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CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1223

[Docket No. CPSC–2013–0025]

Safety Standard for Infant and Cradle Swings

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: In June 2012, the U.S. Consumer Product Safety Commission (CPSC) published a consumer product safety standard for infant swings under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The standard incorporated by reference ASTM F2088–12a, *Standard Consumer Safety Specification for Infant Swings,* the voluntary standard for infant swings that was in effect at the time. Because the standard applied to both infant and cradle swings, in 2020, ASTM changed the title of the voluntary standard by adding cradle swings to the title. ASTM has now issued a revised standard, ASTM F2088–24, *Standard Consumer Safety Specification for Infant and Cradle Swings.* The CPSIA sets forth a process for updating mandatory standards for durable infant or toddler products that are based on a voluntary standard, when a voluntary standards organization revises the standard. Consistent with the CPSIA update process, this direct final rule updates the mandatory standard to incorporate by reference ASTM's 2024 version of the voluntary standard. It also revises the mandatory standard to include ''cradle swings'' to align with the voluntary standard.

DATES: The rule is effective on September 14, 2024, unless the Commission receives a significant adverse comment by July 1, 2024. If the Commission receives such a comment, it will publish a document in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of September 14, 2024.

ADDRESSES: You can submit comments, identified by Docket No. CPSC–2013–0025, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by email, except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/Hand Delivery/Courier/Confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: *https://www.regulations.gov,* and insert the docket number, CPSC–2013–0025, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Will Cusey, Small Business Ombudsman, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7945 or (888) 531–9070; email: *sbo@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Authority

Section 104(b)(1) of the CPSIA requires the Commission to assess the effectiveness of voluntary standards for durable infant or toddler products and adopt mandatory standards for these products. 15 U.S.C. 2056a(b)(1). The mandatory standard must be ''substantially the same as'' the voluntary standard, or it may be ''more stringent than'' the voluntary standard, if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the product. *Id.*

Section 104(b)(4)(B) of the CPSIA specifies the process for updating the Commission's rules when a voluntary standards organization revises a standard that the Commission incorporated by reference under section 104(b)(1). First, the voluntary standards organization must notify the Commission of the revision. Once the Commission receives this notification, the Commission may reject or accept the revised standard. The Commission may reject the revised standard by notifying the voluntary standards organization, within 90 days of receiving notice of the revision, that it has determined that the revised standard does not improve the safety of the consumer product and that it is retaining the existing standard. If the Commission does not take this action to reject the revised standard, the revised voluntary standard will be considered a consumer product safety standard issued under section 9 of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2058), effective 180 days after the Commission received notification of the revision or on a later date specified by the Commission in the **Federal Register**. 15 U.S.C. 2056a(b)(4)(B).

B. Safety Standard for Infant and Cradle Swings

Under section 104(b)(1) of the CPSIA, the Commission adopted a mandatory rule for infant swings, codified in 16 CFR part 1223, ''Safety Standard for Infant Swings.'' The rule incorporated by reference ASTM F2088–12a, *Standard Consumer Safety Specification for Infant Swings,* with modifications to make the standard more stringent. 77 FR 66703 (Nov. 7, 2012). The mandatory standard

included performance requirements and test methods, as well as requirements for warning labels and instructions, to address hazards to children. At the time the Commission published the final rule, ASTM F2088–12a was the current version of the voluntary standard.

In 2013, ASTM notified CPSC that it had issued a revised standard and the Commission published a direct final rule to update 16 CFR part 1223, incorporating by reference the new ASTM F2088–13, with no modifications. 78 FR 37706 (June 24, 2013). ASTM later approved two more revisions: ASTM F2088–15 and ASTM F2088–19. However, ASTM did not notify CPSC of these revisions under CPSIA section 104(b)(4)(B). Consequently, these revised standards did not become the mandatory standards by operation of law, and the Commission did not update the mandatory standard to incorporate by reference these revised ASTM standards. In 2020, ASTM notified CPSC that it had issued a further revised standard, ASTM F2088–20, and the Commission published a direct final rule to update 16 CFR part 1223, incorporating by reference ASTM F2088–20, with no modifications.[1] 86 FR 4961 (Jan. 19, 2021). In 2021, ASTM notified CPSC that it had issued another revised standard, ASTM F2088–21, and the Commission published a direct final rule to update 16 CFR part 1223, incorporating by reference ASTM F2088–21, with no modifications. 86 FR 59609 (Oct. 28, 2021). In 2022, ASTM notified CPSC that it had issued an additional revision, ASTM F2088–22, and the Commission published a direct final rule to update 16 CFR part 1223, incorporating by reference ASTM F2088–22, with no modifications. 87 FR 57390 (Sep. 20, 2022). ASTM F2088–22 is the current mandatory standard incorporated by reference in 16 CFR part 1223.

In February 2024, ASTM published a revision to the voluntary standard, approving ASTM F2088–24. On March 18, 2024, ASTM notified CPSC of the revision. On March 28, 2024, the Commission provided notice in the **Federal Register** of the availability of the revised standard and sought comments on the effect of the revisions. 89 FR 21497. CPSC did not receive any comments.

As discussed below, based on CPSC staff's review of ASTM F2088–24, the Commission will allow the revised voluntary standard to become the mandatory standard because the revised requirements in the voluntary standard either improve the safety of infant and cradle swings, or are neutral with respect to safety.[2] In addition, with this update, the Commission is now revising the mandatory standard to align with the 2020 change to the title of the voluntary standard by including the words ''cradle swings.'' Accordingly, by operation of law under section 104(b)(4)(B) of the CPSIA, ASTM F2088–24 will become the mandatory consumer product safety standard for infant and cradle swings on September 14, 2024. 15 U.S.C. 2056a(b)(4)(B). This direct final rule updates 16 CFR part 1223 to incorporate by reference the revised voluntary standard, ASTM F2088–24.

II. Revisions to ASTM F2088

ASTM F2088–24 includes several substantive additions and revisions, revisions to clarify existing requirements, and editorial revisions that do not alter substantive requirements in the standard or affect safety. The standard continues to apply to both infant and cradle swings.[3]

A. Substantive and Clarifying Revisions

ASTM F2088–24 contains substantive changes to requirements in section 6.9 that address the strangulation and entrapment hazard to non-occupants associated with tethered straps and cords on swings. 16 CFR part 1223, incorporating by reference ASTM F2088–22, addresses the strangulation hazard posed by a length of strap that can wrap around an infant's neck and specifies that any accessible tethered straps on the underside of the seat must not exceed 16 inches. The 16-inch length limit is based on the approximate perimeter of a 5th percentile 6-month-old small head probe used in other infant product standards (section X1.4).

However, accessible tethered straps on the underside of the seat can form an opening with other parts of the swing, also posing an entanglement or strangulation hazard. CPSC staff identified two incidents demonstrating this hazard involving products that would have passed the 16-inch ASTM F2088–22 tethered strap requirement and raised the issue with ASTM.[4] In a non-fatal incident in 2018,[5] a 10-month-old infant became entangled around the neck in the tethered straps on the underside of an infant swing that formed an opening in conjunction with the fabric seat of the product, resulting in injuries. In a fatal incident in 2020,[6] a 10-month-old was found ''tangled'' and not breathing with the tethered straps around the infant's neck; the straps formed an opening in conjunction with the fabric seat of the swing.

Revisions in ASTM F2088–24 address the head entrapment and strangulation hazard by requiring that: (1) an opening under the swing (formed by the tethered strap by itself, with other straps, or in conjunction with the product) is either too small to allow an infant's head to fit or large enough to allow an infant's torso (and head) to pass through, and (2) if the opening is large enough to pass an infant's torso, the tethered strap portion of the opening cannot be manipulated to loop around an infant's neck. The revised requirements and corresponding test methods ensure that any openings bounded by the strap are either too small for an infant's head to enter or are large enough for the infant's head to escape (without also posing a strangulation hazard in the strap portion of the opening). Several revisions in the standard relate to this change.

First, the Terminology section of ASTM F2088–24 adds definitions for ''cord'' (section 3.1.3) and ''strap'' (section 3.1.13) and revises the definition of ''tethered strap'' (section 3.1.15). ASTM added the word ''cord'' to the requirements related to tethered straps throughout the standard. Using both ''cord'' and ''strap'' in the relevant requirements and defining these terms ensures that all components that present the same hazard are included within the relevant requirements. Consistent with this change, the defined term ''tethered strap'' was expanded to include ''and/or cord,'' and the wording of the definition was revised—previously it included only straps that attached a restraint system or seat to the product frame; as revised, it includes any accessible and exposed strap or cord behind or below the occupant support surface with both ends secured to the product or itself. This revised definition addresses the

[1] One revision to ASTM F2088–20 was to change the title for the standard from ''Standard Consumer Safety Specification for Infant Swings'' to ''Standard Consumer Safety Specification for Infant and Cradle Swings.'' The change to the title did not alter the scope of the standard; performance requirements and test methods for cradle swings had been in the scope of the standard since ASTM first adopted it. The revision was a clarifying change to the title to make it clear that the standard also applied to cradle swings.

[2] The Commission voted 5–0 on May 21, 2024, to approve this rule.

[3] An infant swing is ''a swing that enables an infant in a seated position to swing or glide and is intended for use with infants from birth until infant attempts to climb out of the swing (approximately 9 months).'' A cradle swing is ''a swing which is intended for use by an infant lying flat to swing or glide and is intended for use with infants from birth until infant begins to push up on hands and knees (approximately 5 months).''

[4] Staff letter to Ms. Costello, chair of ASTM F15.21 on Infant Swings, dated October 1, 2020.

[5] August 2018, IDI 180814HCC1899.

[6] December 2020, IDI 210616CCC3129.

fact that hazardous straps/cords can be part of or be attached to any component of the product and not just the restraint system or seat.[7]

Second, ASTM F2088–24 includes revised provisions in the Performance Requirements section (section 6.9) and Test Methods section (section 7.16). Where ASTM F2088–22 simply specified a 16-inch length limit for a tethered strap that is accessible on the underside of the seat, ASTM F2088–24 states that when tested under conditions specified in section 7 of the standard, all tethered straps and cords that form a bounded opening, alone or in conjunction with the product (1) must not allow the passage of the small head probe, or (2) must allow the passage of the large head probe, and the strap/cord portion of the bounded opening must not form a loop with a perimeter greater than 7.4 inches. Revised test methods in section 7.16 modify the test set-up and initial conditions for testing to ensure that the product is secured, the loop formed below the product is not influenced by weight in the seat, and the buckles and/or hardware are positioned to allow for the maximum length of any strap/cord to be accessible from behind or below the occupant support surface during testing.

ASTM F2088–24 also adds the use of a 3/4-inch diameter clamping surface tool during the strap/cord evaluation test method to ensure consistency during the application of the pull force. During the assessment of the bounded openings, the test methods specify the insertion forces to be used with the small and large head probes (10 and 5 pounds, respectively).[8] The insertion forces allow for compression of soft goods in the testing area and consistency in testing. After the large head probe test in the evaluation of the bounded opening, the test methods also include a provision to use a 7.4-inch circumference cylindrical probe to evaluate the strap/cord length and tautness. The standard includes new figures (figures 14, 15, 16, and X1.1) to provide dimensions and illustrations of the small head probe, large head probe, and cylindrical probe.

CPSC considers the revisions in ASTM F2088–24 to be an improvement to safety because the revisions address entrapment and strangulation hazards posed by openings created by accessible tethered straps under the swing and other parts of the product; this hazard is not addressed by ASTM F2088–22. Limiting the length of a tethered strap alone, as ASTM F2088–22 does, is less effective to address the entrapment and strangulation hazard because it does not address the size of an opening formed with the strap/cord and other parts of the product. The intent of the 16-inch maximum length requirement was to prevent the head of a child 6-months or older from becoming entangled if an exposed tethered strap formed a loop with itself. However, the requirement does not account for a strap that creates a bounded opening with other parts of the swing, which could create an opening large enough to allow the head of an infant to enter, and consequently, become entangled. Additionally, the requirement did not address that adjoined straps can pose an entrapment hazard. The revised requirements in ASTM F2088–24 address those hazard patterns. The revised requirements ensures that the opening formed in conjunction with the strap/cord is either (1) small enough to prevent an infant's head from entering and getting entrapped and posing a strangulation hazard,[9] or (2) large enough for an infant's head to escape and not get entrapped and not pose a strangulation hazard when in the bounded opening.[10] If the opening is large enough to allow an infant's torso and head to pass, an additional test ensures that the strap portion of the opening is not loose/long enough to wrap around an infant's neck; this test uses a 7.4-inch circumference probe to verify strap cannot form loop around it.[11]

These revisions in ASTM F2088–24 are an improvement to the safety of the swings because they address the head entrapment and entanglement hazards demonstrated in incidents with exposed straps/cords behind or below swings.

B. Non-Substantive Revisions

ASTM F2088–24 also includes several minor additions and revisions that are editorial and do not alter any substantive requirements in the standard. In particular, ASTM F2088–24 updates the list of Referenced Documents and includes several minor wording changes for consistency with the revisions to the tethered strap/cord requirements (*e.g.,* changing ''tethered straps'' to ''tethered straps and cords''). The revised standard also updates section and figure numbers to reflect revised and new sections and figures. ASTM also updated the Rationale section of the standard to provide explanatory information about the revisions.

Because these revisions do not change any substantive requirements, they are neutral regarding the safety of infant and cradle swings.

III. Incorporation by Reference

Section 1223.2 of the direct final rule incorporates by reference ASTM F2088–24. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, section II. Revisions to ASTM F2088 of this preamble summarizes the major provisions of ASTM F2088–24 that the Commission incorporates by reference into 16 CFR part 1223. The standard is reasonably available to interested parties in several ways. Until the direct final rule takes effect, a read-only copy of ASTM F2088–24 is available for viewing on ASTM's website at: *https://www.astm.org/CPSC.htm.* Once the rule takes effect, a read-only copy of the standard will be available for viewing on the ASTM website at: *https://www.astm.org/READINGLIBRARY/.* Additionally, interested parties can purchase a copy of ASTM F2088–24 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; phone: (610) 832–9500; *www.astm.org.* Finally, interested parties can schedule an appointment to inspect a copy of the standard at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814,

[7] The Terminology section also includes two added ''discussion'' points to clarify that neither straps/cords that are part of the restraint system and attached only to the front of the seat, nor straps/cords that are inaccessible or covered by other components of the product, are considered a ''tethered strap and/or cord.'' The hazard indicated in the incidents do not implicate these configurations.

[8] The 10-pound force is based on the force used to evaluate loops and cords in the ASTM Toy Standard and the ANSI standard for Window Coverings (ASTM F2088–24, section X1.9).

[9] As the revised section X1.4 of the Rationale section indicates, the small head probe represents the 5th percentile 6-month-old child because that is the youngest child with the developmental abilities to become entrapped.

[10] As the new section X1.5 of the Rational section indicates, the large head probe represents the 97th percentile 3-year-old child.

[11] As the new section X1.5 of the Rational section indicates, the 7.4-inch circumference limit was selected to provide a safety factor based on an average neck circumference of about 8.3 inches for a 5th percentile 3- to 6-month-old infant and is consistent with the cord length requirements in the Play Yards Standard (ASTM F406).

telephone: (301) 504–7479; email: *cpsc-os@cpsc.gov.*

IV. Certification

Section 14(a) of the Consumer Product Safety Act (15 U.S.C. 2063(a)) requires manufacturers, including importers, of products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, to certify that the products comply with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program, or, for children's products, on tests of a sufficient number of samples by a third-party conformity assessment body accredited by CPSC to test according to the applicable requirements. As noted, standards issued under section 104(b)(1)(B) of the CPSIA are ''consumer product safety standards.'' Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Because infant and cradle swings are children's products, a CPSC-accepted third party conformity assessment body must test samples of the products. Products subject to part 1223 also must comply with all other applicable CPSC requirements, such as the lead content requirements in section 101 of the CPSIA;[12] the phthalates prohibitions in section 108 of the CPSIA[13] and 16 CFR part 1307; the tracking label requirements in section 14(a)(5) of the CPSA;[14] and the consumer registration form requirements in section 104(d) of the CPSIA.[15] ASTM F2088–24 makes no changes that would impact any of these existing requirements.

V. Notice of Requirements

In accordance with section 14(a)(3)(B)(vi) of the CPSA, the Commission previously published a notice of requirements (NOR) for accreditation of third-party conformity assessment bodies (third-party labs) for testing infant and cradle swings and codified the requirement at 16 CFR 1112.15(b)(8). 78 FR 15836 (March 12, 2013). The NOR provided the criteria and process for CPSC to accept accreditation of third-party conformity assessment bodies for testing infant and cradle swings to 16 CFR part 1223. The NORs for all mandatory standards for durable infant or toddler products are listed in the Commission's rule, ''Requirements Pertaining to Third Party Conformity Assessment Bodies,'' codified in 16 CFR part 1112. *Id.* For consistency, the rule amends the notice of requirements in § 1112.15(b)(8) of 16 CFR part 1112 to read ''16 CFR part 1223, Safety Standard for Infant and Cradle Swings.''

ASTM F2088–24 includes revised requirements for testing infant and cradle swings. The revision requires the use of a small head probe, a large head probe, a ¾-inch clamping surface tool, and a 2.355-inch diameter cylinder probe. The small head probe, large head probe, and clamping surface tool are common test equipment used by third-party labs on several juvenile products that are subject to CPSC mandatory standards, such as play yards (ASTM F406 uses all three tools), infant walkers (ASTM F977 uses the small head probe and clamping tool), high chairs (ASTM F404 uses the clamping tool), toys (ASTM F963 uses the clamping tool), infant bouncers (ASTM F2167 uses the clamping tool), and strollers (ASTM F833 uses the clamping tool). Accordingly, third-party labs that test juvenile products are likely to already have this test equipment.

However, third-party labs will need to buy or construct a cylindrical probe of 2.355 inches in diameter to perform the strap/cord length and tautness test (section 7.16.8). The building materials are easily accessible from supply stores and the probe would be simple to construct. The cost to procure or build the cylindrical probe is estimated to be approximately $50.

Accordingly, the revisions do not significantly change the way that third-party labs test these products for compliance with the safety standard for swings. In addition, the existing accreditations that the Commission has accepted for testing requirements in earlier versions of ASTM F2088, including ASTM F2088–22, will cover testing to the revised standard. Therefore, the Commission considers the existing CPSC-accepted laboratories for the testing requirements in ASTM F2088–22 to be capable of testing to ASTM F2088–24 as well. Accordingly, the existing NOR for this standard will remain in place, and CPSC-accepted third party conformity assessment bodies are expected to update the scope of the testing laboratories' accreditations to reflect the revised standard in the normal course of renewing their accreditations.

VI. Direct Final Rule Process

On March 28, 2024, the Commission provided notice in the **Federal Register** of the revision to the standard and requested comment on whether the revision improves the safety of swings covered by the standard. 89 FR 21497. CPSC did not receive any comments. Now, the Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551–559) generally requires agencies to provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency ''for good cause finds'' that notice and comment are ''impracticable, unnecessary, or contrary to the public interest.'' *Id.* 553(b)(B). The Commission concludes that when it updates a reference to an ASTM standard that the Commission incorporated by reference under section 104(b) of the CPSIA, notice and comment are not necessary.

The purpose of this direct final rule is to update the reference in the Code of Federal Regulations (CFR) so that it reflects the version of the standard that takes effect by statute. This rule updates the reference in the CFR, but under the terms of the CPSIA, ASTM F2088–24 would take effect as the new CPSC standard for infant and cradle swings in the absence of any action by the Commission. Thus, public comments would not lead to substantive changes to the standard or to the effect of the revised standard as a consumer product safety rule under section 104(b) of the CPSIA. Under these circumstances, notice and comment are unnecessary.

In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and that are not expected to generate significant adverse comments. *See* 60 FR 43108 (Aug. 18, 1995). ACUS recommends that agencies use the direct final rule process when they act under the ''unnecessary'' prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments. CPSC did not receive any adverse comments about the requirements in this update in response to the Notice of Availability published on March 28, 2024.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective on September 14, 2024. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be ''one where the commenter explains why the rule would be inappropriate,'' including an assertion

[12] 15 U.S.C. 1278a.

[13] 15 U.S.C. 2057c.

[14] 15 U.S.C. 2063(a)(5).

[15] 15 U.S.C. 2056a(d).

that undermines ''the rule's underlying premise or approach,'' or a showing that the rule ''would be ineffective or unacceptable without change.'' 60 FR 43108, 43111. As noted, this rule updates a reference in the CFR to reflect a change that occurs by statute.

If the Commission receives a significant adverse comment, the Commission will withdraw this direct final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

VII. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As discussed in section VI. Direct Final Rule Process of this preamble, the Commission has determined that further notice and the opportunity to comment are unnecessary for this rule. Therefore, the RFA does not apply. CPSC also notes the limited nature of this document, which merely updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

VIII. Paperwork Reduction Act

The current mandatory standard includes requirements for marking, labeling, and instructional literature that constitute a ''collection of information,'' as defined in the Paperwork Reduction Act (PRA; 44 U.S.C. 3501–3521). The Commission took the steps required by the PRA for information collections when it promulgated 16 CFR part 1223, and the marking, labeling, and instructional literature for infant and cradle swings are currently approved under Office of Management and Budget (OMB) Control Number 3041–0159. The revision does not affect the information collection requirements or approval related to the standard.

IX. Environmental Considerations

The Commission's regulations provide for a categorical exclusion from any requirement to prepare an environmental assessment or an environmental impact statement where they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

X. Preemption

Section 26(a) of the CPSA provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the Federal standard. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued under that provision ''consumer product safety standards.'' Therefore, once a rule issued under section 104 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

XI. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standards organization revises a standard that the Commission adopted as a mandatory standard, the revision becomes the CPSC standard 180 days after notification to the Commission, unless the Commission determines that the revision does not improve the safety of the product, or the Commission sets a later date in the **Federal Register**. 15 U.S.C. 2056a(b)(4)(B). The Commission is taking neither of those actions with respect to the revised standard for infant and cradle swings. Therefore, ASTM F2088–24 automatically will take effect as the new mandatory standard for infant and cradle swings on September 14, 2024, 180 days after the Commission received notice of the revision. As a direct final rule, unless the Commission receives a significant adverse comment within 30 days of this notice, the rule will become effective on September 14, 2024.

XII. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a ''major rule.'' The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a ''major rule.''

Pursuant to the CRA, OIRA has determined that this rule does not qualify as a ''major rule,'' as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects

16 CFR Part 1112

Consumer protection, Third party conformity assessment body requirements, Audit.

16 CFR Part 1223

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Safety, Toys.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

■ 1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063.

■ 2. Amend § 1112.15 by revising paragraph (b)(8) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) * * *

(8) 16 CFR part 1223, Safety Standard for Infant and Cradle Swings;

* * * * *

■ 3. Revise part 1223 to read as follows:

PART 1223—SAFETY STANDARD FOR INFANT AND CRADLE SWINGS

Sec.

Authority: 15 U.S.C. 2056a.

§ 1223.1 Scope.

This part establishes a consumer product safety standard for infant and cradle swings (including combination swings).

§ 1223.2 Requirements for infant and cradle swings.

Each infant and cradle swing (including combination swings) must comply with all applicable provisions of ASTM F2088–24, *Standard Consumer Safety Specification for Infant and*

Cradle Swings, approved on February 1, 2024. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504–7479, email *cpsc-os@cpsc.gov,* or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.* A read-only copy of the standard is available for viewing on the ASTM website at *https://www.astm.org/READINGLIBRARY/.* You may obtain a copy from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959; telephone (610) 832–9500; *www.astm.org.*

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2024–11792 Filed 5–29–24; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA–2024–N–2357]

Advisory Committee; Science Advisory Board to the National Center for Toxicological Research; Termination; Removal From List of Standing Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the termination of the Science Advisory Board to the National Center for Toxicological Research (NCTR). This document announces the reasons for termination and removes the Science Advisory Board to the NCTR from the Agency's list of standing advisory committees.

DATES: This rule is effective May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Ashley Groves, Designated Federal Officer, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., 50–719, Jefferson, AR 72079, 870–543–7956, *Ashley.Groves@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Science Advisory Board to the National Center for Toxicological Research (the Committee) was established on June 2, 1973 (38 FR 18478). The Committee advises the Commissioner of Food and Drugs or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and as required, any other product for which FDA has regulatory responsibility.

The Committee is no longer needed and will be terminated on June 2, 2024. Over the past several years, the Committee has met very infrequently, and the effort and expense of maintaining the Committee are no longer justified. The Science Board to FDA (Science Board) provides advice to the Commissioner and other appropriate officials on specific complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Committee provides advice that supports the Agency in keeping pace with technical and scientific developments, including in regulatory science; and input into the Agency's research agenda; and on upgrading its scientific and research facilities and training opportunities. It also provides, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs. In the future, any issues on which NCTR requires expert advice will be addressed by utilizing the Science Board with additional augmentation of expertise by appropriate subject matter experts serving as temporary members on that committee.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule.

