	2	1	59	281
NY	10	156	0	27	932	1125
OH	7	83	0	0	68	158
OK	0	0	7	10	52	69
OR (2019)	0	92	8	30	24	154
PA	27	45	0	0	54	126
RI	0	2	15	2	23	42
SC	0	10	0	0	152	162
SD	0	63	47	37	8	155
TN	1	9	16	103	484	613
TX	54	114	36	0	4,310	4514
UT (2019)	0	1	0	17	307	325
VA	8	38	9	0	596	651
VT (2019)	0	38	16	0	5	59
WA (2019)	10	47	4	31	266	358
WI	4	41	0	0	111	156
WV	0	5	6	5	46	62
WY	0	10	1	0	12	23
Territories						
Puerto Rico	41	86				127
Total	**428**	**2,793**	**327**	**645**	**13,696**	**17,889**
40 states	320	1,949	297	499	11,878	14,943

B. ASHRAE 90.1–2019 Affordability Analysis

1. Cost Benefit Analysis

In its Final Determination of improved energy efficiency for commercial buildings, including multifamily buildings, DOE completes both a ''qualitative'' analysis and a ''quantitative'' analysis to assess increased efficiency of ASHRAE Standard 90.1.[153] In addition to a quantitative and qualitative analysis of the new code, PNNL publishes a cost benefit analysis of each of the codes, which considers the added, or incremental cost for the new standard. In addition, PNNL has published its methodology for evaluating the cost-effectiveness of commercial energy code changes, including multifamily buildings, and that methodology is used by HUD and USDA for this determination.[154] For more detail on the methodology developed by DOE for their cost-benefit analysis, see PNNL's 2015 cost-effectiveness report.[155]

Evaluating cost-effectiveness requires three primary steps: (1) evaluating the energy and energy cost savings of code changes, (2) evaluating the incremental and replacement costs related to the changes, and (3) determining the cost-effectiveness of energy code changes based on those costs and savings over time. The DOE methodology estimates the energy impact by simulating the effects of the code change(s) on typical new buildings, assuming both old and new code provisions are implemented fully and correctly. The methodology does not estimate rates of code adoption or compliance. Cost-effectiveness is defined primarily in terms of LCC evaluation, although the DOE methodology includes several metrics intended to assist states considering adoption of new codes.

2. Building Prototypes

The basis for DOE's ASHRAE 90.1 cost-benefit analysis are16 prototype building models representing different commercial sector building types. Of the 16 prototypes modeled by DOE, two are multifamily buildings-a 4-floor mid-rise apartment building and a 10-floor high-rise apartment building. Table 25 provides detailed characteristics of the mid-rise prototype.

[153] 86 FR 40543 (July 28, 2021), *Final Determination Regarding Energy Efficiency Improvements in ANSI/ASHRAE/IES Standard 90.1-2019, https://www.govinfo.gov/content/pkg/FR-2021-07-28/pdf/2021-15971.pdf.*

[154] PNNL, *Methodology for Evaluating Cost-Effectiveness of Commercial Energy Code Changes,* January 2015, *https://www.pnnl.gov/main/publications/external/technical_reports/PNNL-23923.pdf.*

[155] Ibid.

Table 25. Mid-Rise Apartment Building Prototype Characteristics[156]

GENERAL	
Building Type	Multifamily residential building
Gross Floor Area	33,700 sf
Building Shape	Rectangle
Aspect Ratio	2.75 (152 ft x 56 ft)
Number of Floors	4
Activity Area	Each floor has 8 (25'x38') apartments, except ground floor which has 7 apartments and one lobby/office
Window-to-Wall Ratio	15% (4ft high view windows)
Floor Height	10 ft
Floor-to-Ceiling Height	10 ft (for the office area only)
Exterior Wall	Steel-framed wall
Roof	Insulation entirely above deck, metal deck roof
Floor	8" Slab-on-grade
INTERNAL LOADS	
Occupancy	
Number of People	78 persons total (average 2.5 persons per apartment unit)
Lighting	
Average Power Density	• Apartment units: 0.36 w/sf
	• Corridors: 0.5 w/sf
	• Office area: 1.1 w/sf
Plug Load	
Average Power Density	0.62 w/sf
HVAC	
Heating Type	Gas furnace
Cooling Type	Split system DX (one per apartment)
Fan Control	Constant volume
Distribution/Terminal Units	Single zone/direct air
Cooling T-stat	75°F (no setback assumed)
Heating T-stat	70°F (no setback assumed)
WATER HEATER	
Water Heater Type	Individual residential electric storage water heater
Tank Capacity, gallons	20 (per apartment unit)
Supply Temperature, °F	120

3. ASHRAE 90.1–2019 Incremental Costs

Table 26 provides annual cost savings, added construction costs, and net LCC savings for the mid-rise multifamily prototype building.[157] Cost estimates typically use current national average prices. Labor costs are based on estimated hours and current crew labor rates from RS Means. In some cases, cost estimates completed for a prior code cycle are still applicable and are adjusted for inflation rather than creating a new cost estimate or obtaining current unit prices throughout the cost estimate. Where cost estimates are updated, inflation factors specific to the equipment are used. These inflation factors are developed for each specific equipment or insulation type by comparing RS Means from the time of the estimate with the current RS Means.

[156] PNNL, *Impacts of Standard 90.1–2007 for Commercial Buildings at State Level, https://www.pnnl.gov/main/publications/exter00nal/technical_reports/PNNL-18544.pdf.*

[157] Special tabulation provided by DOE/PNNL to HUD of costs and savings for mid-rise multifamily buildings only, 9/2/21.

Added construction costs average $574/building, or just $18/unit. This low average per-unit increase in cost is because in two of the climate zones analyzed, construction costs are expected to be lower for ASHRAE 90.1–2019 relative to the USDA-HUD 2007 baseline: construction costs for ASHRAE 90.1–2019 are projected to decrease by $257/unit in Climate Zone 2A, and by $142/unit in Climate Zone 4A. Conversely, the highest increase is projected to be $285/unit in Climate Zone 3B, followed by $274 per unit in Climate Zone 3A. Added or incremental construction cost can be negative for some building types for some of the following reasons:

- Fewer light fixtures are required when the allowed lighting power is reduced. Also, changes from fluorescent to LED technology result in reduced lighting costs in many cases and longer lamp lives, requiring fewer lamp replacements.
- Smaller heating, ventilating, and air-conditioning (HVAC) equipment sizes can result from the lowering of heating and cooling loads due to other efficiency measures, such as better building envelopes. For example, Standard 90.1–2019 has more stringent fenestration U-factors for some climate zones. This results in smaller equipment and distribution systems, resulting in a negative first cost.[158]

Annual energy cost savings average $7,153 per building, or $224 per unit, yielding LCC savings of an estimated $188,337 per building or $5,886 per unit. Simple paybacks are immediate in two of the five climate zones analyzed, and 0.4 to 1.5 years in the remaining climate zones, resulting in an extremely fast average payback of just 0.1 years.