Notice and public comment and a delayed effective date are unnecessary because the Committee is not being adequately used, and termination of the committee is effective on June 2, 2024, in accordance with 21 CFR 14.55. This final rule merely removes the name of the Science Advisory Board to the National Center for Toxicological Research from the list of standing advisory committees in § 14.100 (21 CFR 14.100).

Therefore, the Agency is amending § 14.100(e) as set forth in the regulatory text of the document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committee, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

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

Authority: 5 U.S.C. 1001 *et seq.;* 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264, 284m, 284m–1; Pub. L. 107–109, 115 Stat. 1419.

§ 14.100 [Amended]

■ 2. Amend § 14.100 by removing paragraph (e).

Dated: May 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–11811 Filed 5–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General License 8N

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of a Web General License.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing one general license (GL) issued pursuant to the Venezuela Sanctions Regulations: GL 8N, which was previously made available on OFAC's website.

DATES: GL 8N was issued on May 10, 2024. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov/.*

Background

On May 10, 2024, OFAC issued GL 8N to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations (VSR), 31 CFR part 591. GL 8N was made available on OFAC's website (*https://ofac.treasury.gov/*) when it was issued. GL 8N supersedes GL 8M, which was issued on November 16, 2023. GL 8N has an expiration date of November 15, 2024. The text of this GL is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations

31 CFR Part 591

GENERAL LICENSE NO. 8N

Authorizing Transactions Involving Petróleos de Venezuela, S.A. (PdVSA) Necessary for the Limited Maintenance of Essential Operations in Venezuela or the Wind Down of Operations in Venezuela for Certain Entities

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions and activities prohibited by Executive Order (E.O.) 13850 of November 1, 2018, as amended by E.O. 13857 of January 25, 2019, or E.O. 13884 of August 5, 2019, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), that are ordinarily incident and necessary to the limited maintenance of essential operations, contracts, or other agreements, that: (i) are for safety or the preservation of assets in Venezuela; (ii) involve PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest; and (iii) were in effect prior to July 26, 2019, are authorized through 12:01 a.m. eastern standard time, November 15, 2024, for the following entities and their subsidiaries (collectively, the ''Covered Entities''):

- Halliburton
- Schlumberger Limited
- Baker Hughes Holdings LLC
- Weatherford International, Public Limited Company

Note to paragraph (a). Transactions and activities necessary for safety or the preservation of assets in Venezuela that are authorized by paragraph (a) of this general license include: transactions and activities necessary to ensure the safety of personnel, or the integrity of operations and assets in Venezuela; participation in shareholder and board of directors meetings; making payments on third-party invoices for transactions and activities authorized by paragraph (a) of this general license, or incurred prior to April 21, 2020, provided such activity was authorized at the time it occurred; payment of local taxes and purchase of utility services in Venezuela; and payment of salaries for employees and contractors in Venezuela.

(b) Except as provided in paragraph (d) of this general license, all transactions and activities prohibited by E.O. 13850, as amended, or E.O. 13884, each as incorporated into the VSR, that are ordinarily incident and necessary to the wind down of operations, contracts, or other agreements in Venezuela involving PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, and that were in effect prior to July 26, 2019, are authorized through 12:01 a.m. eastern standard time, November 15, 2024, for the Covered Entities.

(c) Paragraph (a) of this general license does not authorize:

(1) The drilling, lifting, or processing of, purchase or sale of, or transport or shipping of any Venezuelan-origin petroleum or petroleum products;

(2) The provision or receipt of insurance or reinsurance with respect to the transactions and activities described in paragraph (c)(1) of this general license;

(3) The design, construction, installation, repair, or improvement of any wells or other facilities or infrastructure in Venezuela or the purchasing or provision of any goods or services, except as required for safety;

(4) Contracting for additional personnel or services, except as required for safety; or

(5) The payment of any dividend, including in kind, to PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest.

(d) This general license does not authorize:

(1) Any transactions or dealings related to the exportation or reexportation of diluents, directly or indirectly, to Venezuela;

(2) Any loans to, accrual of additional debt by, or subsidization of PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, including in kind, prohibited by E.O. 13808 of August 24, 2017, as amended by E.O. 13857, and incorporated into the VSR; or

(3) Any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V, or any transactions or activities with any blocked person other than the blocked persons identified in paragraphs (a) and (b) of this general license.

(e) Effective May 10, 2024, General License No. 8N, dated November 16, 2023, is replaced and superseded in its entirety by this General License No. 8N.

Lisa M. Palluconi,

Deputy Director, Office of Foreign Assets Control.

Dated: May 10, 2024.

Bradley T. Smith,

Director, Office of Foreign Assets Control.

[FR Doc. 2024–11846 Filed 5–29–24; 8:45 am]

BILLING CODE 4810–AL–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1236

[FDMS No. NARA–24–0012; NARA–2024–037]

RIN 3095–AC18

Federal Records Management: Digitizing Temporary Records

AGENCY: National Archives and Records Administration (NARA).

ACTION: Direct final rule.

SUMMARY: In June 2023, the National Archives and Records Administration (NARA) issued GRS Transmittal 34, which introduced GRS 4.5 Digitizing Records. NARA is updating the regulations to incorporate GRS 4.5 and ensure agencies use the proper authorization for disposing of temporary records that have been digitized. We added guidance directing agencies to manage temporary digital records according to the requirements. We also clarified language regarding when agencies may dispose of the scheduled source records. Additionally, we are harmonizing language in existing regulations with the new amendments.

DATES: This rule is effective August 28, 2024 without further action, unless adverse comment is received by July 1, 2024. If adverse comment is received, NARA will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments on this rule, identified by RIN 3095–AC18, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: Regulation_comments@nara.gov.* Include RIN 3095–AC18 in the subject line of the message.
- *Mail (for paper, disk, or CD–ROM submissions):* Send comments to Regulation Comments Desk (External Policy Program, Strategy & Performance Division (MP)); Suite 4100; National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001.
- *Hand delivery or courier:* Deliver comments to the front desk at 8601

Adelphi Road, College Park, MD, addressed to: Regulations Comments Desk, External Policy Program; Suite 4100.

FOR FURTHER INFORMATION CONTACT: Edward Germino, Strategy and Performance Division, by email at *regulation_comments@nara.gov,* or by telephone at 301–837–3758. Contact *rmstandards@nara.gov* with any questions on records management standards and policy.

SUPPLEMENTARY INFORMATION:

Background

In June 2023, the National Archives and Records Administration (NARA) released GRS Transmittal 34, which introduced a new schedule called GRS 4.5 Digitizing Records to specifically address the handling of digitized source records. Previously, these records were covered under GRS 5.2 Transitory and Intermediary Records. With this update, we have revised 36 CFR 1236.36 to provide agencies with the proper authority for managing digitized temporary records. We also clarified language in § 1236.36 regarding when agencies may dispose of the scheduled source records.

In subpart D, we previously used the term ''original source records.'' However, we removed the word ''original'' because the source records may or may not be the original versions. We are also making this change in the heading for § 1236.36. The term ''source records'' refers to the records that underwent digitization and validation as part of a digitization project.

Finally, we have added guidance to § 1236.30 directing agencies to manage temporary digital records according to the requirements in 36 CFR part 1236 subparts A, B, and C.

Regulatory Analysis

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

The Office of Management and Budget (OMB) has reviewed this rulemaking and determined it is not ''significant'' under section 3(f) of Executive Order 12866. It is not significant because it applies only to Federal agencies, updates the regulations due to a statutory requirement, the new requirements are being added to clarify ones that agencies have already been required to follow, and is not establishing a new program. The requirements are necessary to comply with statute and to ensure agencies are appropriately preserving records.

Regulatory Flexibility Act (5 U.S.C. 601, et seq.)

This review requires an agency to prepare an initial regulatory flexibility analysis and publish it when the agency publishes the proposed rule. This requirement does not apply if the agency certifies that the rulemaking will not, if promulgated, have a significant economic impact on a substantial number of small entities (*5 U.S.C. 603*). We certify, after review and analysis, that this rulemaking will not have a significant adverse economic impact on small entities.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

The Paperwork Reduction Act of 1995 (PRA) (*44 U.S.C. 3501, et seq.*) requires that agencies consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from OMB for each collection of information we conduct, sponsor, or require through regulations. This rulemaking does not impose additional information collection requirements on the public that are subject to the Paperwork Reduction Act.

Executive Order 13132, Federalism

Executive Order 13132 requires agencies to ensure State and local officials have the opportunity for meaningful and timely input when developing regulatory policies that may have a substantial, direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. If the effects of the rule on State and local governments are sufficiently substantial, the agency must prepare a Federal assessment to assist senior policymakers. This rulemaking will not have any effects on State and local governments within the meaning of the E.O. Therefore, no federalism assessment is required.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104–4; 2 U.S.C. 1532)

The Unfunded Mandates Reform Act requires that agencies determine whether any Federal mandate in the rulemaking may result in State, local, and Tribal governments, in the aggregate, or the private sector, expending $100 million in any one year. NARA certifies that this rulemaking does not contain a Federal mandate that may result in such an expenditure.

List of Subjects in 36 CFR Part 1236

Archives and records, Digital records, Digitization, Records management.

For the reasons discussed in the preamble, NARA amends 36 CFR part 1236 as follows:

PART 1236—ELECTRONIC RECORDS MANAGEMENT

■ 1. The authority citation for part 1236 continues to read as follows;

Authority: 44 U.S.C. 2904, 3101, 3102, 3105, 3301, 3302, and 3312.

■ 2. Revise § 1236.30 to read as follows:

§ 1236.30 Requirements for digitizing temporary records.

(a) If an agency intends to digitally reproduce (digitize) temporary records in order to use the digitized records in place of the source records, the agency must:

(1) Digitize the record to the standards in § 1236.32;

(2) Validate the digitization according to § 1236.34; and

(3) Manage the digital records according to the requirements in subparts A, B, and C of this part.

(b) When an agency disposes of source records, the agency must follow the requirements in § 1236.36.

■ 3. In § 1236.32, revise paragraphs (a), (b), and (c) to read as follows:

§ 1236.32 Digitization standards.

* * * * *

(a) Capture all information contained in the source records;

(b) Include all the pages or parts from the source records;

(c) Ensure the agency can use the digitized records for all the purposes the source records serve, including the ability to attest to transactions and activities;

* * * * *

■ 4. In § 1236.34, revise paragraphs (a) and (b) to read as follows:

§ 1236.34 Validating digitization.

(a) Agencies must validate that the digitized records are of suitable quality to replace source records.

(b) Agencies may establish their own validation process or use third-party processes to validate that the digitized records comply with § 1236.32. The process may be project-based or agency-wide policy.

* * * * *

■ 5. Revise § 1236.36 to read as follows:

§ 1236.36 Disposing of source records.

(a) When an agency disposes of source records, it must have an approved agency records schedule or identify an applicable General Records Schedule.

(b) When an agency has validated that the digitized versions meet the standards in § 1236.32, the agency may destroy the source records according to General Records Schedule (GRS) 4.5 Digitizing Records.

(c) Agencies must consider any existing legal restrictions, such as a litigation hold, before destroying the source records.

(d) Agencies must manage the digitized records in the same way it would have managed the source records. Agencies must retain the digitized records for the remaining portion of any retention period established by the applicable records schedule.

(e) Agencies do not need NARA approval to destroy scheduled temporary source records they have digitized according to this part.

Colleen J. Shogan,

Archivist of the United States.

[FR Doc. 2024–11910 Filed 5–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 215, 234, and 252

[Docket DARS–2023–0047]

RIN 0750–AL83

Defense Federal Acquisition Regulation Supplement: Data Requirements for Commercial Products for Major Weapon Systems (DFARS Case 2023–D010)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 that clarifies the data to be provided for certain procurements related to major weapon systems.

DATES: Effective May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Jeanette Snyder, telephone 703–508–7524.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 88 FR 88554 on December 22, 2023, to implement section 803 of the James M. Inhofe National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2023 (Pub. L. 117–263). Section 803 modifies 10 U.S.C. 3455 to provide additional guidance regarding data requirements to support a determination of commerciality and price reasonableness for certain procurements associated with major weapon systems. Two respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided as follows:

A. Summary of Significant Changes From the Proposed Rule

There are no significant changes from the proposed rule.

B. Analysis of Public Comments

1. Negative Impacts of the Rule

Comment: One respondent indicated that the requirement to provide expanded data in support of commercial products added by section 803 presents a significant burden and risk to contractors. Many defense industrial base suppliers are commercial companies that also offer their products and services to DoD. For these suppliers, the statutory obligation to comply with the expanded data requirements will force commercial businesses to implement a compliance infrastructure to segregate and archive business data. The additional cost associated with this cannot be offset by raising product prices in a competitive commercial marketplace and is of no value to commercial buyers. As such, many of these suppliers may simply forgo the opportunity to enter into contracts with DoD. In addition, the requirements for disclosure increase the risk that highly sensitive commercial sales data will be disclosed to competitors, which creates a significant business risk for small and medium-sized suppliers.

Response: This rule implements the additional guidance provided in section 803 of the NDAA for FY 2023 regarding data requirements to support a determination of commerciality and a determination of price reasonableness for certain procurements associated with major weapon systems. For the commerciality determination, section 803, as implemented in this rule, allows contractors to, for example, identify the comparable commercial product it sells or that is sold in the commercial market and provide the contracting officer a comparison between the physical characteristics and functionality of such a product and the subsystem, component, or spare part, if available. For the price reasonableness determination, section 803, as implemented in this rule, allows the offeror to provide or give the contracting officer access to a representative sample of prices paid for the same or similar commercial products under comparable terms and conditions and, if not feasible, to provide the prices paid for the same or similar commercial products sold under different terms and conditions. In addition, offerors may redact customer information, which alleviates any business risk. This information should be readily available to commercial companies via their sales records, so companies should not need to establish a compliance infrastructure to segregate and archive business data. Therefore, this rule does not impose additional administrative costs or recordkeeping burdens on commercial companies that would cause them to no longer be willing to do business with DoD.

Comment: One respondent indicated that the significant compliance burden and business risk levied by section 803 will give commercial companies a choice of: (1) establishing and maintaining separate production lines for commercial and defense products; or (2) exiting the defense industrial base. Isolating defense production from commercial production requires substantial upfront investment in facilities and workforce and drives significant inefficiency in production. Given recent instability in DoD's budget processes and timing, expanding capacity in this way may be unfeasible for many companies in today's defense industrial base. The cause and effect of the changes made by section 803 will likely not only result in protracted acquisition cycle times but also adversely affect the cost of products sold to DoD and industry's ability to deliver timely requirements in support of the warfighters. In addition, it is likely to increase sole-source suppliers and compound DoD's current challenges in accessing the most innovative technologies, products, and services, which is not in the interest of the taxpayer, the warfighter, or the industrial base.

Response: Section 803 of the NDAA for FY 2023 provides additional guidance regarding data requirements to support a determination of commerciality and a determination of price reasonableness for certain

procurements associated with major weapon systems. The additional guidance provides clarity to offerors and contracting officers regarding what is required for such determinations to simplify and expedite procurements. This information should be readily available to commercial companies via their product information and sales records, so commercial companies should not need to establish separate production lines or exit the DoD market. This rule should not result in an increase in sole-source suppliers, nor should it affect DoD's ability to access innovative technologies, products, and services.

Comment: One respondent indicated that section 803 struck sections of law (10 U.S.C. 3455(d)(1)(B)(i–iv)) that provide for an incremental approach to seeking data to determine reasonableness of price for commercial products. In determining price reasonableness, this long-standing framework required contracting officers to start with the least expensive and most reliable, relevant data (*e.g.,* price data) and move down the spectrum to data that is most expensive and time-consuming to collect and analyze (*e.g.,* cost data). This incremental approach was intended to keep acquisitions efficient, prices low, and decisions unbiased. In striking this incremental approach, section 803 sets conditions for contracting officers to start the process with an immediate demand for cost data, likely leading to increased acquisition cycle times, as well as increased tensions during contract negotiations, not only between DoD and the contractor but also between the contractor and their suppliers.

Response: Section 803, as implemented in this rule at DFARS 234.7002(e)(1) and (2), continues to require contracting officers to first request price data. DFARS 234.7002(e)(3) directs contracting officers to only request additional information from the offeror if the price data is insufficient to determine price reasonableness and approval to do so has been obtained. As such, this rule maintains the long-standing framework for contracting officers to first request price data from offerors and, therefore, should not affect acquisition cycle time or contract negotiations.

Comment: One respondent indicated that implementation of section 803 will likely compound DoD's current challenges in leveraging multi-use technologies, stimulating expansion of domestic production and investment in advanced manufacturing technologies, and potentially accelerate growing fragility of suppliers, particularly small businesses. As noted in the National Defense Industrial Strategy, DoD-unique requirements make DoD an unattractive customer, particularly for small businesses and nontraditional defense contractors, thus impeding competition and increasing the likelihood of sole-source situations. The respondent indicated that the compliance cost and the risk of exposure of business-sensitive data jeopardizes the ability of small businesses, in particular, to remain viable in the commercial marketplace. This may leave them no choice but to exit the defense market, which will increase the fragility of the defense industrial base. The loss of these suppliers will also lead to time-consuming and expensive processes to requalify new vendors if they can be found. Aerospace prime contractors would be uniquely impacted by such departures, as many suppliers are subject to specific airworthiness standards and Federal Aviation Administration qualifications. As such, the increased burden, compliance cost and risk of exposure imposed by the implementation of section 803 may result in the need to identify and qualify new suppliers, which may increase costs on current programs, drive delays in the delivery of critical capability to the warfighter, and impede DoD's efforts to meet increased contracting small business goals.

Response: Section 803 of the NDAA for FY 2023 provides additional guidance that clarifies to offerors and contracting officers as to what is required to be submitted to simplify and expedite procurements. This information should be readily available to small businesses via their sales data; therefore, it should not impose an additional burden to the extent that businesses would exit the defense market or that prime contractors would need to locate new qualified subcontractors. In addition, any business risk is alleviated, as the rule also allows offerors to redact sensitive customer information. This rule should not affect DoD's ability to leverage multi-use technologies, stimulate the expansion of domestic production and investment in advanced manufacturing technologies, or meet its small business goals.

Comment: One respondent indicated that 10 U.S.C. 3455, unlike the Truth in Negotiations Act (10 U.S.C. chapter 271), does not provide a waiver and the only exception for data submission is for commercially available off-the-shelf (COTS) items. Accordingly, some suppliers may only be willing to provide COTS-based solutions to remain clear of the requirements imposed by section 803. This will result in the loss of benefit of modern manufacturing capability to perform in-line modifications of commercial aircraft to meet DoD needs. Instead of a commercial derivative military aircraft being assembled on a commercial production line, the alternative is a complete COTS aircraft being disassembled, modified, and reassembled. This will result in a significant increase in cost to DoD and a significant delay in delivery of capability to the warfighter.

Response: FAR 15.403–1(b)(1) and (2) provide exceptions to the requirement to provide data to support a determination of price reasonableness as specified in this rule at DFARS 234.7002(e)(1). Section 803 allows the offeror to provide, or give the contracting officer access to, a representative sample of prices paid for the same or similar commercial products under comparable terms and conditions and, if not feasible, to provide, or give the contracting officer access to, the prices paid for the same or similar commercial products sold under different terms and conditions. Since this rule allows offerors to give contracting officers access to this information, it should actually reduce any contractor burden. This information should be readily available to offerors via their sales records; therefore, it should not impose an additional burden to the extent that contractors would be willing to only provide COTS items to DoD. Since this rule clarifies the data offerors are to provide to the contracting officer to determine price reasonableness, the rule may expedite contract negotiations, decrease acquisition cycle time, and expedite delivery of capability to the warfighter.

2. Clarifications

Comment: One respondent indicated the proposed rule DFARS text referencing ''subsystems of major weapon systems and components and spare parts of major weapon systems and subsystems'' is awkward and confusing. It appears that the language is referring to ''subsystems of major weapon systems'' and ''components and spare parts of major weapon systems and of subsystems of major weapon systems.''

Response: The text at DFARS 212.102(a)(iii)(A), 212.209(a)(1), and 215.403–1(c)(3)(A) has been amended to incorporate the recommended change.

Comment: One respondent indicated that the proposed rule text at DFARS 234.7002(d)(4)(ii) makes no sense. If the offeror does not sell a comparable commercial product, then how can the

offeror provide a comparison of the comparable commercial product. The comparison should be between the product being offered and the most comparable commercial product in the commercial marketplace.

Response: The text at DFARS 234.7002(d)(4)(ii) has been amended to require the offeror to provide the contracting officer a comparison between the physical characteristics and functionality of the most comparable commercial product in the commercial market and the subsystem, component, or spare part, if available.

Comment: One respondent indicated the proposed rule text at DFARS 234.7002(e)(3) is incomplete. The ''if/then'' statement is missing the ''then'' portion. The respondent asked why the DAR Council had removed the rest of the language in paragraph (3), which states ''. . . the contracting officer shall request the offeror to submit other relevant information, including uncertified cost data. However, no uncertified cost data may be required in any case in which there are sufficient non-Government sales of the same item to establish reasonableness of price.''

Response: The text at DFARS 234.7002(e)(3)(i) and (ii) has been moved to 234.7002(e)(3) to include the ''if/then'' statement in one paragraph for clarity. Regarding the deletion of the language in paragraph (e)(3), the proposed rule text at DFARS 234.7002(e)(1) clarifies the data to be submitted by offerors and, as such, replaces the existing text at DFARS 234.7002(e)(3) that was removed in the proposed rule.

C. Other Changes

The text at DFARS 234.7002(d)(4) is amended to add the following to the end of the phrase for clarity: ''then the offeror is required to''. Paragraph (b)(1)(ii) of the basic and alternate I of the provision at DFARS 252.215–7010 is amended to clarify that the information to be provided by the offeror pursuant to this paragraph is also for purposes of determining commerciality. Paragraph (d)(3) of the basic and alternate I of the provision at DFARS 252.215–7010 is also amended to add a cross reference to DFARS 234.7002(e) for clarity. In addition, minor editorial changes are made in the basic and alternate I of the provision.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This final rule amends the provision at DFARS 252.215–7010, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data. However, this proposed rule does not impose any new requirements on contracts at or below the SAT, for commercial products including COTS items, or for commercial services. The provision will continue to not apply to acquisitions at or below the SAT and will continue to apply to acquisitions of commercial products, excluding COTS items, and to acquisitions of commercial services.

IV. Expected Impact of the Rule

DoD does not expect this final rule to have a significant impact on the Government or offerors because it merely clarifies the data an offeror is required to provide to the contracting officer when a subsystem of a major weapon system or a component or spare part of a major weapon system or of a subsystem of a major weapon system is proposed as a commercial product. Specifically, this rule clarifies the data an offeror is required to provide to support the contracting officer's determination of price reasonableness and commerciality. This rule will also allow an offeror to give the contracting officer access to the data, in lieu of submitting it, and to redact certain customer information from such data.

This rule is expected to result in the timely submission of data, which may decrease the time it takes for a contracting officer to determine a product to be commercial, to determine price reasonableness, and to award a contract.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VII. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

This rule is necessary to implement section 803 of the James M. Inhofe National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2023. The objective of this rule is to implement section 803, which modifies 10 U.S.C. 3455 to clarify the data an offeror is required to provide to the contracting officer to support a commerciality determination and a price reasonableness determination when a subsystem of a major weapon system or a component or spare part of a major weapon system or of a subsystem of a major weapon system is proposed as a commercial product.

No significant issues were raised by the public comments in response to the initial regulatory flexibility analysis.

Based on data from the Federal Procurement Data System for fiscal years 2021 through 2023, DoD awarded an average of approximately 50,260 commercial contracts related to major weapon systems to an average of 2,685 unique small entities per year. Therefore, this rule is expected to apply to approximately 2,685 small entities per fiscal year.

This rule does not impose any new reporting, recordkeeping, or other compliance requirements for small entities. The information being collected falls under the currently approved information collection requirements under Office of Management and Budget (OMB) Control Number 0704–0574, Defense Federal Acquisition Regulation Supplement (DFARS) Part 215; Only One Offer and Related Clauses in DFARS 252.

There are no known alternatives that would accomplish the stated objectives of the applicable statute.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies to this final rule. However, these changes to the DFARS do not impose additional information collection requirements to the paperwork burden previously approved by OMB under OMB Control Number 0704–0574, Defense Federal Acquisition Regulation Supplement (DFARS) Part 215; Only One Offer and Related Clauses in DFARS 252.