Table 26. ASHRAE 90.1-2019 Added Costs and Savings – National (2021 dollars) (2019 Edition vs. 2007 Baseline)

	Per Square Foot			
Climate Zone	Annual Cost Savings, $/ft²	Added Construction Cost, $/ft²	Net LCC Savings, $/ft²	Simple Payback Years
2A	0.253	-0.244	6.37	Immediate
3A	0.213	0.260	5.42	1.2
3B	0.186	0.270	4.89	1.5
4A	0.206	-0.135	5.68	Immediate
5A	0.207	0.075	5.44	0.4
National Weighted Average	0.212	0.017	5.58	0.1

	Per Building			Per Unit		
Climate Zone	Annual Savings $/bldg.	Added Construction Cost, $/bldg.	Net LCC Savings $/bldg.	Annual Savings $/unit	Added Construction Cost, $/unit	Net LCC Savings $/unit
2A	8,536	(8,233)	214,924	267	-257	6,716
3A	7,187	8,772	182,871	225	274	5,715
3B	6,276	9,110	164,989	196	285	5,156
4A	6,950	(4,555)	191,643	217	-142	5,989
5A	6,984	2,531	183,546	218	79	5,736
National Weighted Average	7,153	574	188,337	224	18	5,886

4. State-Level Results

Table 27 provides multifamily added costs and savings for ASHRAE 90.1–19 over the 2007 edition for individual states.[159] Most states (38 states plus the District of Columbia) show lower per-unit added costs for adoption of ASHRAE 90.1–2019 compared to the 2007 standard. Incremental cost savings per unit range from a low of $44 in Illinois to a high of $347 in Delaware. Only 13 states show increased incremental costs: Alabama, Georgia, Mississippi, North Carolina, Nevada, Oklahoma, South Carolina, South Dakota, Tennessee, and Wisconsin. For these 10 states, increased costs average $169/unit, ranging from $22/unit in Nevada to $297/unit in South Dakota. The average incremental cost for all states is just −3/unit.

[158] See, for example, PNNL: *https://www.energycodes.gov/sites/default/files/2021-07/Cost-effectiveness_of_ASHRAE_Standard_90-1-2019-NorthCarolina.pdf.*

[159] Ibid., DOE/PNNL Special Tabulation provided to HUD 9/2/21. Note that many states have already adopted more recent versions of the code than ASHRAE 90.1–2007. As a result, actual costs and savings can both be expected to be lower for those states.

Table 27. ASHRAE 90.1-2019 Added Costs and Savings – States (2021 dollars)

State	Current Code	Incremental Cost $/Unit	Energy Cost Savings $/bldg/yr	Energy Cost Savings, $/unit/yr	Net LCC Savings, Scenario 1 (Publicly-Owned), $/unit	Net LCC Savings, Scenario 2 (Privately-Owned), $/unit	Simple Payback (Years)
AK	No Code	(319)	7,828	245	9,652	8,604	Immediate
AL	2013	210	10,493	328	6,275	5,705	0.9
AR	2007	(23)	5,736	179	5,321	4,835	Immediate
AZ	Home Rule	(234)	5,702	178	6,466	5,938	Immediate
CA	2019	-	-	-	-	-	-
CO	No Code	(72)	6,208	194	5,630	5,201	Immediate
CT	2019	-	-	-	-	-	-
DC	2019	-	-	-	-	-	-
DE	2013	(347)	6,208	194	6,537	5,778	Immediate
FL	2013	(127)	5,871	183	6,657	6,039	Immediate
GA	2013	229	9,515	297	5,693	5,213	1.1
HI	Home Rule	(297)	5,938	186	11,457	10,357	Immediate
IA	2007	(117)	5,601	175	5,975	5,458	Immediate
ID	2013	(60)	7,592	237	5,135	4,698	Immediate
IL	2013	(44)	8,536	267	6,450	6,028	Immediate
IN	2007	(182)	5,770	180	6,527	5,970	Immediate
KS	No Code	(308)	5,972	187	6,655	6,113	Immediate
KY	2007	(328)	9,211	288	5,947	5,377	Immediate
LA	2007	(172)	6,782	212	6,237	5,627	Immediate
MA	2019	-	-	-	-	-	-
MD	2019	-	-	-	-	-	-
ME	No Code	(56)	4,994	156	7,160	6,461	Immediate
MI	2013	(88)	6,782	212	6,475	5,978	Immediate
MN	2010	(54)	7,659	239	6,915	6,271	Immediate
MO	No Code	(333)	7,457	233	6,434	5,902	Immediate
MS	No Code	161	8,199	256	5,985	5,527	0.7
MT	2019	-	-	-	-	-	-
NC	2010	157	4,859	152	5,125	4,699	0.9
ND	No Code	(57)	6,276	196	6,220	5,584	Immediate
NE	2013	(124)	7,085	221	5,546	5,072	Immediate
NH	2010	(6)	7,018	219	7,022	6,394	Immediate
NJ	2019	-	-	-	-	-	-
NM	2013	(305)	7,794	244	5,807	5,300	Immediate
NV	2013	22	6,613	207	5,150	4,758	0.1
NY	2016	(305)	6,917	216	8,454	7,754	Immediate
OH	2007	(192)	6,984	218	6,151	5,640	Immediate
OK	No Code	150	7,389	231	5,330	4,836	0.8
OR	2019	-	-	-	-	-	-
PA	2013	(256)	5,061	158	6,524	5,811	Immediate
PR	2010	0	8,098	253	-	-	0.0
RI	2007	(200)	5,668	177	8,171	7,518	Immediate
SC	2007	186	6,276	196	5,684	5,221	0.9
SD	No Code	297	6,343	198	5,359	4,945	1.6
TN	2007	118	5,061	158	6,086	5,525	0.5
TX	2013	(155)	6,276	196	5,581	5,182	Immediate
UT	2019	-	-	-	-	-	-
VA	2013	(275)	6,006	188	5,297	4,754	Immediate
VT	2019	-	-	-	-	-	-
WA	2019	-	-	-	-	-	-
WI	2010	59	5,027	157	6,400	5,909	0.3
WV	2010	(96)	6,343	198	6,093	5,479	Immediate
WY	No Code	(180)	5,736	179	5,952	5,426	Immediate
Average		(93)	6,670	208	6,388	5,822	Immediate

Key: No Code=No statewide code; Home Rule = Home Rule state.