List of Subjects in 48 CFR Parts 212, 215, 234, and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 215, 235, and 252 are amended as follows:

■ 1. The authority citation for parts 212, 215, 234, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 2. Amend section 212.102 by revising paragraph (a)(iii)(A) to read as follows:

212.102 Applicability.

(A) * * *

(iii) * * *

(A) Determine in writing that the acquisition meets the ''commercial product'' or ''commercial service'' definition in FAR 2.101. See 234.7002(b) and (c) for subsystems of major weapon systems and components and spare parts of major weapon systems and of subsystems of major weapon systems;

* * * * *

■ 3. Amend section 212.209 by revising paragraph (a)(1) to read as follows:

212.209 Determination of price reasonableness.

(a) * * *

(1) In the case of major weapon systems, for subsystems of major weapon systems and components and spare parts of major weapon systems and of subsystems of major weapon systems acquired as commercial products in accordance with subpart 234.70, shall use information submitted under 234.7002(e); and

* * * * *

PART 215—CONTRACTING BY NEGOTIATION

■ 4. Amend section 215.403–1 by revising paragraph (c)(3)(A) to read as follows:

215.403–1 Prohibition on obtaining certified cost or pricing data (10 U.S.C. chapter 271 and 41 U.S.C. chapter 35).

* * * * *

(c) * * *

(3) * * *

(A) Follow the procedures at PGI 215.403–1(c)(3) for pricing commercial products or commercial services, except see 234.7002(e) for pricing commercial subsystems of major weapon systems and components and spare parts of major weapon systems and of subsystems of major weapon systems.

* * * * *

215.403–3 [Amended]

■ 5. Amend section 215.403–3 in paragraph (c) by removing ''234.7002(d)'' and adding ''234.7002(e)'' in its place.

PART 234—MAJOR SYSTEM ACQUISITION

■ 6. Amend section 234.7002 by—

■ a. Revising paragraph (b)(2);

■ b. Adding paragraph (b)(3);

■ c. Revising paragraphs (c)(1)(ii), (c)(2) and (d); and

■ e. Adding a paragraph (e); and

The revisions and additions read as follows:

234.7002 Policy.

* * * * *

(b) * * *

(2) The contracting officer determines in writing that the subsystem is a commercial product in accordance with 212.102(a)(iii). For a subsystem of a major weapon system proposed as a commercial product that has not previously been determined to be a commercial product (see 212.102(a)(ii)), follow the procedures in paragraph (d) of this section.

(3) This paragraph (b) shall apply only to subsystems of major weapon systems that are acquired by DoD through a—

(i) Prime contract;

(ii) Modification to a prime contract; or

(iii) Subcontract under a prime contract for the acquisition of a subsystem proposed as a commercial product that has not previously been determined to be a commercial product (see 212.102(a)(ii)).

(c) * * *

(1) * * *

(ii) The contracting officer determines in writing that the component or spare part is a commercial product in accordance with 212.102(a)(iii). For a component or spare part proposed as a commercial product that has not previously been determined to be a commercial product (see 212.102(a)(ii)), follow the procedures in paragraph (d) of this section.

(2) This paragraph (c) shall apply only to components and spare parts that are acquired by DoD through a—

(i) Prime contract;

(ii) Modification to a prime contract; or

(iii) Subcontract under a prime contract for the acquisition of a component or spare part proposed as a commercial product that has not previously been determined to be a commercial product (see 212.102(a)(ii)).

(d) *Commerciality determination.* To the extent necessary to make a commercial product determination in accordance with 212.102(a)(iii) that relies on paragraph (1), (2), (3), (4), or (5) of the ''commercial product'' definition at FAR 2.101 for a subsystem, component, or spare part as described in paragraphs (b) and (c) of this section, the provision at 252.215–7010, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data, requires the offeror to—

(1) Identify the comparable commercial product the offeror sells to the general public or nongovernmental entities for other than governmental purposes;

(2) Provide a comparison between the physical characteristics and functionality of the comparable commercial product and the subsystem, component, or spare part, including—

(i) For products under paragraph (3)(i) of the ''commercial product'' definition at FAR 2.101, a description of the modification and documentation to support that the modification is customarily available in the marketplace; or

(ii) For products under paragraph (3)(ii) of the ''commercial product'' definition at FAR 2.101, a detailed description of the modification and detailed technical data to demonstrate that the modification is minor (*e.g.,* information on production processes and material differences); and

(3) Provide the national stock number (NSN) for the comparable commercial product, if one is assigned, and the NSN for the subsystem, component, or spare part, if one is assigned; or

(4) If the offeror does not sell a comparable commercial product to the general public or nongovernmental entities for other than governmental

purposes, then the offeror is required to—

(i) Notify the contracting officer in writing that it does not sell such a comparable product; and

(ii) Provide the contracting officer a comparison between the physical characteristics and functionality of the most comparable commercial product in the commercial market and the subsystem, component, or spare part, if available.

(e) *Relevant information to determine price reasonableness.* For products relying on paragraph (3)(ii) of the ''commercial product'' definition at FAR 2.101, see FAR 15.403–1(c)(3)(iii)(C). See 212.209(a) for requirements of 10 U.S.C. 3453 with regard to market research.

(1) Unless an exception at FAR 15.403–1(b)(1) or (2) applies—

(i) To the extent necessary to make a determination of price reasonableness, the contracting officer shall require the offeror to submit to or provide the contracting officer access to a representative sample, as determined by the contracting officer, of prices paid for the same or similar commercial products under comparable terms and conditions by both Government and commercial customers and the terms and conditions of such sales; or

(ii) If the contracting officer determines that the offeror cannot provide or give access to sufficient information described in this paragraph (e)(1) to determine the reasonableness of price, the contracting officer shall require the offeror to submit or provide the contracting officer access to a representative sample, as determined by the contracting officer, of the prices paid for the same or similar commercial products sold under different terms and conditions and the terms and conditions of such sales.

(2) The contracting officer shall allow the offeror to redact only information provided pursuant to paragraph (e)(1) of this section that identifies the customer, if the offeror certifies in writing for each sale that the customer is a—

(i) Government customer (*e.g.,* Federal, State, local, or foreign government);

(ii) Commercial customer purchasing the product for governmental purposes; or

(iii) Commercial customer purchasing the product for a commercial, mixed, or unknown purpose.

(3) If the contracting officer determines that the information submitted pursuant to paragraph (e)(1) of this section is not sufficient to determine the reasonableness of price because the comparable commercial product provided by the offeror is not a valid basis for price analysis or the proposed price is not reasonable after evaluating sales data, then the contracting officer shall obtain approval from an official one level above the contracting officer, without power of delegation, and require the offeror to submit other relevant information regarding the basis for price or cost, including information on labor costs, material costs, and overhead rates.

(4) An offeror shall not be required to submit information described in paragraph (e)(1) of this section with regard to a commercially available off-the-shelf item. An offeror may be required to submit such information with regard to any other item that was developed exclusively at private expense only after the head of the contracting activity determines in writing that the information submitted pursuant to paragraph (e)(1) of this section is not sufficient to determine the reasonableness of price.

(5) An offeror may submit information or analysis relating to the value of a commercial product to aid in the determination of the reasonableness of the price of such commercial product. A contracting officer may consider such information or analysis in addition to the information submitted pursuant to paragraph (e)(1) of this section. For additional guidance see PGI 234.7002(e)(5).

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 7. Amend section 252.215–7010—

■ a. By removing the provision date ''JAN 2023'' and adding ''MAY 2024'' in its place;

■ b. In paragraph (a) by revising the definition of ''Sufficient non-Government sales'';

■ c. By revising and republishing paragraphs (b) and (d);

■ d. In Alternate I—

■ i. By revising the provision title and date;

■ ii. In paragraph (a) by revising the definition of ''Sufficient non-Government sales''; and

■ iii. By revising and republishing paragraphs (b) and (d).

The additions, revisions and republications read as follows:

252.215–7010 Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data.

* * * * *

(a) * * *

Sufficient non-Government sales means relevant sales data that reflects market pricing and contains enough information to make adjustments covered by Federal Acquisition Regulation (FAR) 15.404–1(b)(2)(ii)(B).

* * * * *

(b) *Exceptions from certified cost or pricing data.* (1) In lieu of submitting certified cost or pricing data, the Offeror may submit a written request for exception by submitting the information described in paragraphs (b)(1)(i) and (ii) of this provision. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted and whether the price is fair and reasonable.

(i) *Exception for prices set by law or regulation—Identification of the law or regulation establishing the prices offered.* If the prices are controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) *Commercial product or commercial service exception.* For a commercial product or commercial service exception, the Offeror shall submit, at a minimum, information that is adequate for determining commerciality and evaluating the reasonableness of the price for this acquisition, including prices at which the same product or service or similar products or services have been sold in the commercial market. Such information shall include—

(A) For products or services previously determined to be commercial, the contract number and military department, defense agency, or other DoD component that rendered such determination, and if available, a Government point of contact;

(B) For subsystems of a major weapon system and components and spare parts of a major weapon system or subsystem of a major weapon system that have not previously been determined to be commercial—

(*1*) The comparable commercial product the Offeror sells to the general public or nongovernmental entities;

(*2*) A comparison between the physical characteristics and functionality of the comparable commercial product and the subsystem, component, or spare part, including—

(*i*) For products under paragraph (3)(i) of the ''commercial product'' definition at FAR 2.101, a description of the modification and documentation to support that the modification is customarily available in the marketplace; or

(*ii*) For products under paragraph (3)(ii) of the ''commercial product''

definition at FAR 2.101, a detailed description of the modification and detailed technical data to demonstrate that the modification is minor (*e.g.,* information on production processes and material differences); and

(*3*) The national stock number (NSN) for the comparable commercial product, if one is assigned, and the NSN for the subsystem, component, or spare part, if one is assigned; or

(*4*) If the Offeror does not sell a comparable commercial product to the general public or nongovernmental entities for purposes other than government purposes, the Offeror shall—

(*i*) Notify the Contracting Officer in writing that it does not sell such a comparable product; and

(*ii*) Provide the Contracting Officer with a comparison of the physical characteristics and functionality of the most comparable commercial product in the commercial market.

(C) For items priced based on a catalog—

(*1*) A copy of or identification of the Offeror's current catalog showing the price for that item; and

(*2*) If the catalog pricing provided with this proposal is not consistent with all relevant sales data, a detailed description of differences or inconsistencies between or among the relevant sales data, the proposed price, and the catalog price (including any related discounts, refunds, rebates, offsets, or other adjustments);

(D) For items priced based on market pricing, a description of the nature of the commercial market, the methodology used to establish a market price, and all relevant sales data. The description shall be adequate to permit the DoD to verify the accuracy of the description;

(E) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item; or

(F) For items provided by nontraditional defense contractors, a statement that the entity is not currently performing and has not performed, for at least the 1-year period preceding the solicitation of sources by DoD for the procurement or transaction, any contract or subcontract for DoD that is subject to full coverage under the cost accounting standards prescribed pursuant to 41 U.S.C. 1502 and the regulations implementing such section.

* * * * *

(d) *Requirements for data other than certified cost or pricing data.* (1) Data other than certified cost or pricing data submitted in accordance with this provision shall include the minimum information necessary to permit a determination that the proposed price is fair and reasonable, to include the requirements in Defense Federal Acquisition Regulation Supplement (DFARS) 215.402(a)(i), 215.404–1(b), and 234.7002(e).

(2) In cases in which uncertified cost data is required, the information shall be provided in the form in which it is regularly maintained by the Offeror or prospective subcontractor in its business operations.

(3) If the Offeror redacts data that identifies the customer (see DFARS 234.7002(e)(2)), then the Offeror shall include, for each sale, the following signed statement with the data submitted:

''By submission of this data, the Offeror *[Offeror insert company name]* certifies that the customer was *[Offeror insert one or more of the following as applicable: a government customer; a commercial customer purchasing the same or similar product for governmental purposes (e.g., Federal, state, local, or foreign government); or a commercial customer purchasing the same or similar product for a commercial, mixed, or unknown purpose].*''

(4) Within 10 days of a written request from the Contracting Officer for additional information to permit an adequate evaluation of the proposed price in accordance with FAR 15.403–3 or DFARS 234.7002(e), the Offeror shall provide either the requested information, or a written explanation for the inability to fully comply.

(5) *Subcontract price evaluation.* (i) Offerors shall obtain from subcontractors the minimum information necessary to support a determination of price reasonableness, as described in FAR part 15 and DFARS part 215.

(ii) No cost data may be required from a prospective subcontractor in any case in which there are sufficient non-Government sales of the same item to establish reasonableness of price.

(iii) If the Offeror relies on relevant sales data for similar items to determine the price is reasonable, the Offeror shall obtain only that technical information necessary—

(A) To support the conclusion that items are technically similar; and

(B) To explain any technical differences that account for variances between the proposed prices and the sales data presented.

* * * * *

Alternate I. * * *

Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Alternate I (MAY 2024)

(a) * * *

Sufficient non-Government sales means relevant sales data that reflects market pricing and contains enough information to make adjustments covered by Federal Acquisition Regulation (FAR) 15.404–1(b)(2)(ii)(B).

* * * * *

(b) *Exceptions from certified cost or pricing data.* (1) In lieu of submitting certified cost or pricing data, the Offeror may submit a written request for exception by submitting the information described in paragraphs (b)(1)(i) and (ii) of this provision. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted and whether the price is fair and reasonable.

(i) *Exception for price set by law or regulation—Identification of the law or regulation establishing the price offered.* If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) *Commercial product or commercial service exception.* For a commercial product or commercial service exception, the Offeror shall submit, at a minimum, information that is adequate for determining commerciality and evaluating the reasonableness of the price for this acquisition, including prices at which the same product or service or similar products or services have been sold in the commercial market. Such information shall include—

(A) For products or services previously determined to be commercial, the contract number and military department, defense agency, or other DoD component that rendered such determination, and if available, a Government point of contact;

(B) For subsystems of a major weapon system and components and spare parts of a major weapon system or subsystem of a major weapon system that have not previously been determined to be commercial—

(*1*) The comparable commercial product the Offeror sells to the general public or nongovernmental entities;

(*2*) A comparison between the physical characteristics and functionality of the comparable commercial product and the subsystem, component, or spare part, including—

(*i*) For products under paragraph (3)(i) of the ''commercial product'' definition at FAR 2.101, a description of the modification and documentation to support that the modification is customarily available in the marketplace; or

(*ii*) For products under paragraph (3)(ii) of the ''commercial product'' definition at FAR 2.101, a detailed description of the modification and detailed technical data to demonstrate that the modification is minor (*e.g.,* information on production processes and material differences); and

(*3*) The national stock number (NSN) for the comparable commercial product, if one is assigned, and the NSN for the subsystem, component, or spare part; or

(*4*) If the Offeror does not sell a comparable commercial product to the general public or nongovernmental entities for purposes other than government purposes, the Offeror shall—

(*i*) Notify the Contracting Officer in writing that it does not sell such a comparable product; and

(*ii*) Provide the Contracting Officer with a comparison of the physical characteristics and functionality of the most comparable commercial product in the commercial market.

(C) For items priced based on a catalog—

(*1*) A copy of or identification of the Offeror's current catalog showing the price for that item; and

(*2*) If the catalog pricing provided with this proposal is not consistent with all relevant sales data, a detailed description of differences or inconsistencies between or among the relevant sales data, the proposed price, and the catalog price (including any related discounts, refunds, rebates, offsets, or other adjustments);

(D) For items priced based on market pricing, a description of the nature of the commercial market, the methodology used to establish a market price, and all relevant sales data. The description shall be adequate to permit the DoD to verify the accuracy of the description;

(E) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item; or

(F) For items provided by nontraditional defense contractors, a statement that the entity is not currently performing and has not performed, for at least the 1-year period preceding the solicitation of sources by the DoD for the procurement or transaction, any contract or subcontract for the DoD that is subject to full coverage under the cost accounting standards prescribed pursuant to 41 U.S.C. 1502 and the regulations implementing such section.

(2) The Offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and to determine the reasonableness of price.

* * * * *

(d) *Requirements for data other than certified cost or pricing data.* (1) Data other than certified cost or pricing data submitted in accordance with this provision shall include all data necessary to permit a determination that the proposed price is fair and reasonable, to include the requirements in Defense Federal Acquisition Regulation Supplement (DFARS) 215.402(a)(i), 215.404–1(b), and 237.7002(e).

(2) In cases in which uncertified cost data is required, the information shall be provided in the form in which it is regularly maintained by the Offeror or prospective subcontractor in its business operations.

(3) If the Offeror redacts data that identifies the customer (see DFARS 234.7002(e)(2)), then the Offeror shall include, for each sale, the following signed statement with the data submitted:

''By submission of this data, the Offeror *[Offeror insert company name]* certifies that the customer was *[Offeror insert one or more of the following as applicable: a government customer (e.g., Federal, state, local, or foreign government); a commercial customer purchasing the same or similar product for governmental purposes; or a commercial customer purchasing the same or similar product for a commercial, mixed, or unknown purpose].*''

(4) The Offeror shall provide information described as follows: *[Insert description of the data and the format that are required, including access to records necessary to permit an adequate evaluation of the proposed price in accordance with FAR 15.403–3 or DFARS 234.7002(e).]*

(5) Within 10 days of a written request from the Contracting Officer for additional information to support proposal analysis, the Offeror shall provide either the requested information, or a written explanation for the inability to fully comply.

(6) *Subcontract price evaluation.* (i) Offerors shall obtain from subcontractors the information necessary to support a determination of price reasonableness, as described in FAR part 15 and DFARS part 215.

(ii) No cost information may be required from a prospective subcontractor in any case in which there are sufficient non-Government sales of the same item to establish reasonableness of price.

(iii) If the Offeror relies on relevant sales data for similar items to determine the price is reasonable, the Offeror shall obtain only that technical information necessary—

(A) To support the conclusion that items are technically similar; and

(B) To explain any technical differences that account for variances between the proposed prices and the sales data presented.

* * * * *

[FR Doc. 2024–11515 Filed 5–29–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225, and 252

[Docket DARS–2023–0042]

RIN 0750–AL40

Defense Federal Acquisition Regulation Supplement: Limitation on the Acquisition of Certain Goods Other Than United States Goods (DFARS Case 2021–D022)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement two sections of the National Defense Authorization Act for Fiscal Year 2021, one section of the National Defense Authorization Act for Fiscal Year 2022, one section of the National Defense Authorization Act for Fiscal Year 2023, and one section of the Consolidated Appropriations Act, 2023. These statutes remove limitations and restrictions on certain components that are no longer required and add new limitations on other components, subject to exceptions.

DATES: Effective May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Bass, telephone 703–717–3446.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 88 FR 80472 on November 17, 2023, to implement sections 845 and 1603 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Pub. L. 116–283); section 816 of the NDAA for FY 2022 (Pub. L. 117–81); section 853 of the NDAA for FY 2023 (Pub. L. 117–263), and section 8016 of the Consolidated Appropriations Act of 2023 (Pub. L. 117–328). These sections amend 10 U.S.C. 2534, now 10 U.S.C. 4864, to require acquisition of certain items and components from the national technology and industrial base. The national technology and industrial base is defined at 10 U.S.C. 4801 as the United States, Australia, Canada, New Zealand, or the United Kingdom.

One respondent submitted public comments in response to the proposed rule. There are no changes made to the final rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments is provided, as follows:

Comment: A respondent recommended the words ''weighing more than 400 pounds'' be removed. The respondent provided that exempting satellites weighing less than 400 pounds cedes a large part of the U.S. market for star trackers to foreign suppliers that have been funded largely by the European Space Agency, and that the foreign suppliers currently dominate the high quality small star tracker market. The respondent stated that the exemption of satellites weighing less than 400 pounds also discourages members of the national technology and industrial base from investing and participating in possibly the most attractive segment of the U.S. star tracker market and the market as a whole. Lastly, the respondent recommended that DoD develop and include a DFARS clause that requires procurement of star trackers from domestic sources for satellites, including those weighing less than 400 pounds, and that this requirement should be included in U.S. Government agency procurements for information and services provided by commercial satellite systems.

Response: Section 1603 amends 10 U.S.C. 2534(a), now 10 U.S.C. 4864, and adds star trackers to the list of items that must be procured from manufacturers in the national technology and industrial base. The statute applies to a ''star tracker used in a satellite weighing more than 400 pounds whose principal purpose is to support the national security, defense, or intelligence needs of the United States Government''. The rule implements this statutory requirement accordingly.

Moreover, the DFARS clause at 252.225–7064, Restriction on Acquisition of Satellite Star Trackers, is prescribed at DFARS 225.7004–7(d) for use in solicitations and contracts requiring the acquisition of satellite star trackers, including solicitations and contracts that exceed the simplified acquisition threshold (SAT) and that use FAR part 12 procedures for the acquisition of commercial products, including COTS items, and for the acquisition of commercial services. Lastly, as provided in section III of this preamble, DoD intends to apply the clause to contracts for the acquisition of commercial products including COTS items and for the acquisition of commercial services.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

The clause at DFARS 252.225–7063, Restriction on Acquisition of Components of T–AO 205 Class Vessels, is prescribed at DFARS 225.7004–7(c) for use in solicitations and contracts requiring the acquisition of components of T–AO 205 and T–ARC class vessels, including solicitations and contracts that exceed the SAT and that use FAR part 12 procedures for the acquisition of commercial products, including COTS items, and for the acquisition of commercial services. The clause at DFARS 252.225–7064, Restriction on Acquisition of Satellite Star Trackers, is prescribed at DFARS 225.7004–7(d) for use in solicitations and contracts requiring the acquisition of satellite star trackers, including solicitations and contracts that exceed the SAT and that use FAR part 12 procedures for the acquisition of commercial products, including COTS items, and for the acquisition of commercial services.

Consistent with the analysis that DoD provided in the proposed rule with regard to the application of the requirements of sections 845 and 1603 of the NDAA for FY 2021 (Pub. L. 116–283) and section 852 of the NDAA for FY 2023 (Pub. L. 117–263), which amend 10 U.S.C. 4864, DoD has made the determination to apply the statute, as implemented in the clauses at DFARS 252.225–7063 and 252.225–7064 to contracts and subcontracts for the acquisition of commercial products including COTS items, and to the acquisition of commercial services, as defined at Federal Acquisition Regulation 2.101.

The requirements of 10 U.S.C. 4864 do not apply to a contract or subcontract for an amount at or below the SAT. Therefore, the clauses will not apply to acquisitions at or below the SAT.

IV. Expected Impact of the Rule

The final rule adds procurement limitations on the acquisition of star trackers for certain national security satellites and certain components for T–AO 205 and T–ARC class vessels, requiring they are manufactured in the national technology and industrial base: the United States, Australia, Canada, New Zealand or the United Kingdom in accordance with 10 U.S.C. 4864.

The rule is not expected to have a significant impact on the Government, offerors, or contractors. The satellite star trackers and components for the T–AO 205 and T–ARC class of vessels are the types of items that are readily available in the marketplace, so limitation to national technology and industrial base sources is not viewed as having a significant impact on the availability of sources. Further, the rule provides waiver procedures to the limitation.

The domestic source restriction does not apply to—

(1) Contracts or subcontracts that do not exceed the simplified acquisition threshold;

(2) The acquisition of spare or repair parts needed to support components for naval vessels manufactured outside the United States; and

(3) Large medium-speed diesel engines for icebreakers or special mission ships.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an

interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VII. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

DoD is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement statutes that remove limitations and restrictions no longer required, and that require the procurement of star trackers for certain national security satellites, as well as certain components for T–AO 205 and T–ARC class vessels, from the national technology and industrial base: the United States, Australia, Canada, New Zealand, or the United Kingdom.

The objective of the rule is to implement sections 845 and 1603 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Pub. L. 116–283); section 816 of the NDAA for FY 2022 (Pub. L. 117–81); and section 853 of the NDAA for FY 2023 (Pub. L. 117–263). Section 845 of the NDAA for FY 2021 amends 10 U.S.C. 4864(a) to update the list of components for naval vessels at paragraphs (a)(2)(A) through (E). Subsequently, section 816 of the NDAA for FY 2022 added to the list of components for naval vessels welded shipboard anchor and mooring chain, without size restrictions, at 10 U.S.C. 4864(a)(2)(F). Section 845 also added components for T–AO 205 class vessels at 10 U.S.C. 4864(a)(4). Section 853 of the NDAA for FY 2023 added T–ARC class vessels at 10 U.S.C. 4864(a)(4) along with the component list for T–AO 205 class vessels. Section 1603 of the NDAA for FY 2021 added limitations on procurement of satellite star trackers at 10 U.S.C. 4864(a)(5).

No significant issues were raised by public comments regarding the initial regulatory flexibility analysis.