All states show energy cost savings, both those with incremental cost increases and those that show lower incremental costs. Annual energy cost savings average $208/unit, ranging from $152/unit (North Carolina) to $328/unit

(Alabama). For the prototype 32-unit mid-rise building, this translates into an average annual cost savings of $6,670/building, ranging from $4,859 annual cost savings in North Carolina to $10,493 in Alabama.

The annual energy cost savings relative to lower incremental costs in many states yield ''negative'' simple paybacks in these states; where that is the case, Table 27 shows these paybacks as ''immediate.'' Average simple payback for all states is immediate. The states showing lower incremental costs show immediate paybacks: For example, Ohio shows a decrease in first costs of $192 per unit, but annual energy cost savings of $218, in which case the payback on this investment is immediate.

Table 27 also shows life cycle cost savings for this investment. Average Life Cycle Cost savings for privately owned buildings are $5,822/unit, with LCC savings estimated to be highest in Hawaii ($10,357 per building) and lowest in Idaho ($4,698 per building).

5. Total Life Cycle Cost Savings

Table 28 shows total estimated LCC Savings for ASHRAE 90.1–2019 relative to ASHRAE 90.1–2007. For the total estimated units that could be impacted by the adoption of this code, incremental costs will be an estimated $1.49 million lower than the cost of construction to the 2007 baseline. Annual energy cost savings are estimated to be $3.1 million, and national LCC savings $83.4 million for privately owned buildings. Costs and savings for states that have already adopted the 2019 standard are excluded from these totals, on the assumption that housing will already be built to this standard, and no additional costs will be incurred or savings realized. Additionally, states that have adopted a more recent version than ASHRAE 90.1–2007 are expected to see reduced costs as well as reduced savings compared to the analysis that relies on ASHRAE 90.1–2007 as a baseline.

Table 28. Total Life Cycle Savings – States (2021 dollars)
(ASHRAE 90.1-2019 against 90.1-2007 Baseline)

State	Total Units	Annual Energy Cost Savings, $/state	Added Construction Cost, $/state	Net LCC Savings, Scenario 1 (Publicly-Owned), $/state	Net LCC Savings, Scenario 2 (Privately-Owned), $/state	Simple Payback (Years)
AK	56	18,363	(17,891)	540,498	481,807	Immediate
AL	270	66,046	56,652	1,694,138	1,540,410	0.9
AR	196	35,132	(4,546)	1,043,000	947,731	Immediate
AZ	374	87,148	(87,543)	2,418,464	2,220,902	Immediate
CA	505	-	-	-	-	-
CO	530	94,440	(38,000)	2,984,092	2,756,653	Immediate
CT	118	-	-	-	-	-
DC	96	-	-	-	-	-
DE	50	9,700	(17,344)	326,856	288,899	Immediate
FL	1,248	319,754	(157,903)	8,308,340	7,537,246	Immediate
GA	614	129,477	140,483	3,495,238	3,200,678	1.1
HI	2	922	(595)	22,914	20,714	Immediate
IA	6	1,164	(702)	35,851	32,751	Immediate
ID	122	18,523	(7,332)	626,446	573,192	Immediate
IL	338	66,286	(14,968)	2,179,969	2,037,417	Immediate
IN	92	20,371	(16,781)	600,445	549,228	Immediate
KS	59	12,939	(18,165)	392,658	360,683	Immediate
KY	158	28,987	(51,810)	939,575	849,615	Immediate
LA	197	44,658	(33,857)	1,228,616	1,108,558	Immediate
MA	360	-	-	-	-	-
MD	624	-	-	-	-	-
ME	74	18,023	(4,135)	529,859	478,130	Immediate
MI	130	28,099	(11,377)	841,739	777,180	Immediate
MN	471	102,798	(25,327)	3,256,772	2,953,840	Immediate
MO	425	83,348	(141,603)	2,734,363	2,508,516	Immediate
MS	0	-	-	-	-	-
MT	86	-	-	-	-	-
NC	935	168,579	146,890	4,792,171	4,393,892	0.9
ND	25	4,903	(1,423)	155,494	139,599	Immediate
NE	191	33,430	(23,764)	1,059,288	968,665	Immediate
NH	152	38,464	(962)	1,067,365	971,847	Immediate
NJ	134	-	-	-	-	-
NM	100	17,714	(30,471)	580,750	530,034	Immediate
NV	281	44,442	6,222	1,447,028	1,337,109	0.1
NY	1,125	300,101	(342,804)	9,510,726	8,723,108	Immediate
OH	158	31,319	(30,320)	971,893	891,097	Immediate
OK	69	12,877	10,331	367,761	333,713	0.8
OR	154	-	-	-	-	-
PA	126	24,710	(32,283)	822,084	732,143	Immediate
PR	127	-	-	-	-	0.0
RI	42	12,089	(8,414)	343,199	315,743	Immediate

State	Total Units	Annual Energy Cost Savings, $/state	Added Construction Cost, $/state	Net LCC Savings, Scenario 1 (Publicly-Owned), $/state	Net LCC Savings, Scenario 2 (Privately-Owned), $/state	Simple Payback (Years)
SC	162	34,333	30,062	920,830	845,845	0.9
SD	155	29,090	46,087	830,705	766,478	1.6
TN	613	137,669	72,389	3,730,628	3,386,779	0.5
TX	4,514	875,739	(699,639)	25,191,762	23,392,691	Immediate
UT	325	-	-	-	-	-
VA	651	101,587	(179,150)	3,448,464	3,094,969	Immediate
VT	59	-	-	-	-	-
WA	358	-	-	-	-	-
WI	156	33,061	9,211	998,409	921,760	0.3
WV	62	12,290	(5,949)	377,780	339,669	Immediate
WY	23	4,123	(4,147)	136,895	124,794	Immediate
National	17,889	3,102,699	(1,490,877)	90,953,068	83,434,084	Immediate

The Regulatory Impact Analysis at *www.regulations.gov* provides a more granular analysis of the estimated cost benefits associated with building to the ASHRAE 90.1–2019 standard, taking into account each state's current baseline code. Using current state baselines, Table 29 (also RIA Figure 30) estimates a total incremental cost savings of $9.2 million, and a LCC savings of $44.1 million (at a 3 percent discount rate).