DoD reviewed data from the Federal Procurement Data System for FY 2021, 2022, and 2023, excluding contracts that do not exceed the simplified acquisition threshold, for the following product service codes: 7G22, 2835, 2010, 3815, 1040, 5925, 2040, beginning with 70 (for example, information technology hardware and software), and 7435. DoD made an average of 712 awards per year, of which 401 were made to small entities, an average of 56 percent awarded to small entities over the three fiscal years.

It is expected that this rule will benefit small businesses. The rule will continue to provide small businesses the opportunity to participate in the manufacture of star trackers for certain national security satellites and certain components for T-AO 205 and T–ARC class vessels in support of the national technology and industrial base.

This rule does not include any new reporting, recordkeeping, or other compliance requirements for small businesses.

The rule exempts acquisitions equal to or less than the simplified acquisition threshold. There are no other known significant alternative approaches to the rule that would meet the requirements of the statute.

VIII. Paperwork Reduction Act

This final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 212, 225, and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 212, 225, and 252 are amended as follows:

■ 1. The authority citation for 48 CFR parts 212, 225, and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 212—ACQUISITION OF COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES

■ 2. Amend section 212.301 by—

■ a. Removing paragraphs (f)(x)(X) and (Y);

■ b. Redesignating paragraphs (f)(x)(M) through (W) as (f)(x)(N) through (X);

■ c. Adding a new paragraph (f)(x)(M);

■ d. Redesignating paragraphs (f)(x)(Z) through (NN) as paragraphs (f)(x)(Y) through (MM);

■ e. In the newly redesignated paragraph (f)(x)(Y), removing ''Pub. L.'' and adding ''Public Law'' in its place;

■ f. In the newly redesignated paragraph (f)(x)(MM), removing ''225.7010–5'' and adding ''225.7004–7(b)'' in its place; and

■ g. Adding paragraphs (f)(x)(NN) and (OO).

The additions read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

(f) * * *

(x) * * *

(M) Use the clause at 252.225–7019, Restriction on Acquisition of Anchor and Mooring Chain, as prescribed in 225.7004–7(a), to comply with 10 U.S.C. 4864 and section 8041 of the Fiscal Year 1991 DoD Appropriations Act (Pub. L. 101–511) and similar sections in subsequent DoD appropriations acts.

* * * * *

(NN) Use the clause at 252.225–7063, Restriction on Acquisition of Components of T–AO 205 and T–ARC Class Vessels, as prescribed in 225.7004–7(c), to comply with 10 U.S.C. 4864.

(OO) Use the clause at 252.225–7064, Restriction on Acquisition of Certain Satellite Components, as prescribed in 225.7004–7(d), to comply with 10 U.S.C. 4864.

* * * * *

PART 225—FOREIGN ACQUISITION

225.7001 [Amended]

■ 3. Amend section 225.7001 in the definition of ''Component'' by removing ''component except that for use in 225.7007'' and adding ''component, except that for use in 225.7004–2(b)(6)'' in its place.

■ 4. Revise section 225.7004 to read as follows:

225.7004 Restrictions on the procurement of goods other than U.S. goods.

■ 5. Add section 225.7004–0 to read as follows:

225.7004–0 Scope.

This section implements 10 U.S.C. 4864.

■ 6. Revise sections 225.7004–1 through 225.7004–4 to read as follows:

Sec.

* * * * *

225.7004–1 Definitions.
225.7004–2 Restrictions.
225.7004–3 Exceptions.
225.7004–4 Implementation of restriction on certain naval vessel components.

* * * * *

225.7004–1 Definitions.

As used in this section—

National technology and industrial base means the persons and organizations that are engaged in production activities conducted within the United States, Australia, Canada,

New Zealand, and the United Kingdom of Great Britain and Northern Ireland (United Kingdom). (10 U.S.C. 4801)

Star tracker means a navigational tool used in a satellite weighing more than 400 pounds whose principal purpose is to support the national security, defense, or intelligence needs of the U.S. Government.

225.7004–2 Restrictions.

Except as provided in 225.7004–3, do not acquire any of the following items, either as end products or components, unless the manufacturer of the items is part of the national technology and industrial base:

(a) Buses, if multipassenger motor vehicles are purchased, leased, rented, or made available under contracts for transportation services.

(b) Components for naval vessels, to the extent they are unique to marine applications (see also 225.7004–4 for implementation of the restriction for naval vessels):

(1) Gyrocompasses.

(2) Electronic navigation chart systems.

(3) Steering controls.

(4) Propulsion and machinery control systems.

(5) Totally enclosed lifeboats.

(6) Welded shipboard anchor and mooring chain. See also 225.7004–5.

(c) Large medium-speed diesel engines for new construction of auxiliary ships using funds available for National Defense Sealift Fund programs or Shipbuilding and Conversion, Navy.

(d) For T–AO 205 and T–ARC class vessels:

(1) Auxiliary equipment, including pumps, for all shipboard services.

(2) Propulsion system components, including engines, reduction gears, and propellers.

(3) Shipboard cranes.

(4) Spreaders for shipboard cranes.

(e) Star trackers.

225.7004–3 Exceptions.

(a) *Contracts under the simplified acquisition threshold.* The restrictions at 225.7004–2 do not apply to a contract or subcontract that does not exceed the simplified acquisition threshold.

(b) *Buses.* The restriction at 225.7004–2(a) does not apply in the following circumstances:

(1) Buses manufactured outside the national technology and industrial base are needed for temporary use because buses manufactured in the national technology and industrial base are not available to satisfy requirements that cannot be postponed. Such use may not, however, exceed the lead time required for acquisition and delivery of buses manufactured in the national technology and industrial base.

(2) The requirement for buses is temporary in nature. For example, to meet a special, nonrecurring requirement or a sporadic and infrequent recurring requirement, buses manufactured outside the national technology and industrial base may be used for temporary periods of time. Such use may not however, exceed the period of time needed to meet the special requirement.

(3) Buses manufactured outside the national technology and industrial base are available at no cost to the U.S. Government.

(c) *Components for naval vessels.* The restriction at 225.7004–2(b) does not apply to acquisition of spare or repair parts needed to support components for naval vessels manufactured outside the United States. Support includes the purchase of spare gyrocompasses, electronic navigation chart systems, steering controls, propulsion and machinery control systems, totally enclosed lifeboats, and welded shipboard anchor and mooring chain.

(d) *Components for auxiliary ships.* The restriction at 225.7004–2(c) does not apply to large medium-speed engines for icebreakers or special mission ships.

(e) *Star trackers.* The restriction at 225.7004–2(e) does not apply to acquisition programs that have received Milestone A approval as defined in 10 U.S.C. 4211 before October 1, 2021, as documented by the requiring activity official performing program management responsibilities. The contracting officer shall include the Milestone A approval documentation in the contract file.

225.7004–4 Implementation of restriction on certain naval vessel components.

(a) The statute at 10 U.S.C. 4864(h) prohibits the use of contract clauses or certifications to implement the restriction at 225.7004–2(b) for naval vessel components.

(b) Agencies shall accomplish implementation of the restriction at 225.7004–2(b) through use of management and oversight techniques that achieve the objectives of this section without imposing a significant management burden on the Government or the contractor involved.

■ 7. Add sections 225.7004–5 through 225.7004–7 to read as follows:

Sec.

* * * * *

225.7004–5 Additional restrictions on anchor and mooring chain.

225.7004–6 Waiver of restrictions.

225.7004–7 Contract clauses.

* * * * *

225.7004–5 Additional restrictions on anchor and mooring chain.

(a) In accordance with section 8041 of the Fiscal Year 1991 DoD Appropriations Act (Pub. L. 101–511) and similar sections in subsequent DoD appropriations acts, do not acquire welded shipboard anchor and mooring chain, unless—

(1) It is manufactured in the United States, including cutting, heat treating, quality control, testing, and welding (both forging and shot blasting process); and

(2) The cost of the components manufactured in the United States exceeds 50 percent of the total cost of components.

(b) The statute at 10 U.S.C. 4864 also restricts acquisition of welded shipboard anchor and mooring chain, when used as a component of a naval vessel; however, the Appropriations Act restriction described in paragraph (a) of this section takes precedence over the restriction of 10 U.S.C. 4864 cited in 225.7004–2(b)(6).

225.7004–6 Waiver of restrictions.

(a) *Welded shipboard anchor and mooring chain.* (1) In accordance with section 8016 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), the secretary of the department responsible for acquisition may waive the restrictions in 225.7004–2(b)(6) and 225.7004–5, on a case-by-case basis, if—

(i) Sufficient domestic suppliers are not available to meet DoD requirements on a timely basis; and

(ii) The acquisition is necessary to acquire capability for national security purposes.

(2) Document the waiver in a written determination and findings containing—

(i) The factors supporting the waiver; and

(ii) A certification that the acquisition must be made in order to acquire capability for national security purposes.

(3) Provide a copy of the determination and findings to the House and Senate Committees on Appropriations.

(b) *Star trackers.* The waiver criteria at paragraph (c) of this section apply, except that the USD(A&S) may delegate the authority to waive a restriction for a star tracker for a particular foreign country to the service acquisition executive, without power of redelegation (section 1603, National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283)).

(c) *Waiver of restrictions of 10 U.S.C. 4864(a).* The restrictions on certain foreign purchases at 225.7004–2 may be waived, except as provided in paragraphs (a) and (b) of this section, as follows:

(1)(i) USD(A&S), without power of delegation, may waive a restriction for a particular item for a particular foreign country upon determination that—

(A) U.S. producers of the item would not be jeopardized by competition from a foreign country, and that country does not discriminate against defense items produced in the United States to a greater degree than the United States discriminates against defense items produced in that country; or

(B) Application of the restriction would impede cooperative programs entered into between DoD and a foreign country, or would impede the reciprocal procurement of defense items under a memorandum of understanding providing for reciprocal procurement of defense items under 225.872, and that country does not discriminate against defense items produced in the United States to a greater degree than the United States discriminates against defense items produced in that country.

(ii) A notice of the determination to exercise the waiver authority shall be published in the **Federal Register** and submitted to the congressional defense committees at least 15 days before the effective date of the waiver.

(iii) The effective period of the waiver shall not exceed 1 year.

(iv) For contracts entered into prior to the effective date of a waiver, provided adequate consideration is received to modify the contract, the waiver shall be applied as directed or authorized in the waiver to—

(A) Subcontracts entered into on or after the effective date of the waiver; and

(B) Options for the procurement of items that are exercised after the effective date of the waiver, if the option prices are adjusted for any reason other than the application of the waiver.

(2) The head of the contracting activity may waive a restriction on a case-by-case basis upon execution of a determination and findings that any of the following applies:

(i) The restriction would cause unreasonable delays.

(ii) Satisfactory quality items manufactured in the national technology and industrial base are not available.

(iii) Application of the restriction would result in the existence of only one source for the item in the national technology and industrial base.

(iv) Application of the restriction is not in the national security interests of the United States.

(v) Application of the restriction would adversely affect a U.S. company.

(3) A restriction is waived when it would cause unreasonable costs. The cost of an item of national technology and industrial base origin is unreasonable if it exceeds 150 percent of the offered price, inclusive of duty, of items that are not of national technology and industrial base origin.

225.7004–7 Contract clauses.

(a) Unless a waiver has been granted, use the clause at 252.225–7019, Restriction on Acquisition of Anchor and Mooring Chain, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, that exceed the simplified acquisition threshold and that require welded shipboard anchor or mooring chain.

(b) Use the clause at 252.225–7062, Restriction on Acquisition of Large Medium-Speed Diesel Engines, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, that exceed the simplified acquisition threshold and that require large medium-speed diesel engines for new construction of auxiliary ships using funds available for National Defense Sealift Fund programs or Shipbuilding and Conversion, Navy unless—

(1) An exception at 225.7004–3(d) applies; or

(2) A waiver has been granted.

(c) Unless a waiver has been granted, use the clause at 252.225–7063, Restriction on Acquisition of Components of T–AO 205 and T–ARC Class Vessels, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, that exceed the simplified acquisition threshold and that require components of T–AO 205 and T–ARC class vessels.

(d) Use the clause at 252.225–7064, Restriction on Acquisition of Certain Satellite Components, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, that exceed the simplified acquisition threshold unless—

(1) An exception at 225.7004–3(e) applies; or

(2) A waiver has been granted.

225.7006 [Removed and Reserved]

■ 8. Remove and reserve section 225.7006.

225.7006–1, 225.7006–2, 225.7006–3, and 225.7006–4 [Removed]

■ 9. Remove sections 225.7006–1, 225.7006–2, 225.7006–3, and 225.7006–4.

225.7007 [Removed and Reserved]

■ 10. Remove and reserve section 225.7007.

225.7007–1, 225.7007–2, and 225.7007–3 [Removed]

■ 11. Remove sections 225.7007–1, 225.7007–2, and 225.7007–3.

225.7008 [Removed and Reserved]

■ 12. Remove and reserve section 225.7008.

225.7009–1 [Amended]

■ 13. Amend section 225.7009–1 by removing ''Section'' and adding ''section'' in its place.

225.7010 [Removed and Reserved]

■ 14. Remove and reserve section 225.7010.

225.7010–1, 225.7010–2, 225.7010–3, 225.7010–4, and 225.7010–5 [Removed]

■ 15. Remove sections 225.7010–1, 225.7010–2, 225.7010–3, 225.7010–4, and 225.7006–5.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 16. Amend section 252.225–7019—
■ a. By revising the section heading, introductory text, clause date, and paragraph (a);
■ b. In paragraph (b) by removing '', four inches or less in diameter,''; and
■ c. In paragraph (d) by removing '', four inches or less in diameter''.

The revisions read as follows:

252.225–7019 Restriction on Acquisition of Anchor and Mooring Chain.

As prescribed in 225.7004–7(a), use the following clause:

Restriction On Acquisition of Anchor and Mooring Chain (MAY 2024)

(a) *Definition.* As used in this clause—

Component means an article, material, or supply incorporated directly into an end product.

* * * * *

252.225–7037 and 252.22–7038 [Removed and Reserved]

■ 17. Remove and reserve sections 252.225–7037 and 252.225–7038.

252.225–7062 [Amended]

■ 18. Amend section 252.225–7062 introductory text by removing ''225.7010–5'' and adding ''225.7004–7(b)'' in its place.

■ 19. Add section 252.225–7063 to read as follows:

252.225–7063 Restriction on Acquisition of Components of T–AO 205 and T–ARC Class Vessels.

As prescribed in 225.7004–7(c), use the following clause:

Restriction on Acquisition of Components of T–AO 205 AND T–ARC Class Vessels (MAY 2024)

(a) *Restriction.*

(1) In accordance with 10 U.S.C. 4864, the following components of T–AO 205 and T–ARC class vessels must be manufactured in the United States, Australia, Canada, New Zealand, or the United Kingdom of Great Britain and Northern Ireland (United Kingdom):

(i) Auxiliary equipment, including pumps, for all shipboard services.

(ii) Propulsion system components, including engines, reduction gears, and propellers.

(iii) Shipboard cranes.

(iv) Spreaders for shipboard cranes.

(2) The Contractor shall deliver under this contract only T–AO 205 and T–ARC class vessel components, as described in paragraph (a)(1) of this clause, manufactured in the United States, Australia, Canada, New Zealand, or the United Kingdom (10 U.S.C. 4864).

(b) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (b), in subcontracts for the components described in paragraph (a)(1) of this clause that exceed the simplified acquisition threshold, including subcontracts for commercial products and commercial services.

(End of Clause)

■ 21. Add section 252.225–7064 to read as follows:

252.225–7064 Restriction on Acquisition of Certain Satellite Components.

As prescribed in 225.7004–7(d), use the following clause:

Restriction On Acquisition of Certain Satellite Components (MAY 2024)

(a) *Definition.* As used in this clause—

Star tracker means a navigational tool used in a satellite weighing more than 400 pounds whose principal purpose is to support the national security, defense, or intelligence needs of the U.S. Government.

(b) *Restriction.* In accordance with 10 U.S.C. 4864, a star tracker must be manufactured in the United States, Australia, Canada, New Zealand, or the United Kingdom of Great Britain and Northern Ireland (United Kingdom). The Contractor shall deliver under this contract only star trackers manufactured in the United States, Australia, Canada, New Zealand, or the United Kingdom.

(c) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (c), in subcontracts for star trackers that exceed the simplified acquisition threshold, including subcontracts for commercial products and commercial services.

(End of clause)

[FR Doc. 2024–11514 Filed 5–29–24; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 225 and 252

[Docket DARS–2023–0018]

RIN 0750–AL33

Defense Federal Acquisition Regulation Supplement: Restriction on Certain Metal Products (DFARS Case 2021–D015)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is issuing a final rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act of Fiscal Year 2021 that provides restrictions on the acquisition of certain covered materials from The Democratic People's Republic of North Korea, The People's Republic of China, The Russian Federation, and The Islamic Republic of Iran.

DATES: Effective May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Bass, telephone 703–717–3446.

SUPPLEMENTARY INFORMATION:

I. Background

DoD published a proposed rule in the **Federal Register** at 88 FR 25609 on April 27, 2023, to implement section 844 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Pub. L. 116–283). Section 844 amends 10 U.S.C. 2533c (redesignated 10 U.S.C. 4872) and removes from the restriction ''material melted'' and replaces it with ''material mined, refined, separated, melted''. In addition, the reference to ''tungsten'' is removed and replaced with ''covered material'' in the exception for commercially available-off-the-shelf (COTS) items to the restriction of 50 percent or more by weight. The final rule also implements section 854 of the NDAA for FY 2024 (Pub. L. 118–31) that amends the effective date in section 844(b) of the NDAA for FY 2021. Section 854 extends the effective date of the restriction from 5 years to 6 years. Nine respondents submitted public comments in response to the proposed rule.

II. Discussion and Analysis

DoD reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments is provided, as follows:

A. Summary of Significant Changes From the Proposed Rule

Revisions were made at DFARS 225.7018–2 to implement the new effective date of the restriction in accordance with section 854 of the NDAA for FY 2024. Consequently, the dates of the current restrictions were revised to provide an effective date through December 31, 2026, and to reflect that the new restrictions will be effective on January 1, 2027. Conforming revisions were also made in the DFARS clause at 252.225–7052, Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten.

B. Analysis of Public Comments

1. Support for the Rule

Comment: Most respondents strongly supported the proposed rule. A few respondents stated that implementation of the restriction will help to strengthen domestic supply chains and help to establish secure domestic sourcing requirements. A respondent conveyed support for the rule and provided the restriction will contribute to the redevelopment of domestic rare earth production capacity.

Response: DoD acknowledges the respondents' support for the rule.

2. Strengthen the Defense Industrial Base

Comment: A respondent requested the opportunity to meet and strategize with DoD representatives of the Defense Acquisition Regulations System.

Response: While undergoing the Title 48 CFR rulemaking process, information regarding a rule is pre-decisional, deliberative Government information that cannot be shared with the public. In the context of public notice and comment in the course of rulemaking, it would be inappropriate to meet with individual members of the public to strategize about a pending rule.

3. Availability of Domestic Sources or Suppliers

a. Disruption in the U.S. Supply Chain

Comment: A few respondents shared concerns regarding the market dominance of Chinese rare earth metals, the impacts of the restriction, and the potential disruption in the U.S. domestic supply chains.

Response: Implementation of the statutory sourcing requirements in accordance with 10 U.S.C. 2533c (now 10 U.S.C. 4872), as amended by section 844 of the NDAA for FY 2021, is a necessary step to support the development of secure suppliers and transition defense critical supply chains to secure sources. DoD has supported the effective implementation of the statutory sourcing requirements through existing and planned investments in compliant suppliers. If compliant suppliers are not available for specified applications, the statute authorizes DoD to issue a nonavailability determination until a compliant supplier becomes available.

b. Samarium-Cobalt (Sm-Co) Magnets

Comment: A respondent specified that it is the only U.S.-based, vertically integrated domestic supplier of samarium cobalt magnets and discussed the impacts of their current rare earth metals supplier and its subsequent foreign ownership status. The respondent further states that they have spoken to potential domestic rare earth metal suppliers and their transition to becoming a domestic supplier is in its infancy at best.

Response: Implementation of the statutory sourcing requirements, in coordination with existing and planned DoD investments in the rare earth magnet supply chain, will support the development of compliant suppliers for rare earth concentrates, oxides, metals, and magnets. If compliant suppliers are not available for specified applications, the statute authorizes DoD to issue a nonavailability determination until a compliant supplier becomes available. DoD notes that the statute permits sourcing from domestic suppliers as well as suppliers located in other countries that source outside of the four covered countries: North Korea, Russia, Iran, or the People's Republic of China.

4. National Security Risks

Comment: Many respondents relayed their overall concerns with the Chinese rare earth metals market dominance and the associated national security risks.

Response: The principal benefit of this rule is that it continues the transition of the defense industrial base toward sourcing strategic and critical materials from suppliers other than the covered countries of North Korea, Russia, Iran, and the People's Republic of China. This requirement, in combination with existing and planned DoD investments, demonstrates DoD's commitment to support secure suppliers and to reduce the national security risks associated with over-reliance on, and the dominance of, the Chinese market.

5. Effective Date of Restriction

Comment: A few respondents expressed concern that domestic sources would not be available by the effective dates established in the rule. A respondent specifically recommended DoD advocate that Congress amend the statute to replace the specific effective dates with, instead, an effective date 180 days after the Secretary of Defense certifies to Congress that sufficient domestic sources are available to meet DoD's needs.

Response: Section 844(b) of the NDAA for FY 2021, as amended by section 854 of the NDAA for FY 2024, expressly states the effective date of the restrictions. As such, DoD cannot implement any other effective dates. DoD notes that section 854 extends the effective date of the restriction by one additional year to January 1, 2027. The restriction at DFARS 225.7018–2 reflects the statutory effective date as a clear demand signal and timetable to DoD's industry partners. DoD encourages industry to diligently seek and develop compliant domestic sources by the stated effective dates.

6. Recycled Material Exception

Comment: A respondent inquired about the applicability of the restriction to an end item containing a covered material that is a neodymium-iron-boron magnet manufactured from recycled material if the milling of the recycled material and sintering of the final magnet takes place in the United States. The respondent recommends DoD consider the same recycled material exception to be applied to the other magnets subject to the statutory restriction.

Response: The statutory requirements for exceptions in 10 U.S.C. 4872(c)(3)(C) state that the restriction under subsection (a) does not apply to the purchase by DoD of an end item containing a covered material that is a neodymium-iron-boron magnet manufactured from recycled material if the milling of the recycled material and sintering of the final magnet takes place in the United States. The section 844 amendments to 10 U.S.C. 2533c (now 10 U.S.C. 4872) did not add exceptions for the remaining covered materials, defined in the statute.

7. Statutory Implementation

Comment: A few respondents expressed support for the rule but highlighted specific areas for further consideration by DoD. A respondent welcomed the revision of the exception to the restriction to include COTS items that are 50 percent or more by weight to all covered items, including but no longer limited to only tungsten. However, the respondent opined that implementing this change would be problematic because of a lack of consistent methodology to determine whether an item qualifies for the exception. Another respondent expressed support for the proposed change because it would reduce foreign influence in America's critical mineral supply chain. However, the respondent also commented that the restriction should be expanded to include other critical mineral products, specifically cobalt metal powder and refined cobalt.

Response: DoD understands that cobalt metal powder is part of the samarium-cobalt magnet supply chain and will be subject to this statutory restriction. The rule implements section 844 of the NDAA for FY 2021, which replaces the reference to ''tungsten'' with ''covered material'' in the exception for COTS items to the restriction of 50 percent or more by weight. When identifying whether the COTS items exception applies to the end item, DoD encourages industry to consult the relevant procuring activity for the acquisition on how best to demonstrate compliance to the exception. DoD expects industry to use a reasonable and reliable process to determine an end item's composition and weight.

In regard to further expanding the restriction to include cobalt metal powder and refined cobalt, the statutory restriction includes, for samarium-cobalt magnets, the entire supply chain from mining or production of a cobalt and samarium ore, through production of finished magnets. (Also see the response provided for the comment category at 8b, Commercially Available Off-the-Shelf (COTS) Items Applicability.)

8. Recommended Revisions

a. Nonavailability Determination

Comment: A respondent recommended implementation of the restriction with use of the authority for a class nonavailability determination until viable supplier sources in compliance with the new restrictions

are verified. Another respondent recommended use of the same process created for a nonavailability determination under the specialty metals requirements and the current waiver process to allow for the use of noncompliant materials in case of a shortage. Additionally, the respondent recommends the ability for contractors and subcontractors to request nonavailability determinations, a public notice of the requests, and a process for manufacturers to demonstrate compliance and the ability to supply materials.

Response: The DFARS authorizes DoD to issue both individual and class nonavailability determinations if compliant materials are unavailable, as stated at DFARS 225.7018–4. The nonavailability determination process for this statute is largely aligned with the existing nonavailability determination process for specialty metals in accordance with 10 U.S.C. 4863 (see 225.7003–3).