Table 29. Incremental Costs and Energy Savings Resulting from Adoption of ASHRAE 90.1-2019 (2021 dollars)

Current ASHRAE 90.1 Standard	Number of States	Annual Number of Units Affected*	Total Incremental Costs	Net Present Value of Energy Savings	
				3% Discount Rate	7% Discount Rate
No Statewide Code	10	1,596	-$662,487	$21,397,225	$14,072,666
2007	7	1,264	-392,015	5,460,546	3,591,328
2010	3	1,557	-594,671	4,027,640	2,648,924
2013	17	7,508	-6,613,942	11,338,502	7,457,180
2016	3	2,519	-983,227	1,894,844	1,246,214
2019	11	2,673	0	0	0
Total	**51**	**17,117**	**-$9,246,342**	**$44,118,757**	**$29,016,311**

C. Final Affordability Determination—ASHRAE 90.1–2019

In light of the significant estimated savings, both annual and LCC savings, and the nominal cost increase shown in Tables 27 and 28, HUD and USDA have determined that the adoption of ASHRAE 90.1–2019 will not negatively impact the affordability of the multifamily housing covered by this notice. As shown in Table 27, the national average incremental cost for adoption of this edition is −3/unit, while the annual energy cost savings per unit averages $208/unit. In all but 10 states, the incremental costs of building to this standard have in fact decreased, not increased, relative to the current HUD and USDA ASHRAE 90.1–2007 standard: in none of these states is the added construction cost more than $297/unit, and in that state (South Dakota), annual energy cost savings are estimated to be $198/year, yielding a rapid Simple Payback of just 1.6 years. Average (unweighted) payback for all states is immediate, with 10 states having payback period of up to 1.6 years. Estimated first costs are also a nominal fraction of total construction costs: the weighted national average of 0.017 $/sf (less than two cents) in added costs represents just 0.16 percent of the estimated total building cost of $218/sf. Finally in every state analyzed, the net LCC savings are positive, with a weighted national average of $5,822 for privately owned buildings.

V. Impact on Availability of Housing

EISA requires that HUD and USDA assess both the affordability and availability of housing covered by the Act. This section of this notice addresses the impact that the EISA requirements would have on the ''availability'' of housing covered by the Act. ''Affordability'' is assumed to be a measure of whether a home built to the updated energy code is affordable to potential homebuyers or renters, while ''availability'' of housing is a measure associated with whether builders will make such housing available to consumers at the higher code level; *i.e.,* whether the higher cost per unit as a result of complying with the revised code will impact whether that unit is

likely to be built or not. A key aspect of determining the impact on availability is the proportion of affected units in relation to total units funded by HUD and USDA or total for sale units. These issues are discussed below.

A. 2009 IECC—Single Family

In its 2015 Final Determination adopting the 2009 IECC, HUD concluded ''[t]hough both higher construction costs and hedonic increases in demand for more energy-efficient housing are expected to contribute to an increase in housing prices or contract rents, HUD and USDA do not project such higher prices to decrease the quantity of affordable housing exchanged in the market.'' [160]

The current proposed update of IECC requirements constitutes a more expansive impact. The per unit cost is greater than for the previous rule. Revised estimate of the upfront cost of building to 2021 IECC is approximately $7,229, ranging from a low upfront incremental cost of $3,662 in Climate Zone 1 to a high of $8,845 in Climate Zone 8. Likewise, the geographic scope of the impact of the proposed rule is also more extensive than in 2015. In 2015, construction only in those 16 states that had not yet adopted the 2009 IECC or its equivalent was directly affected. Conversely, only five jurisdictions have adopted a standard that meets or exceeds the 2021 IECC requirements. Under this notice, more than 100,000 newly built units would have to comply with the 2021 IECC standard, compared to an estimate of 11,500 annually for the 2015 notice that required IECC 2009 as a minimum standard. This merits a more detailed discussion of the potential impacts on the availability of housing to program participants as well as the housing market overall. As set forth in this section of this notice, HUD and USDA find that there would be no noticeable impact on the supply of housing covered by this notice; there are many ways for both homebuyers and builders to address the costs of the notice if buying or building to the 2021 IECC is not advantageous; but, under very specific conditions, availability could be constrained.

The focus of this availability analysis is on the purchase of newly built homes by FHA-insured borrowers. While other covered programs are important, FHA-insured single family purchases represent the overwhelming majority of units that would be affected by final adoption of the proposed standards. Homebuyers and builders of single family homes will be more sensitive to the IECC requirement than renters and builders affected by the ASHRAE 90.1 update because the estimated incremental cost for single family homes is greater than the incremental cost of updating ASHRAE 90.1.

1. Builder Impacts

Builders are required to build to the 2021 IECC standard only if they wish to sell the new home to a borrower who has a mortgage insured by FHA or guaranteed by USDA. If builders predict that the construction costs outweigh the expected private benefits of building to the 2021 IECC standard, then the supply of newly built homes for FHA-financed borrowers could contract. However, one of several incentives for builders to build to the 2021 IECC standard is to preserve FHA-insured borrowers as potential customers.

FHA-insured borrowers can be a large portion of potential buyers of new construction in some markets. As shown below, in 2020, FHA-insured loans financed just one percent of the purchases of newly built homes in the Northeast, 8.3 percent in the Midwest, 11.0 percent in the West, and a significantly higher market share of 24.5 percent of purchases in the South.

The regions where construction activity is high (*e.g.,* South and West) are also areas where a higher share of buyers of new construction are FHA-insured. In such markets, builders would be more inclined to build to the energy code required by this notice. Having more potential customers increases competition for a home and would reduce the opportunity costs of time on market.