The statutory sourcing requirement is important to transition supply chains to secure suppliers of strategic and critical materials. The existing regulations authorize DoD to issue individual and class nonavailability determinations if needed for national security in cases where compliant materials are not available. The process for class nonavailability determinations also provides opportunity for interested parties and manufacturers to provide information to DoD regarding the availability of compliant materials that would be relevant to the decision.

As provided at DFARS 225.7018–4, the Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)) must issue a public notice of the intent to make a class nonavailability determination at least 30 days prior to issuing the nonavailability determination, to the maximum extent practicable consistent with the protection of national security. Following the public notice, interested parties, including producers of covered materials, may provide relevant information. The USD(A&S) will take the information provided into consideration when determining whether to issue a class nonavailability determination. When issuing the final class nonavailability determination, the USD(A&S) will ensure that the class nonavailability determination and supporting rationale will be made publicly available, consistent with the protection of national security and confidential business information.

b. Commercially Available Off-the-Shelf (COTS) Items Applicability

Comment: A respondent stated that it will be problematic to implement the COTS items exception to the restriction of 50 percent or more by weight that includes all ''covered material'' as now defined in 10 U.S.C. 4872 in accordance with section 844 of the NDAA for FY 2021. The respondent further recommended that clarification in the rule is required to provide a consistent methodology for contractors to determine qualification criteria under the exception in the DFARS clause 252.225–7052 at paragraph (c)(1)(i)(A)(*1*), although a respondent acknowledged statutory changes would be required to effect this recommendation. Additionally, a respondent commented that removing the COTS items exception and including the entire and most remote aspects of the supply chain represents a nearly inexecutable burden for companies to manage.

Response: Section 844 is silent on applicability to contracts and subcontracts for the acquisition of commercial products and commercial services. DoD has made a determination of applicability to acquisitions of commercial products including COTS items, except as exempted in the statute. See section III of this preamble.

9. Outside the Scope of the Rule

Comment: A respondent provided information and data on their efforts to establish a tungsten mine in the United Kingdom and requested a point of contact to discuss government funding.

Response: This rule is implementing restrictions in accordance with 10 U.S.C. 4872, as amended by section 844 of the NDAA for FY 2021 and section 854 of the NDAA for FY 2024. Establishment of a tungsten mine and future investment is outside the scope of this rule.

Comment: A respondent encouraged the Government to continue to support research and development on economical and sustainable processing technologies for rare earth elements as well as development of alternatives.

Response: Government research and development efforts for future processing technologies are outside the scope of this rule.

Comment: A respondent recommends creation of a centralized DoD certification process, a trusted marketplace of commercial suppliers, or a qualified list of compliant sources to facilitate the transition across the defense industrial base for future compliance with the statutory restriction.

Response: The creation of a compliant supplier list is outside the scope of the rule. While DoD may explore the potential feasibility of developing a list for this application, in general, DoD does not support establishing a list of preferred sourcing.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This rule amends the clause at DFARS 252.225–7052, Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten. However, this final rule does not impose any new requirements on contracts at or below the SAT, for commercial products including COTS items. DFARS 252.225–7052 does not apply to acquisitions below the SAT, in accordance with 41 U.S.C. 1905, but it applies to contracts for the acquisition of commercial products, including COTS items, except as provided in the statute at 10 U.S.C. 4872(c)(3).

IV. Expected Impact of the Rule

This rule will impact the Government and industry because this rule significantly expands the scope of compliance in accordance with section 844 of the NDAA for FY 2021, section 854 of the FY 2024 NDAA, and 10 U.S.C. 4872.

The current restriction at DFARS 225.7018–2 covers the melting of precursor metals (*e.g.,* samarium metal and cobalt metal) to produce alloys (*e.g.,* samarium-cobalt alloy) and other equivalent processes (*e.g.,* atomization, calcination and reduction, or final consolidation of non-melt derived metals powders). One of the materials covered by this rule at 225.7018–2 and the clause at DFARS 252.225–7052, Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten, is also covered by longstanding restrictions for the acquisition of specialty metals at 225.7003–2 (10 U.S.C. 4875) and under the clause at DFARS 252.225–7009, Restriction on Acquisition of Specialty Metals, that includes the same coverage of production steps (*e.g.,* melt or produce).

This rule expands the scope of product coverage to all upstream mining, refining, separation, and melting of covered materials. Taken together with the overlapping restriction requirement on specialty metals at 225.7003–2 and the clause at DFARS 252.225–7009, Restriction on Acquisition of Specialty Metals, covered materials that are compliant with the

specialty metals clause may not be compliant with the current restriction at DFARS 225.7018–2 or the clause at DFARS 252.225–7052, Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten, nor are they likely to be compliant with this rule.

For example, assume that a contractor purchases a component from a United Kingdom-based supplier, and the assembly contains a samarium-cobalt magnet manufactured in China. This component would be compliant with the specialty metals clause, because the specialty metals clause exempts qualifying country components. However, this rule has no exemption for qualifying country components, and thus the assembly would be noncompliant with the current restriction at DFARS 225.7018–2 and the clause at DFARS 252.225–7052, Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten, in its current form and as amended by this rule.

Further, assume that a company purchases a motor from a U.S. manufacturer, and that U.S. motor manufacturer purchases a magnet from a U.S. company. The U.S. magnet company purchases cobalt metal and samarium metal from China, and these metals are melted in the United States. This magnet would be compliant with both the restriction required by the specialty metals clause at DFARS 252.225–7009, Restriction on Acquisition of Specialty Metals, and the current restriction at 225.7018–2 and the clause at DFARS 252.225–7052, Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten. However, this magnet would not be compliant with the requirements that will be effective on January 1, 2027.

Further, assume that a company produces business jets and modifies them for military use. During a given year, the business jet manufacturer purchases 50 percent of its samarium-cobalt magnet needs from a U.S. source that mines and conducts all subsequent processing steps in the United States. The balance of the company's samarium-cobalt magnets is procured from Chinese sources and the company commingles domestically and Chinese-produced magnets on its production line. In this scenario, the modified business jet is compliant with the restriction at DFARS 225.7003–2 and the clause at DFARS 252.225–7009, Restriction on Acquisition of Specialty Metals, because it is a commercial derivative military article, and the company procures 50 percent of its total needs from a domestic source. However, the modified business jet is potentially noncompliant with the final rule, given the commingling of Chinese and U.S. samarium-cobalt magnets in each aircraft.

Notwithstanding the significant change in scope, DoD notes that Congress enacted this requirement on January 1, 2021, through Public Law 116–283. This five-year phase-in period, now revised to six years by section 854 of the NDAA for FY 2024, provides a reasonable period for industry to develop alternative sources of supply for covered materials from sources other than the People's Republic of China, the Russian Federation, the Democratic People's Republic of North Korea, and the Islamic Republic of Iran.

DoD also notes that it has invested and continues to invest in domestic supply chains for covered materials, such as light and heavy rare earth elements and rare earth magnet manufacture, using authorities under 50 U.S.C. 4533 and 10 U.S.C. 4817 among others. For those materials not currently covered by DoD investments, such as tantalum and tungsten, publicly-traded U.S. companies, including DoD contractors and their subcontractors, already are required to conduct supply chain due diligence on these minerals when they are necessary to the functionality or production of a product manufactured by that company. This requirement stems from section 1502 of Public Law 111–203 (enacted at 17 CFR 240.13p–1) to ensure that such minerals are not supporting armed conflict in the Democratic Republic of Congo and adjoining countries.

The principal benefit of this rule is that it continues to transition the defense industrial base towards the procurement of strategic and critical materials from sources other than North Korea, Russia, Iran, or the People's Republic of China, with the latter constituting the pacing challenge identified in the National Defense Strategy. Notwithstanding the current and long-term challenge posed by China, Russia continues to pose an acute threat. Russia is a major producer and exporter of a wide array of strategic and critical materials, and the extreme volatility in these markets since Russia's invasion of Ukraine demonstrates the national security imperative to build resilience into supply chains for covered materials of this rule.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Congressional Review Act

As required by the Congressional Review Act (5 U.S.C. 801–808) before an interim or final rule takes effect, DoD will submit a copy of the interim or final rule with the form, Submission of Federal Rules under the Congressional Review Act, to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule under the Congressional Review Act cannot take effect until 60 days after it is published in the **Federal Register**. The Office of Information and Regulatory Affairs has determined that this rule is not a major rule as defined by 5 U.S.C. 804.

VII. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and is summarized as follows:

This rule is required to implement section 844 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Pub. L. 116–283), which amends 10 U.S.C. 2533c (now 10 U.S.C. 4872), and section 854 of the NDAA for FY 2024 (Pub. L. 118–31). The objective of the rule is to implement the section 844 revisions to the restriction on the acquisition of covered materials melted or produced in any covered country (*i.e.,* North Korea, the People's Republic of China, Russia, or Iran) to include mined, refined, separated, melted, or produced. In addition, section 844 revises the commercially available off-the-shelf (COTS) items exception to the restriction of 50 percent or more by weight to now include all covered material and remove the individual exception to only tungsten. The term ''covered materials,'' already defined in the statute and at DFARS 225.7018–1, means samarium-cobalt magnets, neodymium-iron-boron magnets, tantalum metals and alloys, tungsten metal powder, and tungsten heavy alloy or any finished or semi-finished component containing tungsten heavy alloy. Section 854 of the NDAA for FY 2024 extends the effective date of the revised requirements by one year.

There were no significant issues raised by the public comments in response to the initial regulatory flexibility analysis.

Based on data from the Federal Procurement Data System for FY 2021, 2022, and 2023, DoD awarded in the United States 26,697 contracts that exceeded the simplified acquisition threshold of $250,000 and were for the acquisition of manufactured end products, excluding those categories that could not include restricted metals (such as clothing and fabrics, books, or lumber products). These contracts were awarded to a total of 3,127 unique entities, of which 1,783 were unique small entities; contracts were awarded to a median of 611 unique small entities per year. It is not known what percentage of these awards involved the specific covered materials from China, North Korea, Russia, or Iran.

There are no projected reporting or recordkeeping requirements. However, there may be compliance costs to track the origin of covered materials.

DoD is exempting acquisitions equal to or less than the simplified acquisition threshold in accordance with 41 U.S.C. 1905. DoD was unable to identify any other alternatives that would reduce burden on small businesses and still meet the objectives of the statute.

VIII. Paperwork Reduction Act

This final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 225 and 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR parts 225 and 252 are amended as follows:

■ 1. The authority citation for parts 225 and 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 225—FOREIGN ACQUISITION

■ 2. Add section 225.7018–0 to read as follows:

225.7018–0 Scope.

This section implements 10 U.S.C. 4872.

■ 3. Revise section 225.7018–2 to read as follows:

225.7018–2 Restriction.

(a) *General.* Except as provided in 225.7018–3 and 225.7018–4—

(1) Effective through December 31, 2026, do not acquire any covered material melted or produced in any covered country, or any end item, manufactured in any covered country, that contains a covered material; and

(2) Effective January 1, 2027, do not acquire any covered material mined, refined, separated, melted, or produced in any covered country, or any end item, manufactured in any covered country, that contains a covered material. (Section 854, Pub. L. 118–31; 10 U.S.C. 4872.)

(b) *Samarium-cobalt magnets and neodymium-iron-boron magnets.* (1) Effective through December 31, 2026, for samarium-cobalt magnets and neodymium-iron-boron magnets, this restriction includes—

(i) Melting samarium with cobalt to produce the samarium-cobalt alloy or melting neodymium with iron and boron to produce the neodymium-iron-boron alloy; and

(ii) All subsequent phases of production of the magnets, such as powder formation, pressing, sintering or bonding, and magnetization.

(2) Effective January 1, 2027, for samarium-cobalt magnets this restriction includes the entire supply chain from mining or production of a cobalt and samarium ore or feedstock, including recycled material, through production of finished magnets, except as provided at 225.7018–3.

(3) The restriction on melting and producing of samarium-cobalt magnets is in addition to any applicable restrictions on melting of specialty metals at 225.7003 and the clause at 252.225–7009, Restriction on Acquisition of Certain Articles Containing Specialty Metals.

(4) Effective January 1, 2027, for neodymium-iron-boron magnets, this restriction includes the entire supply chain from mining of neodymium, iron, and boron through production of finished magnets, except as provided at 225.7018–3.

(c) *Tantalum metals and alloys.* (1) Effective through December 31, 2026, for production of tantalum metals of any kind and alloys, this restriction includes the reduction or melting of any form of tantalum to create tantalum metal including unwrought, powder, mill products, and alloys. The restriction also covers all subsequent phases of production of tantalum metals and alloys.

(2) Effective January 1, 2027, for production of tantalum metals of any kind and alloys, this restriction includes mining or production of a tantalum ore or feedstock, including recycled material, through production of metals of any kind and alloys, except as provided at 225.7018–3.

(d) *Tungsten metal powder and tungsten heavy alloy.* (1) Effective through December 31, 2026, for production of tungsten metal powder and tungsten heavy alloy, this restriction includes—

(i) Atomization;

(ii) Calcination and reduction into powder;

(iii) Final consolidation of non-melt derived metal powders; and

(iv) All subsequent phases of production of tungsten metal powder, tungsten heavy alloy, or any finished or semi-finished component containing tungsten heavy alloy.

(2) Effective January 1, 2027, for production of tungsten metal powder, tungsten heavy alloy, or any finished or semi-finished component containing tungsten heavy alloy, this restriction includes mining or production of a tungsten ore or feedstock, including recycled material, through production of tungsten metal powders, except as provided at 225.7018–3.

■ 4. Amend section 225.7018–3—

■ a. By revising paragraph (c)(1); and

■ b. In paragraph (d)(1) by removing ''this contract;'' and adding ''the contract;'' in its place.

The revision reads as follows:

225.7018–3 Exceptions.

* * * * *

(c) * * *

(1) A commercially available off-the-shelf item (but see PGI 225.7018–3(c)(1) with regard to commercially available samarium-cobalt magnets), other than—

(i) A commercially available off-the-shelf item that is—

(A) 50 percent or more tungsten by weight effective through December 31, 2026; or

(B) 50 percent or more covered material by weight effective January 1, 2027;

(ii) Effective through December 31, 2026, a tantalum metal, tantalum alloy, or tungsten heavy alloy mill product, such as bar, billet, slab, wire, cube, sphere, block, blank, plate, or sheet, that has not been incorporated into an end item, subsystem, assembly, or component; or

(iii) Effective January 1, 2027, a covered material that is a mill product such as bar, billet, slab, wire, cube, sphere, block, blank, plate, or sheet, that has not been incorporated into an end item, subsystem, assembly, or component;

* * * * *

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. Amend section 252.225–7052 by—
■ a. Revising the clause date; and
■ b. Revising paragraphs (b) and (c)(1).
The revisions read as follows:

252.225–7052 Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten.

* * * * *

Restriction on the Acquisition of Certain Magnets, Tantalum, and Tungsten (May 2024)

* * * * *

(b) *Restriction.* (1) Except as provided in paragraph (c) of this clause—

(i) Effective through December 31, 2026, the Contractor shall not deliver under this contract any covered material melted or produced in any covered country, or any end item, manufactured in any covered country, that contains a covered material; and

(ii) Effective January 1, 2027, the Contractor shall not deliver under this contract any covered material mined, refined, separated, melted, or produced in any covered country, or any end item, manufactured in any covered country, that contains a covered material (section 854, Pub. L. 118–31; 10 U.S.C. 4872).

(2)(i)(A) Effective through December 31, 2026, for samarium-cobalt magnets and neodymium-iron-boron magnets, this restriction includes—

(*1*) Melting samarium with cobalt to produce the samarium-cobalt alloy or melting neodymium with iron and boron to produce the neodymium-iron-boron alloy; and

(*2*) All subsequent phases of production of the magnets, such as powder formation, pressing, sintering or bonding, and magnetization.

(B) Effective January 1, 2027, for samarium-cobalt magnets this restriction includes the entire supply chain from mining or production of a cobalt and samarium ore or feedstock, including recycled material, through production of finished magnets.

(ii) The restriction on melting and producing of samarium-cobalt magnets is in addition to any applicable restrictions on melting of specialty metals if the clause at 252.225–7009, Restriction on Acquisition of Certain Articles Containing Specialty Metals, is included in the contract.

(3) Effective January 1, 2027, for neodymium-iron-boron magnets, this restriction includes entire supply chain from mining of neodymium, iron, and boron through production of finished magnets.

(4)(i) Effective through December 31, 2026, for production of tantalum metals of any kind and alloys, this restriction includes the reduction or melting of any form of tantalum to create tantalum metal including unwrought, powder, mill products, and alloys. The restriction also covers all subsequent phases of production of tantalum metals and alloys.

(ii) Effective January 1, 2027, for production of tantalum metals of any kind and alloys, this restriction includes mining or production of a tantalum ore or feedstock, including recycled material, through production of metals of any kind and alloys.

(5)(i) Effective through December 31, 2026, for production of tungsten metal powder and tungsten heavy alloy, this restriction includes—

(A) Atomization;

(B) Calcination and reduction into powder;

(C) Final consolidation of non-melt derived metal powders; and

(D) All subsequent phases of production of tungsten metal powder, tungsten heavy alloy, or any finished or semi-finished component containing tungsten heavy alloy.

(ii) Effective January 1, 2027, for production of tungsten metal powder, tungsten heavy alloy, or any finished or semi-finished component containing tungsten heavy alloy, this restriction includes mining or production of a tungsten ore or feedstock, including recycled material, through production of tungsten metal powders, tungsten heavy alloy, or any finished or semi-finished component containing tungsten heavy alloy.

(c) *Exceptions.* This clause does not apply—

(1) To an end item containing a covered material that is—

(i) A commercially available off-the-shelf item, other than—

(A) A commercially available off-the-shelf item that is—

(*1*) 50 percent or more tungsten by weight effective through December 31, 2026; or

(*2*) 50 percent or more covered material by weight effective January 1, 2027;

(B) Effective through December 31, 2026, a tantalum metal, tantalum alloy, or tungsten heavy alloy mill product, such as bar, billet, slab, wire, cube, sphere, block, blank, plate, or sheet, that has not been incorporated into an end item, subsystem, assembly, or component;

(ii) Effective January 1, 2027, a covered material that is a mill product such as bar, billet, slab, wire, cube, sphere, block, blank, plate, or sheet, that has not been incorporated into an end item, subsystem, assembly, or component;

(iii) An electronic device, unless otherwise specified in the contract; or

(iv) A neodymium-iron-boron magnet manufactured from recycled material if the milling of the recycled material and sintering of the final magnet takes place in the United States.

* * * * *

[FR Doc. 2024–11513 Filed 5–29–24; 8:45 am]

BILLING CODE 6820–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

[Docket DARS–2024–0001]

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule; technical amendment.

SUMMARY: DoD is amending the Defense Federal Acquisition Regulation Supplement (DFARS) to make needed editorial changes.

DATES: Effective May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer D. Johnson, Defense Acquisition Regulations System, telephone 703–717–8226.

SUPPLEMENTARY INFORMATION: This final rule amends the DFARS to make needed editorial changes to update two outdated hyperlinks at DFARS 252.204–7012.

List of Subjects in 48 CFR Part 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, 48 CFR part 252 is amended as follows:

■ 1. The authority citation for 48 CFR part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 2. Amend section 252.204–7012—
■ a. By revising the clause date;
■ b. In paragraph (b)(2)(i) by removing ''*http://dx.doi.org/10.6028/*

NIST.SP.800-171'' and adding ''*https://csrc.nist.gov/publications/sp800*'' in its place; and

■ c. In paragraph (b)(2)(ii)(D) by removing ''*https://www.fedramp.gov/resources/documents/*'' and adding ''*https://www.fedramp.gov/documents-templates/*.'' in its place.

The revision reads as follows:

252.204–7012 Safeguarding Covered Defense Information and Cyber Incident Reporting.

* * * * *

Safeguarding Covered Defense Information and Cyber Incident Reporting (MAY 2024)

* * * * *

[FR Doc. 2024–11516 Filed 5–29–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2023–0215; FXES1111090FEDR–245–FF09E21000]

RIN 1018–BH68

Endangered and Threatened Wildlife and Plants; Revision of the Critical Habitat Designation for the Jaguar in Compliance With a Court Order

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are issuing this final rule to comply with a court order to vacate Subunit 4b and a portion of Unit 3 in Arizona from the March 5, 2014, final rule designating lands in Arizona as critical habitat for the jaguar (*Panthera onca*) under the Endangered Species Act of 1973, as amended (Act). In compliance with the court order, this final rule removes approximately 64,797 acres (26,222 hectares) of land within Arizona from the designation of critical habitat for the jaguar. The remaining total acreage of designated critical habitat for the jaguar is approximately 640,124 acres (259,049 hectares) in Pima, Santa Cruz, and Cochise Counties, Arizona.

DATES: This rule is effective May 30, 2024. However, the court order had legal effect immediately upon being filed on August 11, 2023.

FOR FURTHER INFORMATION CONTACT: Heather Whitlaw, U.S. Fish and Wildlife Service, 9828 North 31st Avenue #C3, Phoenix, AZ 85051; telephone: 602–242–0210; email at *incomingazcorr@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:

Previous Federal Actions

On March 5, 2014, we published in the **Federal Register** (79 FR 12572) a final rule designating approximately 764,207 acres (309,263 hectares) of land in New Mexico and Arizona as critical habitat for the jaguar under the Act (16 U.S.C. 1531 *et seq.*). The jaguar's critical habitat designation is set forth in our regulations in title 50 of the Code of Federal Regulations (CFR) at § 17.95(a) (50 CFR 17.95(a)). Please see the March 5, 2014, final rule for a complete discussion of previous Federal actions pertaining to this designation.

On July 22, 2021, we published in the **Federal Register** (86 FR 38570) a final rule revising the critical habitat designation for the jaguar in compliance with a different court order to remove Unit 6 and the New Mexico portion of Unit 5 from the designation. In that final rule, we erroneously stated that the rule removed approximately 110,438 acres (44,693 hectares) of land within New Mexico from the designation of critical habitat for the jaguar. On February 2, 2022, we published a correction in the **Federal Register** (87 FR 5737); the correction stated that the July 22, 2021, rule removed 59,286 acres (23,993 hectares) in New Mexico from the designation of critical habitat for the jaguar.

Background

In 2016, we issued a biological opinion, as required under the Act (16 U.S.C. 1536), regarding the development of a copper mine by the Rosemont Copper Company (Rosemont) on lands administered by the Coronado National Forest. The action area of the proposed mine and associated infrastructure included portions of the critical habitat designation for the jaguar, specifically portions of Unit 3 and Subunit 4b. In our biological opinion, we found that the proposed mine was not likely to jeopardize the continued existence of the jaguar or result in the destruction or adverse modification of its critical habitat.

On September 25, 2017, the Center for Biological Diversity filed a lawsuit against the Service and the U.S. Forest Service. The Center for Biological Diversity alleged that we violated the Act and the Administrative Procedure Act (APA; 5 U.S.C. 551 *et seq.*) in concluding that the mine would not destroy or adversely modify the designated critical habitat. Rosemont intervened and filed a crossclaim challenging the March 5, 2014, final rule's designation of Subunit 4b and a portion of Unit 3 in the Santa Rita Mountains as critical habitat for the jaguar. On February 10, 2020, the Arizona district court denied in part and affirmed in part the Service's critical habitat designation. As part of its decision, the district court found that we erred in designating Unit 3 as occupied critical habitat but granted summary judgement in favor of designating Unit 3 and subunit 4B as unoccupied critical habitat.

Rosemont appealed the district court decision to the U.S. Court of Appeals for the Ninth Circuit. On May 17, 2023, the appellate court affirmed in part and reversed in part the decision of the district court and remanded the relevant portions of the jaguar critical habitat rule for proceedings consistent with its decision. See *Ctr. for Biological Diversity* v. *U.S. Fish and Wildlife Serv.,* 67 F.4th 1027 (May 17, 2023), which is available in Docket No. FWS–R2–ES–2023–0215 on *https://www.regulations.gov.* Upon remand, on August 11, 2023, the Arizona district court ordered the Service to vacate a portion of Unit 3 and all of Subunit 4b as critical habitat. This rule implements the district court's August 11, 2023, order.

Administrative Procedure

This rulemaking is necessary to comply with the August 11, 2023, court order remanding to the agency to vacate the critical habitat designations challenged by Rosemont. Therefore, under these circumstances, the Service Director (Director) has determined, pursuant to 5 U.S.C. 553(b)(3)(B), that prior notice and opportunity for public comment are impracticable and unnecessary. Because the court order had legal effect immediately upon being filed on August 11, 2023, the Director has further determined, pursuant to 5 U.S.C. 553(d)(3), that the agency has good cause to make this rule effective immediately upon publication.