Table 30. Type of Financing of New Single Family Homes (Homes Sold in the United States, 2020)

	Thousands of Homes					Percent Financed			
	Conventional	FHA	VA	Cash	Total	Conventional	FHA	VA	Cash
Northeast	25	(Z)	1	2	28	89.3	**1.0**	3.6	7.1
Midwest	60	6	2	4	72	83.3	**8.3**	2.8	5.6
South	244	96	31	21	392	62.2	**24.5**	7.9	5.4
West	128	19	18	8	173	74.0	**11.0**	10.4	4.6
U.S.	457	122	52	35	665	68.6	**18.3**	7.8	5.3

Source: Annual Characteristics of New Housing, U.S. Census
Z = Less than 500 units or less than 0.5 percent.

The cost to a developer of adopting the standard includes the added building costs, loss of potential customers unwilling to pay the additional price, and any other distortions in design introduced by the regulation. The builder can reasonably be expected to build an affordable home to the 2021 IECC standard if: FHA-insured borrowers are a significant part of the market for newly built homes; there is a sufficient market return from energy efficiency; and the builder is able to pass on some of the cost to the buyer. Under these conditions, which will vary by climate zone and the state of the housing market, availability is not likely expected to be adversely affected. Conversely, builders may be discouraged from building to the higher standard if FHA-insured borrowers are a limited share of the market for new homes, *e.g.,* in the Northeast, where only 1 percent of all new homes are

[160] 80 FR 25901 at 25918 (May 6, 2015).

FHA-financed. However, the impact would be limited because the number of homes likely impacted would be close to zero and, more importantly, there are already states in the Northeast considering adoption of the 2021 or 2024 IECC standards.

A second possibility is that the builder continues to build affordable homes but not to the 2021 IECC. This would be the case when and where there are significant profits from building new homes for low-income homebuyers, even if not FHA-insured, FHA-insured borrowers are not a major part of the market, perhaps because conventional loans are relatively more affordable, the unlikely case that lower-income homebuyers do not place a significant premium on energy efficiency, or the builder is unable to pass on costs to the buyer. Under this scenario, the total supply of affordable housing would not necessarily be adversely affected, but new construction for FHA borrowers could decline. A third possibility is that the profit margin from building affordable housing is so slim that any change to the market could lead to different development decisions. One alternative may be for builders to build housing for higher-income buyers. This strategy could place the home out of reach of some FHA-insured borrowers and thus reduce the availability of some affordable housing. However, in both of these cases, the impact is expected to be limited: estimates of the impact on availability in the price elasticity model shown below indicate the impacts are likely to be limited to an extremely small share of housing supply (0.2 percent of all homes available to FHA-insured home buyers). For further and more detailed discussion of different availability scenarios, see the Regulatory Impact Analysis, Section 10.2 New Construction, Housing Supply, and Availability of Housing.

2. Single Family Market Impacts

The change in market quantity depends not only on the decisions of builders and the real estate industry more broadly but also on the willingness of buyers to absorb a price change. The percentage reduction of quantity is greater as demand and supply are more responsive to price changes and as the incremental cost constitutes a larger portion of the sales price.

The impact on availability, as measured by the quantity of housing, would be given by:

$$\frac{\Delta Q}{\mathrm{Q}} = \left(\frac{E_S \cdot E_D}{E_S - E_D}\right) \cdot \left(\frac{\Delta C}{P}\right)$$

The percentage change in the quantity of housing, $\Delta Q/Q$, depends on the price elasticity of demand E_D (the percentage change in quantity demanded from a percentage change in price), the price elasticity of supply E_S, and the incremental cost ΔC, as a fraction of the pre-regulation sales price P. The percentage reduction of quantity is greater as demand and supply are more responsive to price changes (more price elastic), and the incremental cost constitutes a larger portion of the sales price before the introduction of the cost.[161]

Estimates from studies of the price elasticities of demand and supply vary due to differences in methods, data, and geographies and time periods examined. Generally, the estimate of the price elasticity of demand for housing is below -1, as low as -0.2 for low-income households, but has been estimated to be above -1. Generally, lower income households have a lower measured price elasticity of demand for housing. The positive association between income and the absolute value of price elasticity stems from shelter being a necessary good.[162]

The price elasticity of supply and demand has been estimated at a wide variety of levels for different housing markets, primarily due to differences in the ease of building additional units, depending on the metropolitan area, neighborhood and even type of housing.[163] The incremental cost of adopting the 2021 IECC is expected to be approximately 2 percent of the pre-regulation sales price (a $7,229 incremental cost and $363,000 sales price). Our most cautious estimate is that the approximately 2 percent increase in construction cost would reduce the production of homes for FHA-insured borrowers by 1.5 percent, which represents a 0.2 percent reduction of all homes available to FHA-insured homebuyers.

This estimate is considered a ''worst-case'' scenario because it does not account for any of the positive effects of energy-efficiency. Any adverse impacts on availability would be diminished when there is a perceptible demand for energy-efficient homes.

It is important to note that there would be no adverse effects on the broader availability of housing options for FHA-insured homebuyers if they are able to find close substitutes in other submarkets. Close substitutes may include, for example, relatively new existing housing or code-complaint new homes in adjacent or nearby communities with similar features or amenities. Finding a close substitute may be more difficult in rural areas where there is less available housing stock. USDA guaranteed and direct loans are limited to eligible areas as defined by USDA and exclude central cities. Thus, there could be a greater relative burden on Section 502 guaranteed loans: about half of USDA's guaranteed and direct home loans are to borrowers in rural areas as defined by the 2010 Census as compared to about one-fifth of FHA-insured mortgages (AHS, 2019).

However, adoption of the new code is not expected to have spillover impacts on other housing submarkets given the relatively small size of the directly affected FHA and USDA submarkets. The purchase of new homes by FHA-insured borrowers represents only 2.3 percent of all residential sales in 2020. As a portion of all home purchases (all homebuyers, new and existing homes), FHA-financed purchases of new construction range from slightly more than 0 percent in the Northeast to slightly less than 3.6 percent in the South.

Energy efficiency has also been shown to impart an economic value to buildings. The willingness to pay for this benefit will vary among homebuyers. If there is a sufficient proportion who expect to realize those gains, then there will be a demand for housing built to the 2021 IECC that could partially counteract any adverse impacts on availability. See the discussions in the Regulatory Impact Analysis at *www.regulations.gov* in the ''Capitalization of Energy Efficiency Standard'' section (p.86).

[161] The pass-through rate is the proportion of the cost paid by buyers, which is higher as demand is less price elastic and supply is more price elastic.

[162] Mayo (1981) shows this to be the case when a household must consume a minimum amount of housing (a Stone-Geary utility function).

[163] Gyourko and Saiz (2006) attribute the local variation in construction activity to more than the cost of materials but also to local wages, local topography, and the local regulatory environment.

Empirical studies cited in the RIA suggest there is a statistically significant and positive influence of energy efficiency on real estate values of energy efficient housing.[164] One study examining the residential market in California found that a green label adds about 2.1 percent to the value of a home. This premium is slightly above the costs of bringing a home in compliance with the green labels (Energy Star, LEED, and EnergyPoint).

Another study examined the premium placed on the Energy Star certification on homes in Gainesville, Florida and found that there is a premium for these homes but that the premium diminishes when the home is resold; this finding could suggest that energy efficiency is a motivator for buying newly built homes.[165] Another two studies examined the effects of a label, which would be a voluntary option for the builder, rather than a code, which is obligatory.[166] In another study, researchers found that energy performance certificates do not play a role in determining market value but that energy efficiency itself is capitalized into housing sales prices (about 2 percent for every 10 percent reduction of energy consumption).[167]

A survey by the National Association of Home Builders found that the median borrower was willing to pay an extra $5,000 upfront to save $1,000/year in utility bills.[168] This tradeoff would be equivalent to the resident receiving 10 years of benefits at a 20 percent discount rate or 30 years of benefits at 25 percent discount rate. A recent survey of the National Association of Realtors found that sixty five percent of realtors believed that energy efficiency was valuable in promoting residential units. (However, the majority of realtors (57 percent) were ''not sure'' as to the impact of energy efficiency on sales price.) [169]

A study of commercial buildings showed that a studio with an Energy Star certification will rent for about 3 percent more per square foot and sell for as much as 16 percent more. The authors were able to disentangle the value of the label itself from the value of energy savings stemming from increased energy efficiency. Energy savings were important: a 10 percent decrease in energy consumption led to an increase in value of about one percent over and above the rent and value premium for a labeled building.[170]

All of this empirical research shows that there are profit incentives to providing energy efficiency. Such a price gain would diminish any adverse effects on the supply of housing, although it is also evidence that bidding for energy efficiency could reduce affordability.

3. Evidence From Prior (2009 IECC) Code Adoption

Examining FHA new construction loans by the level of a state's energy-efficiency standards can provide a rough indicator of the potential impact of the IECC on availability. Having required a minimum standard equal to the 2009 IECC (in 2015), the purchase of a new FHA-insured or USDA-guaranteed home could depend on the strictness of the state-wide code relative to the 2009 IECC. However, as shown in Table 19, in states where the state-wide standard is lower than that required by HUD and USDA, the proportion of FHA loans for new construction appears similar to states that have adopted stricter codes. For the group where the state-wide code is at least as stringent as the 2009 IECC, the proportion of FHA-insured new construction loans is 16.9 percent, which is slightly higher than the 15.1 percent for the states where energy codes are below IECC 2009. Despite the cyclical nature of new construction, there is no compelling evidence that the availability of newly built owner-occupied housing will be adversely affected.

[164] Laquatra, J., Housing Market Capitalization of Energy Efficiency Revisited, 2002.

[165] Bruegge, C., Deryugina, T. and Myers, E., 2019. The distributional effects of building energy codes. Journal of the Association of Environmental and Resource Economists, 6(S1), pp. S95–S127.

[166] Bruegge et al., 2016; Kahn, Matthew E., and Nils Kok. ''The capitalization of green labels in the California housing market.'' Regional Science and Urban Economics 47 (2014): 25–34.

[167] Aydin, Erdal, Dirk Brounen, and Nils Kok. ''The capitalization of energy efficiency: Evidence from the housing market.'' Journal of Urban Economics 117 (2020): 103243.

[168] Ford, Carmel. ''How Much Are Buyers Willing to Pay for Energy Efficiency?'' Eye on Housing: National Association of Home Builders Discusses Economics and Housing Policy. April 12, 2019. *https://eyeonhousing.org/2019/04/how-much-are-buyers-willing-to-pay-for-energy-efficiency/*.

[169] National Association of Realtors, REALTORS and Sustainability Report—Residential, 2021, *https://www.nar.realtor/sites/default/files/documents/2021-realtors-and-sustainability-report-04-20-2021.pdf*.

[170] Eichholz, P., N. Kok and J. Quigley, ''Doing Well by Doing Good? Green Office Buildings,'' American Economic Review 100:5 (2010): 2492–2509.

Table 31. FHA-Insured Single Family Forward Loans, 2021 Grouped by Region and Strictness of State-wide Standard

All Regions			
State-wide Energy Standard	**New Construction**	**All Purchase Loans**	**Percent New (%)**
Less than IECC 2009	14,800	98,300	15.1
Same as IECC 2009	61,900	445,800	13.9
Higher than IECC 2009	47,000	226,700	21.0
South			
State-wide Energy Standard	**New Construction**	**All Purchase Loans**	**Percent New**
Less than IECC 2009	5,400	32,600	16.6
Same as IECC 2009	49,390	225,000	21.9
Higher than IECC 2009	37,900	116,000	32.7
West			
State-wide Energy Standard	**New Construction**	**All Purchase Loans**	**Percent New**
Less than IECC 2009	8,090	42,275	19.1
Same as IECC 2009	5,490	32,500	16.9
Higher than IECC 2009	9,050	73,900	12.3
Midwest			
State-wide Energy Standard	**New Construction**	**All Purchase Loans**	**Percent New**
Less than IECC 2009	1,310	23,400	5.6
Same as IECC 2009	5,650	122,000	4.6
Higher than IECC 2009	165	3,270	5.1
Northeast			
State-wide Energy Standard	**New Construction**	**All Purchase Loans**	**Percent New**
Less than IECC 2009	0	0	---
Same as IECC 2009	1,410	66,000	2.1
Higher than IECC 2009	500	33,660	1.5

There is some regional variation. In the South, the proportion of new construction is much higher in states above the IECC 2009 (32.7 percent) than in states below (16.6 percent). In the West, the proportion of FHA new construction is lower in states with energy codes above the IECC 2009 (12.3 percent) than in states below (19.1 percent). A clear pattern is not identifiable in either the Northeast or Midwest. Diverse climate zones and housing markets could explain why different regions appear to respond differently to the energy standard.