Effects of the Rule

This rule is an administrative action to remove approximately 64,797 acres (26,222 hectares) of land within Arizona from the jaguar's critical habitat designation at 50 CFR 17.95(a).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Amendment

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below.

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.95, in paragraph (a), in the entry for ''Jaguar (*Panthera onca*)'', by revising paragraphs (5) and (6), to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

(a) * * *

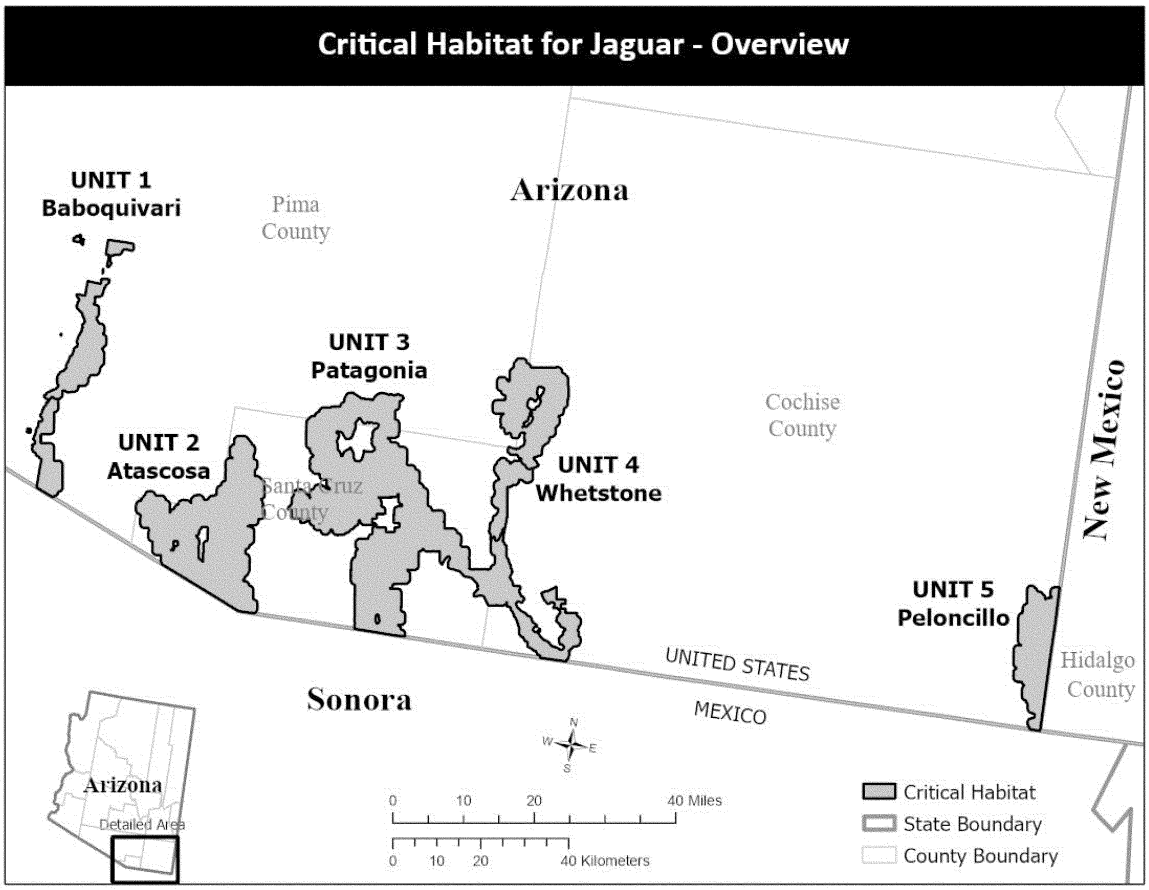
* * * * *

Jaguar (*Panthera onca*)

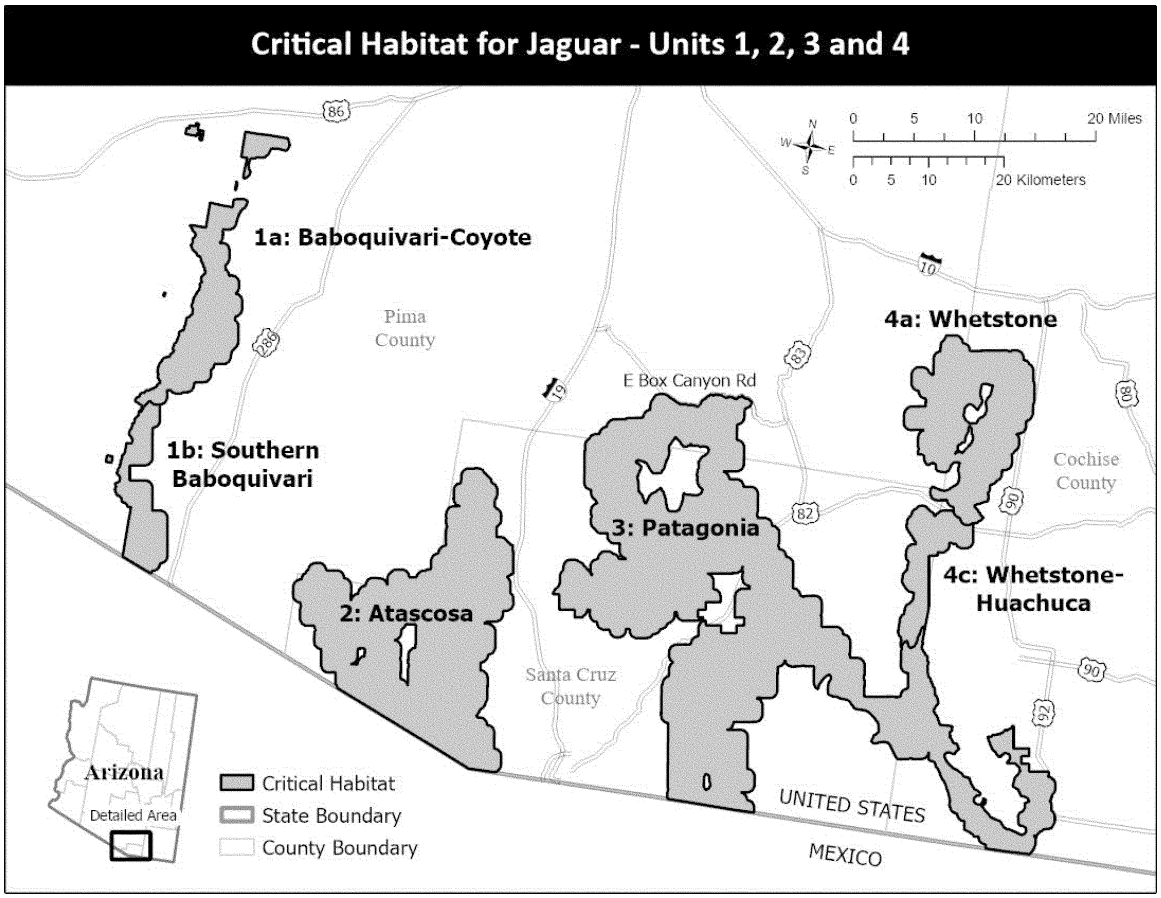
* * * * *

(5) *Note:* Index map follows:

BILLING CODE 4333–15–P



(6) Units 1, 2, 3, and 4: Baboquivari, Atascosa, Patagonia, and Whetstone Units, Pima, Santa Cruz, and Cochise Counties, Arizona. Map of Units 1, 2, 3, and 4 follows:



* * * * *

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2024–11758 Filed 5–29–24; 8:45 am]

BILLING CODE 4333–15–C

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 240523–0145]

RIN 0648–BM75

Pacific Halibut Fisheries of the West Coast; 2024 Catch Sharing Plan and Recreational Management Measures; Correction

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

ACTION: Final rule; correction.

SUMMARY: This action makes two corrections to the 2024 Area 2A Pacific halibut recreational management measures implemented on April 4, 2024. Specifically, NMFS is correcting the open fishing dates listed for the Washington South Coast subarea fishery and a reference to the subarea allocation amount for the Oregon Central Coast nearshore fishery. The date and allocation corrections are to address minor inadvertent transcriptional errors, non-substantive changes to the final rule, and this rule is needed to avoid confusion with the public, enforcement, and management agencies.

DATES: Effective May 29, 2024.

FOR FURTHER INFORMATION CONTACT: Melissa Mandrup, phone: 562–980–3231, or email: *melissa.mandrup@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the Pacific halibut fishery in International Pacific Halibut Commission (IPHC) Regulatory Area 2A (waters off Washington, Oregon, and California) in accordance with the Northern Pacific Halibut Act of 1982 (Halibut Act), 16 U.S.C. 773–773k. As provided in the Halibut Act, the regional fishery management council having authority for the geographic area concerned may develop, and the Secretary of Commerce may implement, regulations governing Pacific halibut fishing in U.S. waters that are in addition to, and not in conflict with, approved IPHC regulations (16 U.S.C. 773c(c)). Since 1988, the Pacific Fishery Management Council (Council) has developed a Catch Sharing Plan, through the Council's public process, that allocates the Area 2A Pacific halibut catch limit, also known as the Fishery Constant Exploitable Yield (FCEY), between treaty tribal and non-tribal harvesters, and among non-tribal commercial and recreational (sport) fisheries, and adopts management measures for these fisheries. NMFS has implemented at 50 CFR 300.63 *et seq.* certain provisions of the Catch Sharing Plan and implemented, in annual rules, annual management measures consistent with the Catch Sharing Plan. A final rule (89 FR 22966, April 3, 2024) implemented management measures for the 2024 recreational fishery, consistent with the recommendations made by the Council in its 2024 Catch Sharing Plan, including the days the fishery is open and subarea allocations in Area 2A. The final rule was effective on April 4, 2024. However, it contained two transcription errors, one for the Washington South Coast subarea and one for the Oregon Central Coast subarea.

Corrections

Season Dates

On page 22967 of the final rule, NMFS inadvertently excluded 2 days the Washington Department of Fish and Wildlife (WDFW) and the Council intended the fishery to be open in the Washington South Coast subarea: May 28 and 30. At its November meeting, the Council recommended NMFS implement specific season dates for fishing in the Washington South Coast subarea. These dates were developed through public meetings held by WDFW, as well as at the Council's September and November meetings. Specifically, the Council recommended to NMFS, based on WDFW's recommendation, that fishing days in the Washington South Coast subarea be ''Open May 2 through May 30, three days per week, Thursday, Sunday, and Tuesday. Memorial Day weekend: open Thursday, May 23. If sufficient quota remains, open June 13, 16, 18, 20, 23, 25, 27, 30. If quota remains after June 30, open up to seven days per week in August and September.'' However, the final rule inadvertently excluded the last Tuesday and Thursday in May: May 28 and 30.

As such, consistent with the intent of the Council, the corrected season dates for the Washington South Coast subarea in May are: May 2, 5, 7, 9, 12, 14, 16, 19, 21, 23, 28, and 30. Closed May 25, 26 and 27.

Subarea Allocation

Under the allocation framework the Council adopted in the Catch Sharing Plan, the Oregon recreational fishery is allocated 29.7 percent of the non-tribal share of the FCEY. The Oregon recreational fishery allocation is further allocated to two subareas; the Oregon Central Coast receiving 93.79 percent and Southern Oregon receiving 3.91 percent (up to 8,000 pounds (lb) [3.6 metric tons [mt]] with the remainder going to the Columbia River subarea). The Oregon Central Coast subarea allocation is further divided into the nearshore fishery receiving 12 percent, the spring all-depth fishery receiving 63 percent, and the summer all-depth fishery receiving 25 percent. Consistent with the allocation the IPHC set for Area 2A in 2024 (89 FR 19275, March 18, 2024) and this framework, the overall Oregon Central Coast subarea allocation is 266,161 lb (120.7 mt) and the nearshore fishery allocation should therefore be 31,939 lb (14.5 mt). However, page 22968 of the final rule incorrectly states the pounds allocated to the nearshore fishery as 31,393 lb (14.5 mt). Therefore, this action corrects that value and establishes the Oregon Central Coast nearshore fishery allocation at 31,939 lb (14.5 mt). The amount in metric tons of 14.5 mt was stated correctly in the original final rule.

Classification

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) authorizes agencies to dispense with notice and comment procedures for rules when the agency for ''good cause'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Assistant Administrator for Fisheries determined there is good cause to waive prior notice and an opportunity for public comment on this action as notice and comment would be impracticable and contrary to the public interest because this action is necessary to correct an inadvertent error in a final rule (89 FR 22966).

Immediate correction of the error is necessary to prevent confusion among participants in the fishery and to ensure that management of the fishery is consistent with State Fish and Wildlife agency recommendations, which were developed with stakeholder feedback, and the Council's intent for the regulations, as developed over two public meetings. The proposed regulations were available for public review during a 30-day public comment period in the proposed rule (89 FR 9105, February 9, 2024), and the final rule (89 FR 22966, April 3, 2024) provided responses to the comments received. Therefore, there is good cause to waive additional public comment and immediate correction of the error is needed to meet the public's expectations based on recommendations made in the Council's 2024 Catch Sharing Plan and in outreach materials distributed by the States of Washington and Oregon. Delaying this correction to engage in notice-and-comment rulemaking would be contrary to the public interest because it would undermine the intent of the rule.

Under section 553(d) of the APA, an agency must delay the effective date of regulations for 30 days after publication, unless the agency finds good cause to make the regulations effective sooner. For the same reasons stated above, the Assistant Administrator for Fisheries has determined good cause exists to waive the 30-day delay in effectiveness. This rule makes only two minor corrections to the final rule, which became effective April 4, 2024. Delaying effectiveness of these corrections would result in conflicts in the regulations and confusion among fishery participants, and would therefore be contrary to the public interest. Additionally, without waiving the 30-day delay in effectiveness, this correction to the season dates would not be effective by May 28 and 30, which the final rule inadvertently omitted as open fishing days in the Washington South Coast subarea, but which were intended to be included.

The Regulatory Flexibility Act, 5 U.S.C. 603 and 604, requires an agency to prepare an initial and a final regulatory flexibility analysis whenever an agency is required by section 553 of the APA, or any other law, to publish a general notice of proposed rulemaking. Because NMFS found good cause under section 553(b)(3)(B) of the APA to forgo publication of a notice of proposed rulemaking, the regulatory flexibility analyses described in 5 U.S.C. 603 and 604 are not required for this rulemaking.

This final rule is not significant under Executive Order 12866.

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

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

Dated: May 24, 2024.

Samuel D. Rauch, III,

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

[FR Doc. 2024–11866 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 697

[Docket No. 240520–0141]

RIN 0648–BM92

Fisheries of the Northeastern United States; Atlantic Coastal Fisheries Cooperative Management Act Provisions; American Lobster Fishery; Removal of American Lobster Effort Control Measures

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

ACTION: Final rule.

SUMMARY: Following the Atlantic States Marine Fisheries Commission's (Commission) withdrawal of Lobster Conservation Management Area 2 and 3 ownership caps and Area 3 maximum trap cap reductions from its Interstate Fishery Management Plan for American Lobster (Lobster Plan), this action

removes those requirements from Federal regulations and clarifies that all other measures included in the October 2, 2023, interim final rule (IFR) remain in effect. This action is intended to support the Commission's management of the lobster fishery and eliminate the potential for inconsistent State and Federal regulations that risk undermining management of the fishery and is necessary to ensure that fishery regulations for the lobster fishery in Federal waters remain compatible with the Lobster Plan and consistent with the Atlantic Coastal Fisheries Cooperative Management Act (Atlantic Coastal Act).

DATES: As of July 1, 2024, the revision to § 697.19(c) and (m) in amendatory instruction 6 of the IFR, 88 FR 67667, 67687–67679 (October 2, 2023), is withdrawn.

ADDRESSES: You may request copies of the supplemental information report prepared for this action at: National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930–2276 or by calling (978) 281–9315. The supporting document is also accessible via the internet at: *https://www.fisheries.noaa.gov/about/greater-atlantic-regional-fisheries-office* or *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Allison Murphy, Fishery Policy Analyst, (978) 281–9122.

SUPPLEMENTARY INFORMATION:

Background

Statutory Authority

These regulations modify Federal lobster fishery management measures in the Exclusive Economic Zone (EEZ) under the authority of section 803(b) of the Atlantic Coastal Act. This authority states that, in the absence of an approved and implemented Fishery Management Plan under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and, after consultation with the appropriate fishery management council(s), the Secretary of Commerce may implement regulations to govern fishing in the EEZ, from 3 to 200 nautical miles offshore. The regulations must be: (1) compatible with the effective implementation of an Interstate Fishery Management Plan developed by the Atlantic States Marine Fisheries Commission; and (2) consistent with the National Standards set forth in section 301 of the Magnuson-Stevens Act. See 16 U.S.C. 5103(b)(1)(A) (establishing Secretary's authority to issue Federal regulations that are compatible with a coastal management plan and consistent with Magnuson-Stevens Act National Standards), 16 U.S.C. 1502(1) (defining ''coastal management plan'').

Purpose and Need for Management

The purpose of this action is to manage the American lobster fishery to maximize resource sustainability, recognizing that Federal management occurs in concert with State management and compatibility between State and Federal measures is crucial to the overall success of American lobster management and required by the Atlantic Coastal Act. NMFS indicated that the agency could make changes to the IFR measures and requested comment on that possibility in the IFR, see 88 FR at 67669; see also 87 FR 41084 (July 11, 2022) (proposed rule requesting comments on measures ultimately included in the IFR); 82 FR 52871 (November 15, 2017) (advance notice of proposed rulemaking (ANPR) requesting comments on change to control date for trap limits in Areas 2 and 3); 79 FR 4319 (January 27, 2014) (ANPR establishing control date and requesting comments). In light of public comments received and to achieve the purpose of the Atlantic Coastal Act, we are withdrawing the Area 2 and 3 ownership caps and Area 3 maximum trap cap reductions that we implemented in the IFR.

Management Measures

Area 2 and 3 Measures

The IFR implemented ownership caps in Areas 2 and 3 and maximum trap cap reductions in Area 3, effective May 1, 2025. These measures complemented the Commission's Addenda XXI and XXII to Amendment 3 to the Lobster Plan, both of which were approved by the Commission in 2013. The objective of these addenda was to scale the southern New England lobster fishery to the diminished size of the resource by addressing latent effort in the fishery and reducing trap limits in an attempt to control harvest to allow for potential stock rebuilding. A full description of those measures is included in the IFR and not repeated here.

During the proposed rule (87 FR 41084, July 11, 2022) comment period, we received several comments stating that our management partners and industry needed additional time to understand these measures, consider them in the current context of the fishery, and provide adequate comment. We delayed implementation of the measures until May 1, 2025, while we accepted additional public comments on these measures as provided in the IFR, which indicated that we would consider any additional comments received and would, if necessary and appropriate, publish a subsequent rule to address any changes. See 88 FR at 67669.

On January 23, 2024, the Commission's Lobster Board withdrew its prior recommendation for implementation of Area 2 and 3 ownership caps and Area 3 maximum trap cap reductions, determining that these measures are no longer relevant in the current context of the fishery. On February 12, 2024, the Commission confirmed the decision of the Lobster Board in a letter to NMFS, citing numerous ways in which the fishery in these Areas has changed. The Commission noted that while the Addenda that originally called for the Area 2 and 3 measures attempted to prevent consolidation, the lag time between Commission approval and NMFS implementation has allowed for consolidation to occur, removing the need for these specific measures. In addition, the Commission expressed concern that the implementation of these measures would change how permits and traps will be bought and sold. The Commission also explained the economics of the fishery in these areas and changing operational needs of harvesters to maintain their businesses, citing increased costs, loss of fishing grounds due to other ocean uses, additional management measures on the American lobster fishery to reduce the risk to North Atlantic right whales posed by the fishery, and the evolution of the fishery in these areas from a lobster fishery to a mixed-crustacean fishery targeting both lobsters and Jonah crabs.

The Atlantic Coastal Act provides that the Secretary ''may implement regulations'' affecting fisheries also regulated by the Commission if no fishery management plan exists pursuant to the Magnuson-Stevens Act and the regulations are ''compatible with the effective implementation of a coastal fishery management plan.'' 16 U.S.C. 5103(b)(1)(A). Removing the Area 2 and 3 measures ensures that Federal regulations continue to complement the Commission's Lobster Plan. Further, this action will minimize confusion between State and Federal requirements. If we do not remove these Area 2 and 3 measures, there would be inconsistent State and Federal lobster regulations, potentially undermining management of the fishery.

Other Management Measures

The IFR also implemented mandatory electronic harvester reporting requirements and corrections. This final

rule makes no changes to those measures, which have already become effective.

Comments and Responses

As noted above, the IFR delayed implementation of certain measures and solicited public comment on them. The comment period ended on December 1, 2023. We received comments from 10 groups: The Atlantic Offshore Lobstermen's Association (AOLA), the Animal Welfare Institute, a group of environmental organizations, 6 members of the fishing industry, and 1 member of the public. Only comments that were applicable to the proposed measures are addressed below.

Comment 1: AOLA stated that the Area 3 maximum trap reductions are inconsistent with the National Standards and are purely an economic reallocation, which is specifically prohibited; that the analysis in the environmental assessment did not rely on the best available science; and that the economic analysis was insufficient because it did not discuss impacts to crew, communities, shoreside employees, and owners.

Response: The commenter's assertions are the same arguments made in *AOLA* v. *Raimondo,* an active lawsuit in the Federal Court for the District of New Hampshire. When developed, the IFR measures reflected the best scientific information available and appropriate consideration of economic and social impacts and was supported by the regulated community, including AOLA. However, NOAA is withdrawing the relevant measures because of changed circumstances in the fishery as articulated by the public and the Commission and because the maintaining the measures would create incompatibility between state and Federal management of the fishery.

Comment 2: AOLA commented against the ownership caps and maximum trap cap reductions, stating that it is unlikely that the level of fishing necessary to harvest optimum yield could be maintained, as these measures seem to encourage the downsizing of offshore vessels.

Response: The 2022 environmental assessment accompanying the IFR noted that it was difficult to predict industry response to these measures, specifically whether traps would be reduced or whether owners would attempt to transfer traps in an attempt to recoup costs. Likewise, it was difficult to assess how fishing practices would have changed. NOAA is withdrawing the Area 2 and 3 IFR measures because of changed circumstances in the fishery and the need for Federal regulations to be compatible with the Commission's Lobster Plan as discussed in the response to comment 1.

Comment 3: AOLA stated that there is no justification for the Area 3 measures, citing multiple reasons. First, the commenter asserted that the majority of fishing effort in Area 3 is on the Gulf of Maine/Georges Bank stock, not the southern New England stock that these measures were intended to conserve. Second, the commenter cited economic impacts, predicting loss in profits and the potential for effort shifts. Third, the commenter discussed how Area 3 permit holders have appropriately scaled their businesses for their trap allocations and lack the ability to consolidate effort. Finally, the commenter stated that they are not aware of any concerns from the fishing industry about the existing level of consolidation in the fishery.

Response: As discussed above, NOAA is withdrawing the Area 3 measures because of changed circumstances in the fishery and the need for Federal regulations to be compatible with the Commission's Lobster Plan. On February 12, 2024, the Commission notified NOAA that the lobster fishery's circumstances had changed and that it no longer supported certain measures in the IFR. Accordingly, the purpose and need for the involved Federal measures no longer exists and NOAA is withdrawing those measures to avoid incompatibility with the Commission Lobster Plan. See 16 U.S.C. 5103(b)(1)(A).

Comment 4: Environmental organizations indicated general support for measures that reduce risk to protected species. These organizations urged us to implement all possible measures as soon as possible and to continue the development of on-demand (or ropeless) gear to minimize risk from persistent vertical buoy lines.

Response: NOAA takes its responsibilities to protect North Atlantic right whales seriously and has expended great effort and resources in doing so. Recent or ongoing efforts include: (1) continued trial and testing of on-demand gear, as facilitated by the approval of several exempted fishing permits and the Northeast Fisheries Science Center's on-demand gear library; (2) support of and participation on the New England Fishery Management Council's On-Demand Gear Conflict Working Group; (3) hosting various on-demand workshops in late 2023; and (4) the February 7, 2024, final rule (89 FR 8333) to close portions of Federal waters north of Cape Cod Bay to lobster fishing every year from February 1 through April 30 to protect right whales on their way to and from their feeding grounds in Cape Cod Bay. This February 7, 2024 final rule is currently in litigation. Our whale protection efforts are continuous and ongoing.

Comment 5: A group of environmental organizations indicated that the maximum trap cap reductions will reduce trap fishing effort thus benefiting both the lobster stock, by reducing the number of traps fished, and whales, by reducing the number of associated fishing lines in the water.