4. Variability in Building Practices in Relation to Energy Codes

Note that there is wide variability in enforcement of, or compliance with, building codes in general. Some states do not adopt statewide building codes, others adopt for only certain building types that may exclude single family housing, some states adopt codes with amendments, while others that have adopted building codes may not enforce them, either in their entirety or only for certain building types.[171]

Conversely, a growing number of builders are incorporating above-code energy efficiency or green building standards that meet or exceed the 2021 IECC as standard building practice. Nearly 2.5 million Energy Star certified single family, multifamily, and manufactured new homes and apartments have been built to date, including more than 140,000 in 2022, representing nearly 10 percent of all U.S. homes built. Homes and apartments that earn Energy Star certification are at least 10 percent more efficient than those built to code. Since 2023, in most states, Version 3.1 of the Energy Star program is the minimum Energy Star standard for single family homes, which is designed to deliver at least 10 percent savings relative to all code versions up to the 2018 IECC. Energy Star Version 3.2 will be implemented in states that adopt the 2021 IECC; Version 3.2 is designed to

[171] Lawrence Berkeley National Laboratory, The Cost of Enforcing Building Codes, Phase I, April 2013. Table 1 shows varying compliance rates: *https://www.researchgate.net/publication/282136731_The_Cost_of_Enforcing_Building_Energy_Codes_Phase_1*.

deliver at least 10 percent energy savings relative to the 2021 IECC.

There are also a smaller number built to the DOE's Zero Energy Ready Home (ZERH) standards. In addition, certain green building standards set Energy Star as a minimum requirement. With the energy efficient new homes tax credit (45L) of up to $2,500 now available for Energy Star Certified Homes and up to $5,000 for DOE Zero Energy Ready Homes for single family homes and, with prevailing wage requirements, up to $2,500 per unit for Energy Star Multifamily New Construction and up to $5,000 per unit for DOE Zero Energy Ready Homes for multifamily homes, the market share for these above-code standards is likely to increase.[172]

There is widespread regional variation in adoption of these standards because they are not typically mandated by municipalities for single family home construction. There are regional variations in above-code standards among builders as well. For example, for Energy Star New Homes, adoption rates in most states are below five percent, with very little in the northeast, while in the southwest the share of Energy Star new homes is much higher, *e.g.,* adoption in Arizona is around 40 percent.[173]

In the multifamily sector, builders frequently build to above code standards such as LEED, Enterprise Green Communities, ICC 700 National Green Building Standard, PHIUS, the Living Building Challenge, or regional programs like Earthcraft. Most of these programs embed Energy Star New Construction within their standards while also addressing other areas of health and disaster resilience requirements. Some municipalities may require one of these above-code standards for new construction of multifamily housing. In the affordable housing sector, each state may also drive the choice of compliance with above-code standards through their Low-Income Housing Tax Credit Qualified Allocation Plans (QAPs). State QAPs may call out these above-code standards specifically or may allocate points to other matching funding streams that incentivize or require specific above-code standards.

B. ASHRAE 90.1–2019—Rental Housing

USDA and HUD have determined that in light of the extremely small incremental first costs, or, in many cases, negative first costs, adoption of ASHRAE 90.1–2019 will not negatively impact the availability of multifamily units financed or insured through these programs. Simple paybacks times are extremely low for the small number of states that will see an increase in first costs, in most cases less than one year. The estimate of the direct cost of construction of moving to this code is not greater than zero. Even if there were a slight increase in construction costs, the estimates of energy savings are sizeable enough such that the benefits would offset the costs for property managers. There could be some builders of multi-family properties who are doubtful of the return and so view the ASHRAE 90.1–2019 requirement as a net burden. For the hesitant developer, there remain other incentives to comply: FHA multifamily loans allow a higher LTV than is common and Low-Income Housing Tax Credits that are frequently used by developers in conjunction with HUD financing often carry a requirement or incentive for energy efficiency. In addition, FHA's lower multifamily Green Mortgage Insurance Premium provides a strong incentive for developers to adopt an above-code standard.

VI. Implementation

Under Section 109(d) of Cranston-Gonzalez (42 U.S.C. 12709), the 2021 IECC and ASHRAE 90.1–2019 standards automatically apply to all covered programs upon the effective date of the specified affordability and availability determinations by HUD and USDA. Accordingly, once a Final Determination has been made by HUD and USDA under section 109(d) (42 U.S.C. 12709(d)) and published, additional notice and comment rulemaking will not be required for the covered programs.

Based on DOE findings on improvements in energy efficiency and energy savings and a subsequent HUD and USDA Final Determination with respect to both housing affordability and availability, HUD and USDA programs specified under EISA will implement procedures to ensure that recipients of HUD and USDA funding, assistance, or insurance comply with the 2021 IECC and ASHRAE 90.1–2019 code requirements, commencing no later than 30 days after the date of publication of a notice of Final Determination. HUD and USDA will take such administrative actions as are necessary to ensure timely implementation of and compliance with the energy codes, to include Mortgagee Letters, notices, notices of Funding Opportunity (NOFOs), Builder's Certification Form HUD–92541, and amendments to relevant handbooks.

In addition, conforming rulemaking will be required to update FHA's single family minimum property standards at 24 CFR 200.926d, Public Housing Capital Fund energy standards at 24 CFR part 905, and HOME property standards at 24 CFR 92.251, although as noted above, this would not entail further notice and comment rulemaking. Similarly, USDA will update minimum energy requirements at 7 CFR part 1924 to conform with the requirements of this notice.

To enable these administrative and conforming rulemaking procedures to be implemented and to provide the industry with adequate time to prepare for these requirements and incorporate them in project plans and specifications, proposals, or applications, adoption of the new construction standards described in this notice will be required as described in Table 32.