Response: The maximum trap cap reduction would have been unlikely to reduce the number of traps fished due to the Area 3 trap allocation and trap transfer program and the financial incentive for lobster businesses to maximize profits by transferring (selling) unused trap allocation. On March 27, 2003, we published a final rule (68 FR 14902) that established a program to set the total number of Area 3 traps per permit. On April 7, 2014, we published a final rule (79 FR 19015) that established a trap transfer program, allowing lobster businesses to transfer (sell) these allocated traps to other lobster businesses. These allocated traps remain an asset of the lobster permit regardless of the permit holder's ability to use any excess allocation created by the lowering of the Area 3 trap cap. In such a trap cap adjustment, there is economic incentive for a permit holder to transfer (sell) this now unusable excess allocation to a lobster business that can use it because their allocation is under the cap. Such a transfer would be subject to a 10-percent conservation tax, which somewhat decreases the overall Area 3 trap allocation with every transfer. Recent public commentary and debate at the Lobster Board, however, suggested that consolidation has already taken place in response to other management measures. Consequently, the actual result of the maximum trap cap reduction would be more of a redistribution than a reduction of trap allocation and, as such, the reduction in traps being fished, and the reduction of lines in the water, would have been expected to be minimal. For more detail on this issue, please see NOAA's Environmental Assessment, section 7.2.2, December 2022, as well as the Supplemental Information Report, section 6.

Comment 6: A group of environmental organizations expressed surprise that comments submitted at the proposed rule stage of this rulemaking that referenced measures to reduce risk to North Atlantic right whales implemented by a September 17, 2021,

final rule (86 FR 51970) were described as not relevant to the action.

Response: The purpose and need of the IFR was not to implement whale protection measures but rather to complement lobster management measures outlined in Addenda XXI, XXII, and XXVI to Amendment 3 to the Lobster Plan (see Lobster EA, section 1.0 Executive Summary—Purpose and Need (August 2022)). All of those Addenda pre-date the September 17, 2021, final rule (86 FR 51970), some by as much as eight years. As such, the IFR did not implement protections for the North Atlantic right whale pursuant to the Marine Mammal Protection Act. Instead, the IFR was promulgated under the Atlantic Coastal Act, which mandates that Federal lobster regulations be compatible with the Commission's Lobster Plan and requires the withdrawal of the IFR that we are announcing today.

Comment 7: Two environmental organizations supported the IFR, requesting whale protection measures to be put into place as soon as possible. One of the organizations indicated that industry has had ample time to understand and come into compliance with these requirements.

Response: Similar to comment 6, this comment conflates NOAA's whale protection efforts and rulemakings with this rulemaking, which implements the agency's responsibilities pursuant to the Atlantic Coastal Act. The purpose of the IFR was to implement lobster management measures outlined in Addenda XXI, XXII and XXVI. The Commission, however, rescinded their request for us to implement these measures by vote on January 23, 2024, and by letter to NOAA on February 12, 2024. We are likewise rescinding the Federal regulations to ensure compatibility with the Commission's Lobster Plan as required by the Atlantic Coastal Act. Management measures for the purposes of reducing the risk from lobster fishing on protected species are implemented through other processes, as described in the response to comment 4. Whether the affected industry had sufficient time to comply with this action is moot, given that, for the reasons stated above, we are removing these requirements.

Comment 8: One member of the fishing industry stated that the Gulf of Maine/Georges Bank stock remains at high levels of abundance and not in need of trap reductions. That industry member also stated that there is no evidence that reducing fishing effort of the Gulf of Maine/Georges Bank lobster stock will address the deterioration of the southern New England lobster stock. Another member of the industry stated that these measures are unnecessary, as juvenile and egg-bearing female lobster are abundant on Georges Bank.

Response: The best available science from the 2020 benchmark stock assessment indicates that the Gulf of Maine/Georges Bank stock remains in favorable condition based on the reference points. The 2020 assessment concluded that the stock is not depleted and overfishing is not occurring, though more recent information made available since both the assessment and the publication of the interim final rule indicates a decline in recruit abundance, triggering other management actions for those fishing on the Gulf of Maine/Georges Bank stock. The decision whether to apply Area 3 measures to all of Area 3 (*i.e.,* harvesters fishing on both the Gulf of Maine/Georges Bank and southern New England lobster stocks), was debated and decided upon by the Lobster Board. Draft Addendum XXI, released for public comment in May 2013, included options for a southern New England permit designation, which would have allowed for the trap reductions to only apply to harvesters fishing on the southern New England stock. The Lobster Board did not select permit designations as a final management measure, thus applying management measures to the entirety of Area 3, including the portion of Area 3 that fishes on the Gulf of Maine/Georges Bank lobster stock. We proposed and implemented these measures based on the Commission's original request for complementary measures in Federal waters. Given their more recent request to withdraw the measures, we are now acting accordingly.

Comment 9: One member of the fishing industry contends that the declines of the southern New England stock are being driven by climate change, not overfishing or excessive fishing pressure, as supported by the action's environmental assessment. Further, the member of the fishing industry stated that we did not establish an adequate link between fishing effort and stock depletion.

Response: The best available science suggests that environmental factors are a significant factor in the decline of the southern New England stock. The 2020 American Lobster Benchmark Stock Assessment made major advances in considering the impact of changing environmental conditions on lobster population dynamics. Environmental factors contributed to the assessment's analysis of regime shifts and associated thresholds by which stock health is now measured. While this information was not directly discussed in the environmental assessment, it was the foundation for stock status discussed in section 6.2.3 of the environmental assessment. While not available to the Commission during the development of Addenda XXI and XXII, a 2016 American Lobster Technical Committee analysis suggests that, despite overfishing not occurring, stabilization of the southern New England lobster stock was only possible with a reduction in exploitation. This analysis thus links fishing effort and recovery of the southern New England lobster stock.

Comment 10: One member of the fishing industry stated that the analysis included in the environmental assessment was out of date, as it relied on the Atlantic States Marine Fisheries commission's 2009 and 2015 benchmark American lobster stock assessments.

Response: The environmental assessment accompanying the IFR made reference to several recent benchmark American lobster stock assessments. At the time the Commission considered and approved Addenda XXI and XXII, the 2009 stock assessment was considered the best available science. Since that time, the 2015 and 2020 assessments have confirmed the continued downward trend in the southern New England lobster stock. Section 6.2.3 of the environmental assessment accompanying the IFR which discusses stock status, uses the best available scientific information from the 2020 benchmark stock assessment.

Comment 11: Five members of the fishing industry commented in opposition to the Area 3 measures, citing changes to the fishery over the last 10 years and financial issues. Two industry members stated that these regulations will create inefficiencies for current fishery participants, with one arguing that these measures would be detrimental to owners with multiple vessels. A third industry member suggested freezing the number of traps at current levels. Other commenters cited the increased cost of fuel and bait, previous investments made to maintain higher allocations following the 2016–2020 trap reductions, and the difficulty of paying and retaining crew members.

Response: We agree with the commenters that imposing the IFR measures could have had some negative impacts to Area 3 harvesters, although we assessed them as slight in the short term when the IFR was released. See 88 FR at 67674–67675. We acknowledge that each business is different, thus impacts are not uniform, with some businesses potentially being more affected by the measures than others. As

discussed in the response to comment 5, the environmental assessment acknowledged that permit holders may respond to these measures differently, by either selling off or redistributing traps. Following requests during the proposed rule comment period, we provided additional time for management partners and industry to understand these measures, consider them in the current context of the fishery, and provide additional comment. Comments by these and other commenters and the recommendation from the Commission confirm that the fishery has changed, and these measures no longer make sense, resulting in the Commission's withdrawal of these measures. We are now withdrawing the Area 3 measures because of changed circumstances in the fishery and the need for Federal regulations to be compatible with the Commission's Lobster Plan. As part of its recommendation to withdraw these measures, the Commission stated that it also intends to evaluate potential replacement measures. We intend to support the Commission during that process.

Comment 12: One industry member and one fishery organization stated that the economic impacts in the environmental assessment were underestimated. In particular, the fishery organization questioned our assumption of a 5-percent profit loss when the Area 3 maximum trap cap reduction may affect up to 18 percent of Area 3 traps.

Response: Based on the input received from comments and the Lobster Board and discussed in greater detail in response to comment 5, consolidation at some level had already taken place. Additional input received indicated that permit holders would be likely to sell traps through the trap transfer program to recoup individual losses. At the fishery level, nearly the same number of traps could be expected to be fished, resulting in similar landings and, therefore, revenue for the fishery overall. That said, as discussed in response to other comments above, given the Commission's more recent request to withdraw the measures, we are now rescinding the Federal regulations to ensure compatibility with the Commission's Plan.

Classification

The NMFS Assistant Administrator has determined that this final rule is consistent with the Atlantic Coastal Fisheries Cooperative Management Act, applicable provisions of the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable law. The agency finds public comment is unnecessary under the Administrative Procedure Act. See 5 U.S.C. 553(b)(B). The Atlantic Coastal Act requires Federal regulations to be ''compatible with the effective implementation of a coastal fishery management plan,'' 16 U.S.C. 5103(b)(1)(A), and following the Commission's modification of the Lobster Plan, the only regulatory option to ensure the regulations are compatible with the revised plan is to maintain the status quo, *i.e.,* to withdraw the relevant provisions of the IFR. If those provisions were to go into effect, the result would be inconsistent management of State and Federal waters, creating confusion for the regulated industry and potential harm to the resource. Moreover, the public has had multiple opportunities to comment on the relevant measures, see 88 FR at 67669 (IFR), 87 FR 41084 (proposed rule), 82 FR 52871 (ANPR), 79 FR 4319 (ANPR), and has done so.

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

A final regulatory flexibility analysis (FRFA) was prepared for this action and described in the IFR. The FRFA incorporated the initial regulatory flexibility analysis (IRFA), a summary of the significant issues raised by the public comments in response to the IRFA and NMFS responses to those comments, and a summary of the analyses completed to support the action. The IRFA and FRFA analyzed the suite of measures considered during this rulemaking, including actions that minimize impacts to small entities. Therefore, the analysis included in the FRFA remains valid. This final rule would remove some of the measures in the IFR, and will, therefore, reduce the overall costs of this action.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, letters to permit holders that also serves as this small entity compliance guide were prepared at both the interim final rule and this final rule stage. Copies of these guide and this rule are available upon request from the Greater Atlantic Regional Office (see **ADDRESSES**), and the guide/permit holder bulletin will be sent to all holders of lobster permits.

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

List of Subjects in 50 CFR Part 697

Fisheries, Fishing.

Dated: May 20, 2024.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, 50 CFR part 697 is amended as follows:

PART 697—ATLANTIC COASTAL FISHERIES COOPERATIVE MANAGEMENT

■ 1. The authority citation for part 697 continues to read as follows:

Authority: 16 U.S.C. 1501 *et seq.*

■ 2. Effective July 1, 2024, NMFS withdraws amendatory instruction 6 of the interim final rule published at 88 FR 67667, on October 2, 2023.

[FR Doc. 2024–11453 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 89, No. 105
Thursday, May 30, 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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

[Docket ID: OPM–2024–0012]

RIN 3206–AO70

Prevailing Rate Systems; Abolishment of Calhoun, Alabama, as a Nonappropriated Fund Federal Wage System Wage Area

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management (OPM) is proposing a rule to abolish the Calhoun, Alabama (AL), nonappropriated fund (NAF) Federal Wage System (FWS) wage area and define Calhoun County, AL, to the Cobb, Georgia, NAF FWS wage area, and Jefferson County, AL, to the Madison, AL, NAF FWS wage area. These changes are necessary because NAF FWS employment in the survey area is now below the minimum criterion of 26 wage employees to maintain a wage area, and the local activities no longer have the capability to conduct local wage surveys.

DATES: Send comments on or before July 1, 2024.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) and title, by the following method:

- *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

All comments received must include the agency name and docket number or RIN for this document. The general policy for comments from members of the public is to make them available for public viewing at *https://www.regulations.gov* without change, including any personal identifiers or contact information. However, OPM retains discretion to redact personal or sensitive information from comments before they are posted.

FOR FURTHER INFORMATION CONTACT: Ana Paunoiu, by telephone at (202) 606–2858 or by email at *paypolicy@opm.gov.*

SUPPLEMENTARY INFORMATION: Under 5 CFR 532.219, OPM may establish a NAF wage area when there are a minimum of 26 NAF wage employees in the survey area, a local activity has the capability to host annual local wage surveys, and the survey area has at least 1,800 private enterprise employees in establishments within survey specifications. The Calhoun, AL, NAF FWS wage area is presently composed of one survey county, Calhoun County, AL, and one area of application county: Jefferson County, AL. The Department of Defense (DOD) notified OPM that there has been a continuing decline of NAF FWS employment in the survey area and the local activities no longer have the capability to conduct local wage surveys. Currently, 15 DOD NAF FWS employees work in Calhoun County.

Since Jefferson County, AL, will have continuing NAF employment and does not meet the regulatory criteria under 5 CFR 532.219 to be a separate survey area, it must be defined as an area of application to another wage area. Section 532.219 lists the regulatory criteria OPM considers when defining FWS wage area boundaries. This rulemaking allows consideration of the following criteria: proximity of largest activity in each county, transportation facilities and commuting patterns, and similarities of the counties in overall population, private employment in major industry categories, and kinds and sizes of private industrial establishments.

In selecting a wage area to which Calhoun County, AL, should be redefined, proximity favors the Cobb, GA, NAF wage area. All other criteria are indeterminate. Based on these findings, OPM is defining Calhoun County as an area of application to the Cobb NAF wage area.

In selecting a wage area to which Jefferson County, AL, should be redefined, proximity favors the Madison, AL, NAF wage area. All other criteria are indeterminate. Based on these findings, OPM is defining Jefferson County as an area of application to the Madison NAF wage area.

The Cobb, GA, wage area would consist of one survey county (Cobb County, GA), and 4 area of application counties (Calhoun County, AL; and Bartow, De Kalb, and Fulton Counties, GA).

The Madison, AL, wage area would consist of one survey county (Madison, AL) and 5 area of application counties (Coffee, Davidson, Hamilton, Jefferson, and Rutherford Counties, AL).

The Federal Prevailing Rate Advisory Committee, the national labor-management committee responsible for advising OPM on matters concerning the pay of FWS employees, recommended these changes by consensus. These changes would be effective on the first day of the first applicable pay period beginning on or after 30 days following publication of the final regulations.

Expected Impact of This Rule

Section 5343 of title 5, U.S. Code, provides OPM with the authority and responsibility to define the boundaries of NAF FWS wage areas. Any changes in wage area definitions can have the long-term effect of increasing pay for Federal employees in affected locations. OPM expects this rulemaking to impact approximately 21 NAF FWS employees. Considering the small number of employees affected, OPM does not anticipate that this proposed rule will substantially impact local economies or have a large impact in local labor markets. However, OPM is requesting comment in this rulemaking regarding the impact. As this and future wage area changes may impact higher volumes of employees in geographical areas and could rise to the level of impacting local labor markets, OPM will continue to study the implications of such impacts in this or future rules as needed.

Regulatory Review

OPM has examined the impact of this rulemaking as required by Executive Orders 12866, 13563, and 14094, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). OMB has determined that this rulemaking is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094.

Regulatory Flexibility Act

The Director of OPM certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities.

Federalism

OPM has examined this rulemaking in accordance with Executive Order 13132, Federalism, and has determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

Civil Justice Reform

This rulemaking meets the applicable standard set forth in Executive Order 12988.

Unfunded Mandates Act of 1995

This rulemaking will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act

This rulemaking does not impose any reporting or record-keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

Office Of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

Accordingly, OPM is proposing to amend 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

■ 1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

■ 2. In Appendix D to subpart B, amend the table by revising the wage area listing for the States of Alabama and Georgia to read as follows:

Appendix D to Subpart B of Part 532—Nonappropriated Fund Wage and Survey Areas

DEFINITIONS OF WAGE AREAS AND WAGE AREA SURVEY AREAS

* * * * *

ALABAMA

MADISON

Survey Area

Alabama:
Madison
Area of Application. Survey area plus:
Alabama:
Jefferson
Tennessee:
Coffee
Davidson
Hamilton
Rutherford

MONTGOMERY

Survey Area

Alabama:
Montgomery
Area of Application. Survey area plus:
Alabama:
Dale
Dallas
Macon

* * * * *

GEORGIA

CHATHAM

Survey Area

Georgia:
Chatham
Area of Application. Survey area plus:
Georgia:
Glynn
Liberty
South Carolina:
Beaufort

COBB

Survey Area

Georgia:
Cobb
Area of Application. Survey area plus:
Alabama:
Calhoun
Georgia:
Bartow
De Kalb
Fulton

COLUMBUS

Survey Area

Georgia:
Columbus
Area of Application. Survey area plus:
Georgia:
Chattahoochee

DOUGHERTY

Survey Area

Georgia:
Dougherty
Area of Application. Survey area.

HOUSTON

Survey Area

Georgia:
Houston
Area of Application. Survey area plus:
Georgia:
Laurens

DEFINITIONS OF WAGE AREAS AND WAGE AREA SURVEY AREAS—Continued

LOWNDES

Survey Area

Georgia:
Lowndes
Area of Application. Survey area plus:
Florida:
Leon

RICHMOND

Survey Area

Georgia:
Richmond
Area of Application. Survey area plus:
South Carolina:
Aiken

* * * * *

[FR Doc. 2024–11826 Filed 5–29–24; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 206, 212, 252, and 270

[Docket DARS–2024–0017]

RIN 0750–AM01

Defense Federal Acquisition Regulation Supplement: Pilot Program To Incentivize Contracting With Employee-Owned Businesses (DFARS Case 2024–D004)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement sections of the National Defense Authorization Acts for Fiscal Year 2022 and Fiscal Year 2024 that authorize DoD to establish a pilot program that allows for the noncompetitive award of certain follow-on contracts to certain employee-owned businesses.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before July 29, 2024, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2024–D004, using either of the following methods:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Search for DFARS Case 2024–D004. Select ''Comment'' and follow the instructions to submit a comment. Please include ''DFARS Case

2024–D004'' on any attached documents.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2024–D004 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Jeanette Snyder, telephone 703–508–7524.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement section 874 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) as amended by section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note). Sections 874 and 872 authorize DoD to establish a pilot program that allows for the noncompetitive award of certain follow-on contracts to employee-owned businesses that meet the definition of a qualified business. The Office of the Under Secretary of Defense (Acquisition and Sustainment), Defense Pricing and Contracting implemented section 874 via a contract policy memorandum dated November 8, 2022.

II. Discussion and Analysis

This rule proposes to add new DFARS part 270, Defense Contracting Programs, to include new subpart 270.X, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, to implement section 874 of the NDAA for FY 2022 and section 872 of the NDAA for FY 2024. This proposed new part 270 will contain contracting programs that are unique to DoD but are not socioeconomic programs such as those located in DFARS part 226, Other Socioeconomic Programs. The proposed subpart 270.X provides the scope, definition, policy, limitations, procedures, solicitation provisions, and contract clause associated with the pilot program. This proposed rule, at DFARS 270.X02, Policy, authorizes contracting officers to award one sole-source, follow-on contract for the continued development, production, or provision of products or services that are the same or substantially similar to those procured under previous contracts awarded by or for DoD to contractors that meet the definition of a qualified business. Although section 874 allows for noncompetitive awards, the proposed rule requires such awards to be supported by written justifications and approvals as required at Federal Acquisition Regulation (FAR) 6.303 and FAR 6.304.

Under the pilot program, contracts are awarded to qualified businesses. Therefore, a definition of ''qualified business'' is added to DFARS 270.X01, Definition, as follows: An S corporation as defined in 26 U.S.C. 1361(a)(1) for which 100 percent of the outstanding stock is held through an employee stock ownership plan as defined in 26 U.S.C. 4975(e)(7).

The proposed rule, at 270.X03, Limitations, specifies that—

- Only a contracting officer may submit an application to participate in the pilot program;
- Contracting officers may only award contracts to contractors that meet the definition of a qualified business;
- Contracting officers may only award one sole-source, follow-on contract to a qualified business for each predecessor contract, unless a waiver is obtained; and
- Unless waived, a qualified business shall not pay more than 50 percent of the amount paid by the Government for contract performance to subcontractors that are not qualified businesses, except when the contract is for a product and subcontracts for materials are not available from another qualified business.

Proposed section 270.X00, Scope of subpart, provides references to the NDAA sections implemented by the subpart. In addition, this section also advises contracting officers the authority to award contracts under the pilot program expires on December 27, 2029.

The proposed solicitation provision, 252.270–70WW, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation, requires offerors to represent that they are a qualified business. The proposed solicitation provision, 252.270–70XX, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Subcontracting Certification, requires offerors to certify that they will comply with the limitations on subcontracting.

The proposed contract clause, 252.270–70YY, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, requires contractors to comply with the limitations on subcontracting. In addition, the clause specifies the information contractors are required to report to contracting officers not later than 30 days after the end of the period of performance of the contract.

Changes are proposed at DFARS 206.302–5 to add the pilot program to the list of authorities agencies may utilize to justify the use of other than full and open competitive procedures. Changes are also proposed at DFARS 212.301 to add the proposed solicitation provisions and contract clause to the list of provisions and clauses that apply to DoD solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This proposed rule proposes two new provisions and a new clause to implement the requirements of section 874 of the NDAA for FY 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) as amended by section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note): (1) DFARS clause 252.270–70WW, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation; (2) DFARS 252.270–70XX, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Certification; and (3) DFARS 252.270–70YY, Pilot Program to Incentivize Contracting with Employee-Owned Businesses. The provisions and clause at DFARS 252.270–70WW, 252.270–70XX and 252.270–70YY are prescribed at DFARS 270.X05 for use in solicitations and contracts for approved acquisitions under the Pilot Program to Incentivize Contracting with Employee-Owned Businesses. DoD does not intend to apply the proposed rule to contracts at or below the SAT. DoD does intend to apply the proposed rule to contracts for the acquisition of commercial products, excluding COTS items, and commercial services.

A. Applicability to Contracts at or Below the Simplified Acquisition Threshold

41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the simplified acquisition threshold. It is intended to limit the applicability of laws to such contracts or subcontracts. 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the Federal Acquisition Regulatory Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or

subcontracts at or below the SAT, the law will apply to them. The Principal Director, Defense Pricing and Contracting (DPC), is the appropriate authority to make comparable determinations for regulations to be published in the DFARS, which is part of the Federal Acquisition Regulation system of regulations. DoD does not intend to make that determination. Therefore, this proposed rule will not apply at or below the simplified acquisition threshold.

B. Applicability to Contracts for the Acquisition of Commercial Products Including COTS Items and for the Acquisition of Commercial Services

10 U.S.C. 3452 exempts contracts and subcontracts for the acquisition of commercial products, including COTS items, and commercial services from provisions of law enacted after October 13, 1994, unless the Under Secretary of Defense (Acquisition and Sustainment) (USD(A&S)) makes a written determination that it would not be in the best interest of DoD to exempt contracts for the procurement of commercial products and commercial services from the applicability of the provision or contract requirement, except for a provision of law that—

- Provides for criminal or civil penalties;
- Requires that certain articles be bought from American sources pursuant to 10 U.S.C. 4862, or that strategic materials critical to national security be bought from American sources pursuant to 10 U.S.C. 4863; or
- Specifically refers to 10 U.S.C. 3452 and states that it shall apply to contracts and subcontracts for the acquisition of commercial products (including COTS items) and commercial services.

The statutes implemented in this proposed rule do not impose criminal or civil penalties, do not require purchase pursuant to 10 U.S.C. 4862 or 4863, and do not refer to 10 U.S.C. 3452. Therefore, section 874 of the NDAA for FY 2022, as amended by section 872 of the NDAA for FY 2024, will not apply to the acquisition of commercial products, including COTS items, or commercial services unless a written determination is made. Due to delegations of authority, the Principal Director, DPC is the appropriate authority to make this determination. DoD intends to make that determination to apply the statutes to the acquisition of commercial products, excluding COTS items, and to the acquisition of commercial services. Therefore, this proposed rule will apply to the acquisition of commercial products, excluding COTS items, and to the acquisition of commercial services.

C. Determination

Given that the requirements of section 874 of the NDAA for FY 2022 and section 872 of the NDAA for FY 2024 were enacted to authorize DoD to establish a pilot program to incentivize contracting with employee-owned businesses for the continued development, production, or provision of products or services, and since the pilot program, thus far, has been utilized for commercial products and commercial services, it is in the best interest of the Government to apply the statutes to contracts for the acquisition of commercial products, excluding COTS items, and commercial services, as defined at Federal Acquisition Regulation 2.101. An exception for contracts for the acquisition of commercial products, excluding COTS items, and commercial services would exclude the contracts intended to be covered by the law, thereby undermining the overarching public policy purpose of the law.