In response to public comment and to better enable builders to adapt to these code requirements, the compliance deadlines are extended beyond the dates in the preliminary determination, as shown in Table 32. As discussed in this notice, rural persistent poverty areas, where capacity to adopt above-code standards may be challenging, have a longer compliance timeline. Due to differing administrative procedures associated with each program, compliance dates vary. The compliance dates differ for example, for competitive grant programs that have notices of funds availability or programs, such as FHA-insured multifamily, that provide for pre-applications before firm commitments, compared to application for building permits for single family construction. The compliance dates are as follows:

(1) For FHA-insured multifamily programs, the standards set forth by this notice are applicable to those properties for which mortgage insurance pre-applications are received by HUD 12 months after the effective date of this determination;

(2) For FHA-insured and USDA-guaranteed single family loan programs, the standards set forth by this notice are applicable to new construction where building permits applications will be or have been submitted on or after18 months after the effective date of this determination;

(3) For the HOME and Housing Trust Fund (HTF) programs, the standards set forth by this notice are applicable to residential new construction projects for which HOME or HTF funds are committed by HOME Participating Jurisdictions or HTF grantees on or after

[172] For multifamily homes, the amounts of the 45L tax credit change to up to $500 per unit for Energy Star Multifamily New Construction and up to $1,000 per unit for DOE Zero Energy Ready Homes if prevailing wage requirements are not met.

[173] *https://www.energystar.gov/newhomes/energy_star_certified_new_homes_market_share.*

180 days after the effective date of this notice;

(4) For Public Housing Capital Fund, the standards set forth by this notice are applicable to HUD approvals of development proposals for new Capital Fund or mixed financed projects on or after12 months after the effective date of this determination;

(5) For new construction occurring in higher needs rural areas across all covered programs, the standards set forth by this notice are applicable on or after 24 months after the effective date of this determination. For the purposes of this notice, these are defined as persistent poverty rural areas, as defined by USDA Economic Research Service. This will include persistent poverty counties coterminous with or persistent poverty census tracts located in rural counties as defined by USDA. USDA will publish a map of rural areas covered by this extension no later than 30 days after the effective date of this notice.

Table 32. Compliance Dates for the New Construction Standards in this Notice

Program	Event	Preliminary Determination Compliance Date	Final Determination Compliance Date
HOME and Housing Trust Fund (HTF)	Participating Jurisdiction or HTF Grantee Funding Commitment	180 days after effective date	180 days after effective date
FHA-Insured Multifamily	Pre-application Submitted to HUD	90 days after effective date	12 months after effective date
FHA-Insured Single Family	Building Permit Application	180 days after effective date	18 months after effective date
Public Housing (Capital Fund, Project Based Vouchers)	HUD approvals of development proposals for new Capital Fund or mixed financed projects	180 days after effective date	12 months after effective date
Competitive Grants (Choice Neighborhoods, Section 202, Section 811)	NOFO Publication	N/A	Next published NOFO after effective date.
Rental Assistance Demonstration		Already effective by Federal Register Notice July 27, 2023	Already effective by Federal Register Notice July 27, 2023
USDA Section 502 Guaranteed Housing Loans	Building Permit Application	180 days after effective date	18 months after effective date
USDA Section 502 Direct Loans	Application Selected for Processing	180 days after effective date	18 months after effective date
USDA Section 523 Mutual Self Help Loans	Application Selected for Processing	180 days after effective date	18 months after effective date
All programs, persistent poverty rural areas*	Program-Specific Event, above	N/A	24 months after effective date

*Persistent poverty rural areas across all programs should follow the area-specific implementation guidance rather than that outlined for each HUD and USDA program.

Compliance Paths

HUD and USDA interpret EISA/Cranston-Gonzalez to mean that any energy code that is determined by a DOE or EPA analysis to have an energy efficiency standard that is equal to or more efficient than what is required under the 2021 IECC or ASHRAE 90.1–2019, is deemed to meet the requirements of the 2021 IECC or ASHRAE 90.1–2019, respectively:

(1) EPA's Energy Star Version 3.2 certification for single family and low-rise multifamily buildings, Energy Star Version 1.2 for multifamily new construction, and DOE's Zero Energy Ready Homes Single Family Version 2 certification or Multifamily Version 2, once it is released on January 1, 2025, certification for multifamily buildings will be accepted as evidence of compliance with the standards addressed in this notice:

(2) Certain energy and green building certifications, provided that they require and provide evidence of energy efficiency levels that meet or exceed the 2021 IECC or ASHRAE 90.1–2019 or include certification through EPA's Energy Star Version 3.2 certification for single family and low-rise multifamily buildings, Energy Star Version 1.2 for multifamily new construction, and DOE's Zero Energy Ready Homes Single Family Version 2 certification or Multifamily Version 2 once released, certification for multifamily buildings. These may include standards referenced in one or more HUD or USDA programs,

such as the ICC–700 National Green Building Standard, Enterprise Green Communities, Energy Star Certified New Homes, Energy Star Indoor Air Plus, Leadership in Energy and Environmental Design (LEED), Living Building Challenge, or Passive House, as well as one or more regional or local standards such as Earthcraft, Earth Advantage, or Greenpoint Rated New Home.[174] HUD and USDA will publish a list, to be updated annually, of those standards that comply with the minimum energy efficiency requirements of this notice. HUD and USDA will also accept certifications of compliance of state or local codes or standards for which credible third-party documentation exists that these meet or exceed the 2021 IECC and ASHRAE 90.1–2019.

(3) 2024 IECC (pending publication). The 2024 IECC has preliminarily been estimated by DOE to be at least 6.66 percent more efficient than the 2021 IECC. Adoption of the prescriptive or performance paths of the 2024 IECC will be an allowable compliance pathway, upon publication of a final efficiency determination by DOE that this edition is more energy efficient than the prior code.

[174] Energy Star Certified New Homes Version 3.2 and DOE's Zero Energy Ready Homes set the 2021 IECC as the baseline standard.

VII. Environmental Impact

A Finding of No Significant Impact with respect to the environment was made in connection with the preliminary determination, in accordance with HUD regulations at 24 CFR part 50 and USDA Rural Development regulations at 7 CFR part 1970, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)), and remains applicable to this final determination. That finding is posted at *www.regulations.gov* and is also available for public inspection between the hours of 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the finding by calling the Regulations Division at 202–402–3055 (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 or 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*.

Damon Smith,

General Counsel, U.S. Department of Housing and Urban Development.

Xochitl Torres Small,

Deputy Secretary, U.S. Department of Agriculture.

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