IV. Expected Impact of the Rule

This proposed rule implements section 874 of the NDAA for FY 2022, as amended by section 872 of the NDAA for FY 2024, which authorizes DoD to establish a pilot program to incentivize contracting with employee-owned businesses that meet the proposed definition of ''qualified business.'' This proposed rule, when finalized, is expected to impact the Government and contractors that participate in the pilot program. This proposed rule is expected to incentivize and expedite the award of follow-on contracts to qualified businesses for the continued development, production, or provision of products or services previously procured by or for DoD. As a result, employee-owned businesses may benefit from more opportunities to contract with DoD, which may benefit DoD by expanding the defense industrial base.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Regulatory Flexibility Act

DoD does not expect this proposed rule, when finalized, to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because it only allows for the award of sole-source, follow-on contracts to qualified businesses under certain circumstances. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This proposed rule is necessary to implement section 874 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note). Sections 874 and 872 authorize DoD to establish a pilot program to incentivize contracting with employee-owned businesses. The pilot program provides for the use of noncompetitive procedures for certain follow-on contracts to qualified businesses wholly-owned through an employee stock ownership plan. A ''qualified business'' is defined as an S corporation (as defined in 26 U.S.C. 1361(a)(1)) for which 100 percent of the outstanding stock is held through an employee stock ownership plan as defined in 26 U.S.C. 4975(e)(7).

The objective of this proposed rule is to implement section 874 of the NDAA for FY 2022 and section 872 of the NDAA for FY 2024 to establish a pilot program to incentivize contracting with employee-owned businesses. The legal basis for the rule is section 874 of the NDAA for FY 2022 and section 872 of the NDAA for FY 2024.

Data from the System for Award Management (SAM) revealed there were 330,704 small entities registered in SAM as of June 2023. Data on the number of small entities that are a qualified business, as defined in the proposed rule, is not available.

The pilot program was implemented on November 8, 2022. To date, eight businesses are participating in the pilot, six of which are small entities. DoD cannot estimate the number of contracting officers who will submit applications for participation in the pilot program, how many applications will be approved for participation, or how many of the subsequent awards will be made to small entities. However, based on current participation, DoD

expects that the pilot program will grow to approximately 16 contractors per year, of which approximately 12 may be small entities.

This proposed rule imposes a new reporting requirement. Not later than 30 days after the end of the period of performance of the contract, contractors participating in the pilot program will be required to submit to the contracting officer the following information: (1) the number of years the contractor has been wholly-owned by its employee stock ownership plan; (2) the contractor's challenges in attracting and retaining a talented workforce; (3) challenges the contractor experienced due to its corporate ownership structure that hinder its ability to contract with DoD in order to scale its technologies and capabilities due to its corporate ownership structure; and (4) challenges the contractor experienced due to its corporate ownership structure in obtaining capital necessary to bridge funding gaps, for example, between prototype demonstration and full-scale development. The annual reporting burden is estimated as follows: 16 respondents, with 16 total annual responses (1 response per respondent), and a total annual burden of 16 hours.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known alternatives that would accomplish the stated objectives of the applicable statutes.

DoD invites comments from small business concerns and other interested parties on the expected impact of this proposed rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this proposed rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2024–D004), in correspondence.

VII. Paperwork Reduction Act

This proposed rule contains information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35). Accordingly, DoD has submitted a request for approval of a new information collection requirement concerning DFARS case 2024–D004, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, to the Office of Management and Budget.

A. Estimate of Public Burden

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The annual reporting burden is estimated as follows:

Respondents: 16.

Total annual responses: 16.

Total annual burden hours: 16.

B. Request for Comments Regarding Paperwork Burden

Written comments and recommendations on the proposed information collection, including suggestions for reducing this burden, should be submitted using the Federal eRulemaking Portal at *https://www.regulations.gov* or by email to *osd.dfars@mail.mil.* Comments can be received up to 60 days after the date of this notice.

Public comments are particularly invited on: whether this collection of information is necessary for the proper performance of the functions of DoD, including whether the information will have practical utility; the accuracy of DoD's estimate of the burden of this information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

To obtain a copy of the supporting statement and associated collection instruments, please email *osd.dfars@mail.mil.* Include DFARS Case 2024–D004 in the subject line of the message.

List of Subjects in 48 CFR Parts 206, 212, 252, and 270

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore, Defense Acquisition Regulations System proposes to amend 48 CFR parts 206, 212, and 252, and add 270 as follows:

PART 206—COMPETITION REQUIREMENTS

■ 1. The authority citation for part 206 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise and republish section 206.302–5 to read as follows:

206.302–5 Authorized or required by statute.

(b) *Application.* Agencies may use this authority to—

(i) Acquire supplies and services from military exchange stores outside the United States for use by the armed forces outside the United States in accordance with 10 U.S.C. 2424(a) and subject to the limitations of 10 U.S.C. 2424(b). The limitations of 10 U.S.C. 2424(b)(1) and (2) do not apply to the purchase of soft drinks that are manufactured in the United States. For the purposes of 10 U.S.C. 2424, soft drinks manufactured in the United States are brand name carbonated sodas, manufactured in the United States, as evidenced by product markings.

(ii) Acquire police, fire protection, airfield operation, or other community services from local governments at military installations to be closed under the circumstances in 237.7401 (section 2907 of Fiscal Year 1994 Defense Authorization Act (Pub. L. 103–160)).

(iii) Acquire products and services under the Pilot Program to Incentivize Contracting with Employee-Owned Businesses (see subpart 270.X).

(c) *Limitations.*

(i) 10 U.S.C. 4141 precludes use of this exception for awards to colleges or universities for the performance of research and development, or for the construction of any research or other facility, unless—

(A) The statute authorizing or requiring award specifically—

(*1*) States that the statute modifies or supersedes the provisions of 10 U.S.C. 4141;

(*2*) Identifies the particular college or university involved; and

(*3*) States that award is being made in contravention of 10 U.S.C. 4141(a); and

(B) The Secretary of Defense provides Congress written notice of intent to award. The contract cannot be awarded until 180 days have elapsed since the date Congress received the notice of intent to award. Contracting activities must submit a draft notice of intent with supporting documentation through channels to the Principal Director, Defense Pricing and Contracting, Office of the Under Secretary of Defense (Acquisition and Sustainment).

(ii) The limitation in paragraph (c)(i) of this subsection applies only if the statute authorizing or requiring award was enacted after September 30, 1989.

(iii) Subsequent statutes may provide different or additional constraints on the award of contracts to specified colleges and universities. Contracting officers should consult legal counsel on a case-by-case basis.

■ Part 212—Acquisition of Commercial Products and Commercial Services

■ 3. The authority citation for part 212 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 4. Amend section 212.301 by adding paragraph (f)(xxii) to read as follows:

212.301 Solicitation provisions and contract clauses for the acquisition of commercial products and commercial services.

* * * * *

(f) * * *

(xxii) *Part 270—Defense Contracting Programs.*

(A) Use the provision at 252.270–70WW, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation, as prescribed at 270.X05(a) to comply with section 874 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note).

(B) Use the provision at 252.270–70XX, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Subcontracting Certification, as prescribed at 270.X05(b), to comply with section 874 of the NDAA for FY 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note).

(C) Use the clause at 252.270–70YY, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, as prescribed at 270.X05(c), to comply with section 874 of the NDAA for FY 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note).

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. The authority citation for part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 6. Add section 252.270–70WW to read as follows:

252.270–70WW Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation.

As prescribed in 270.X05(a), use the following provision:

Pilot Program To Incentivize Contracting With Employee-Owned Businesses—Representation (Date)

(a) *Definition.* As used in this provision, *qualified business* has the meaning given in the Defense Federal Acquisition Regulation Supplement 252.270–70YY, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, clause of this solicitation.

(b) *Representation.* The Offeror represents that it is a qualified business.

(End of provision)

■ 7. Add section 252.270–70XX to read as follows:

252.270–70XX Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Subcontracting Certification.

As prescribed in 270.X05(b), use the following provision:

Pilot Program To Incentivize Contracting With Employee-Owned Businesses—Subcontracting Certification (Date)

(a) *Definition.* As used in this provision, *qualified business* has the meaning given in the Defense Federal Acquisition Regulation Supplement 252.270–70YY, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, clause of this solicitation.

(b) *Limitations on subcontracting.* The Offeror certifies that in performance of the contract it will not expend more than 50 percent of the amount paid under the contract on subcontracts unless—

(1) The subcontract is awarded to a qualified business;

(2) The contract is for products and the subcontract is for materials not available from another qualified business; or

(3) A waiver is granted.

(End of provision)

■ 8. Add section 252.270–70YY to read as follows:

252.270–70YY Pilot Program to Incentivize Contracting with Employee-Owned Businesses.

As prescribed in 270.X05(b), use the following clause:

Pilot Program To Incentivize Contracting With Employee-Owned Businesses (Date)

(a) *Definition.* As used in this clause—

Qualified business means an S corporation as defined in 26 U.S.C. 1361(a)(1) for which 100 percent of the outstanding stock is held through an employee stock ownership plan as defined in 26 U.S.C. 4975(e)(7).

(b) *Limitations on subcontracting.* In performance of the contract, the Contractor shall not expend more than 50 percent of the amount paid under the contract on subcontracts, unless—

(1) The subcontract is awarded to a qualified business;

(2) The contract is for products and the subcontract is for materials not available from another qualified business; or

(3) A waiver is granted.

(c) *Reporting requirement.* Not later than 30 days after the end of the contract period of performance, the Contractor shall submit to the Contracting Officer the following information in writing:

(1) The number of years the Contractor has been wholly-owned by its employee stock ownership plan.

(2) Challenges the Contractor experienced in attracting and retaining a talented workforce in a competitive market.

(3) Challenges the Contractor experienced that hinder its ability to contract with DoD to scale its technologies and capabilities due to the Contractor's corporate ownership structure.

(4) Challenges the Contractor experienced due to its corporate ownership structure in obtaining capital necessary to bridge funding gaps, for example, between prototype demonstration and full-scale development.

(End of clause)

■ 9. Add part 270 to read as follows:

PART 270—DEFENSE CONTRACTING PROGRAMS

Sec.

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

270.000 Scope of part.

This part has been created to facilitate promulgation of additional DFARS coverage of defense-specific contracting programs that do not properly fall under DFARS subchapter D, Socioeconomic Programs, and neither implement nor supplement existing FAR part 19 or parts 22 through 25.

Subpart 270.X—Pilot Program To Incentivize Contracting With Employee-Owned Businesses

270.X00 Scope of subpart.

(a) This subpart implements section 874 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 (Pub. L. 117–81; 10 U.S.C. 3204 note) and section 872 of the NDAA for FY 2024 (Pub. L. 118–31; 10 U.S.C. 3204 note). Sections 874 and 872 authorize the establishment of a pilot program that allows for the noncompetitive award of certain follow-on contracts to contractors that meet the definition of a qualified business (see 270.X01).

(b) The authority to award contracts under this subpart expires on December 27, 2029.

270.X01 Definition.

As used in this subpart—

Qualified business means an S corporation as defined in 26 U.S.C. 1361(a)(1) for which 100 percent of the outstanding stock is held through an employee stock ownership plan as defined in 26 U.S.C. 4975(e)(7).

270.X02 Policy.

(a) The contracting officer may only award one sole-source, follow-on contract to the incumbent contractor if—

(1) The contractor has represented that it is a qualified business; and

(2) The contract is for the continued development, production, or provision of products or services that are the same or substantially similar to those procured under the prior contract awarded to the contractor by or for DoD.

(b) The contracting officer shall not begin negotiations for a sole-source, follow-on contract unless the contracting officer justifies the use of a sole-source contract in accordance with FAR 6.303 and 6.304, citing FAR 6.302–5, Authorized or required by statute, as the exception to full and open competition.

270.X03 Limitations.

(a) Participation in the pilot program is subject to approval by the Under Secretary of Defense (Acquisition and Sustainment), Office of the Principal Director, Defense Pricing and Contracting (Contract Policy). Only a contracting officer may submit an application to participate in the pilot program. See PGI 270.7X04(a).

(b) Contracting officers shall only award—

(1) One sole-source, follow-on contract per predecessor contract to the incumbent contractor unless waived by the head of the contracting activity, delegable to a level no lower than one level above the contracting officer;

(2) Contracts to qualified businesses that have a minimum performance rating of satisfactory for the predecessor contract in the Contractor Performance Assessment Reporting System (see FAR subpart 42.15); and

(3) Contracts to qualified businesses that have certified they will not pay more than 50 percent of the amount paid by the Government for contract performance to subcontractors that are not qualified businesses, except for subcontracts for materials not available from another qualified business when the contract is for products, unless waived by the head of the contracting activity, delegable to a level no lower than one level above the contracting officer.

270.X04 Procedures.

See PGI 270.X04 for procedures and information concerning the pilot program.

270.X05 Solicitation provision and contract clause.

(a) Use the provision at 252.270–70WW, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Representation, in solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial products and commercial services, that include the clause at 252.270–70YY, Pilot Program to Incentivize Contracting with Employee-Owned Businesses.

(b) Unless waived in accordance with 270.7X03(b)(3), use the provision at 252.270–70XX, Pilot Program to Incentivize Contracting with Employee-Owned Businesses—Subcontracting Certification, in solicitations, including solicitations using FAR part 12 procedures for the acquisition of commercial products and commercial services that include the clause at 252.270–70YY, Pilot Program to Incentivize Contracting with Employee-Owned Businesses.

(c) Use the clause at 252.270–70YY, Pilot Program to Incentivize Contracting with Employee-Owned Businesses, in solicitations and contracts, including solicitations and contracts using FAR part 12 procedures for the acquisition of commercial products and commercial services, for approved pilot program acquisitions.

[FR Doc. 2024–11517 Filed 5–29–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Part 252

[Docket DARS–2024–0018]

RIN 0750–AM03

Defense Federal Acquisition Regulation Supplement: Procurement Technical Assistance Program (DFARS Case 2024–D006)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: DoD is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to implement a section of the National Defense Authorization Act for Fiscal Year 2024 that modifies certain definitions associated with the Procurement Technical Assistance Program.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before July 29, 2024, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by DFARS Case 2024–D006, using either of the following methods:

○ *Federal eRulemaking Portal: https://www.regulations.gov.* Search for DFARS Case 2024–D006. Select ''Comment'' and follow the instructions to submit a comment. Please include ''DFARS Case 2024–D006'' on any attached documents.

○ *Email: osd.dfars@mail.mil.* Include DFARS Case 2024–D006 in the subject line of the message.

Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Jeanette Snyder, telephone 703–508–7524.

SUPPLEMENTARY INFORMATION:

I. Background

DoD is proposing to revise the DFARS to implement section 853 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2024 (Pub. L. 118–31; 10 U.S.C. 4951). Section 853 amends the definitions of nonprofit organization and business entities at 10 U.S.C. 4951 for the Procurement Technical Assistance Program. DoD implements the requirements at 10 U.S.C. 4951 through its APEX Accelerators (formerly known as Procurement Technical Assistance Centers), which are managed by the DoD Office of Small Business Programs.

II. Discussion and Analysis

DoD is proposing to modify the contract clause at DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders, to implement section 853 of the NDAA for FY 2024. The clause requires contractors to provide cooperative agreement holders, upon request, with a list of the contractor's employees or offices responsible for entering into subcontracts under defense contracts. This proposed rule amends the definition of cooperative agreement holder in the clause by removing ''private'' from ''a private, nonprofit organization'' and adding a reference to 10 U.S.C. 4951 to update the definition of business entities. Minor edits are made to align the clause with DFARS drafting conventions.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT), for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), and for Commercial Services

This proposed rule amends the clause at DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders. However, this proposed rule does not impose any new requirements on contracts at or below the SAT, for commercial products including COTS items, or for commercial services. The clause will continue to not apply to acquisitions at or below the SAT, and will continue to apply to acquisitions of commercial products excluding COTS items, and to acquisitions of commercial services.

IV. Expected Impact of the Rule

This proposed rule, when finalized, is expected to impact DoD contractors whose contracts include the clause at DFARS 252.205–7000. The clause requires contractors to provide cooperative agreement holders under the Procurement Technical Assistance Program, upon request, with a list of the contractor's employees or offices responsible for entering into subcontracts under defense contracts. As a result of the proposed changes, these contractors may be required to provide the list to different entities that are cooperative agreement holders under the Procurement Technical Assistance Program.

The changes in section 853 allow any type of nonprofit organization to be a cooperative agreement holder under the Procurement Technical Assistance Program. In addition, business entities, including corporations, associations, partnerships, limited liability companies, limited liability partnerships, consortia, not-for-profit, or other legal entities will also be able to be a cooperative agreement holder. These changes are reflected in the proposed revisions to the clause at DFARS 252.205–7000. As a result of the section 853 changes to the Procurement Technical Assistance Program, there may be an increase in the number of entities able to become cooperative agreement holders under the Procurement Technical Assistance Program.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, as amended.

VI. Regulatory Flexibility Act

DoD does not expect this proposed rule, when finalized, to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because this rule merely updates definitions for the cooperative agreement holders under the Procurement Technical Assistance Program. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

This proposed rule is necessary to implement section 853 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2024 (Pub. L. 118–31; 10 U.S.C. 4951). Section 853 modifies the definitions of nonprofit organization and business entities at 10 U.S.C. 4951 for the Procurement Technical Assistance Program. This proposed rule implements the revised definitions in the contract clause at DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders. The clause requires contractors to provide cooperative agreement holders under the Procurement Technical Assistance Program, upon request, with a list of the contractor's employees or offices responsible for entering into subcontracts under defense contracts.

The objective of this proposed rule is to implement section 853 of the NDAA for FY 2024, which is the legal basis for the rule.

According to data from the Procurement Business Intelligence Service, in the last three fiscal years, DoD awarded contracts that included the clause at 252.205–7000 to unique small entities as follows: 5,652 in fiscal year 2021, 5,127 in fiscal year 2022, and 5,663 in fiscal year 2023. This averages out to approximately 5,480 per fiscal year. Therefore, DoD estimates that the number of small entities to which this rule will apply is approximately 5,480.

This proposed rule does not impose any new reporting, recordkeeping, or other compliance requirements for small entities.

This proposed rule does not duplicate, overlap, or conflict with any other Federal rules.

DoD did not identify any significant alternatives to the proposed rule that would accomplish the stated objectives of the statute. Any impact on small entities is expected to be beneficial.

DoD invites comments from small business concerns and other interested parties on the expected impact of this proposed rule on small entities.

DoD will also consider comments from small entities concerning the existing regulations in subparts affected by this proposed rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (DFARS Case 2024–D006), in correspondence.

VII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies to this proposed rule. However, these changes to the DFARS do not impose additional information collection requirements to the paperwork burden previously approved by the Office of Management and Budget (OMB) under OMB Control Number 0704–0286, entitled Defense FAR Supplement (DFARS) Part 205, Publicizing Contract Actions, and DFARS 252.205–7000, Provision of Information to Cooperative Agreement Holders.

List of Subjects in 48 CFR Part 252

Government procurement.

Jennifer D. Johnson,

Editor/Publisher, Defense Acquisition Regulations System.

Therefore 48 CFR 252 is proposed to be amended as follows:

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for 48 CFR part 252 continues to read as follows:

Authority: 41 U.S.C. 1303 and 48 CFR chapter 1.

■ 2. Revise and republish section 252.205–7000 to read as follows:

252.205–7000 Provision of Information to Cooperative Agreement Holders.

As prescribed in 205.470, use the following clause:

Provision of Information to Cooperative Agreement Holders (Date)

(a) *Definition.* As used in this clause—

Cooperative agreement holder means a State or local government; a nonprofit organization; a tribal organization (as defined in section 4(c) of the Indian Self-Determination and Education Assistance Act

(25 U.S.C. 5304(l))); or an economic enterprise (as defined in section 3(e) of the Indian Financing Act of 1974 (25 U.S.C. 1452(e))) whether such economic enterprise is organized for profit or nonprofit purposes; which has an agreement with the Under Secretary of Defense for Acquisition and Sustainment to furnish procurement technical assistance to business entities (as defined in 10 U.S.C. 4951).

(b) The Contractor shall provide cooperative agreement holders, upon their request, with a list of those appropriate employees or offices responsible for entering into subcontracts under defense contracts. The list shall include the business address, telephone number, and area of responsibility of each employee or office.

(c) The Contractor need not provide the listing to a particular cooperative agreement holder more frequently than once a year.

(End of clause)

[FR Doc. 2024–11518 Filed 5–29–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R8–ES–2023–0188; FXES1111090FEDR–245–FF09E21000]

RIN 1018–BH12

Endangered and Threatened Wildlife and Plants; Designation of Critical Habitat for the Dixie Valley Toad

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to designate critical habitat for the Dixie Valley toad (*Anaxyrus williamsi*) under the Endangered Species Act of 1973, as amended (Act). In total, approximately 930 acres (376 hectares) in Churchill County, Nevada, fall within the boundaries of the proposed critical habitat designation. If we finalize this rule as proposed, it would extend the Act's protections to this species' critical habitat. We also announce the availability of a draft economic analysis of the proposed designation of critical habitat for the Dixie Valley toad.

DATES: We will accept comments received or postmarked on or before July 29, 2024. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. eastern time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by July 15, 2024.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the Search box, enter FWS–R8–ES–2023–0188, which is the docket number for this rulemaking. Then, click on the Search button. On the resulting page, in the panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on ''Comment.''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R8–ES–2023–0188, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *https://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: Supporting materials, such as the species status assessment (SSA) report and draft economic analysis (DEA), are available at *https://www.regulations.gov* under Docket No. FWS–R8–ES–2023–0188. For the proposed critical habitat designation, the coordinates or plot points or both from which the map is generated are included in the decision file for this critical habitat designation and are available at *https://www.regulations.gov* under Docket No. FWS–R8–ES–2023–0188.

FOR FURTHER INFORMATION CONTACT: Jodie Mamuscia, Field Supervisor, U.S. Fish and Wildlife Service, Reno Fish and Wildlife Office, 1340 Financial Blvd., Suite 234, Reno, NV 89502; telephone 775–861–6300. 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. Please see Docket No. FWS–R8–ES–2023–0188 on *https://www.regulations.gov* for a document that summarizes this proposed rule.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act (16 U.S.C. 1531 *et seq.*), when we determine that any species warrants listing as an endangered or threatened species, we are required to designate critical habitat, to the maximum extent prudent and determinable. Designations of critical habitat can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 *et seq.*).

What this document does. We propose to designate critical habitat for the Dixie Valley toad, which is listed as an endangered species (see 87 FR 73971; December 2, 2022).

The basis for our action. Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary), to the maximum extent prudent and determinable, to designate critical habitat concurrent with listing. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific data available and be as accurate and as effective as possible. Therefore, we request comments or information from other governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule. We particularly seek comments concerning:

(1) Specific information on:

(a) The amount and distribution of Dixie Valley toad habitat;

(b) Any additional areas occurring within the range of the species (Churchill County, Nevada) that should be included in the designation because they (i) are occupied at the time of listing and contain the physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection, or (ii) are

unoccupied at the time of listing and are essential for the conservation of the species; and

(c) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including managing for the potential effects of climate change.

(2) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(3) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation, and the related benefits of including or excluding specific areas.

(4) Information on the extent to which the description of probable economic impacts in the draft economic analysis is a reasonable estimate of the likely economic impacts and any additional information regarding probable economic impacts that we should consider.

(5) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act. If you think we should exclude any additional areas, please provide information supporting a benefit of exclusion.

(6) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, do not provide substantial information necessary to support a determination. Section 4(b)(2) of the Act directs that the Secretary shall designate critical habitat on the basis of the best scientific data available.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via *https://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *https://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *https://www.regulations.gov.*

Our final determination may differ from this proposal because we will consider all comments we receive during the comment period as well as new information that may become available after this proposal. Based on the new information we receive (and, if relevant, any comments on that new information), our final designation may not include all areas proposed, may include some additional areas that meet the definition of critical habitat, may exclude some areas if we find the benefits of exclusion outweigh the benefits of inclusion and exclusion will not result in the extinction of the species, or may exempt areas owned or controlled by the Department of Defense if we find the Air Station's integrated natural resources management plan (INRMP) provides a conservation benefit to the species in accordance with 50 CFR 424.12(h). In our final rule, we will clearly explain our rationale and the basis for our final decision, including why we made changes, if any, that differ from this proposal.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. We may hold the public hearing in person or virtually via webinar. We will announce any public hearing on our website, in addition to the **Federal Register**. The use of virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On April 7, 2022, we published in the **Federal Register** a proposed rule (87 FR 20374) and emergency listing rule (87 FR 20336) to list the Dixie Valley toad as an endangered species. We determined that designation of critical habitat was prudent but not determinable because we lacked specific information on the impacts of our designation. On December 2, 2022, we published in the **Federal Register** (87 FR 73971) a final rule to list the Dixie Valley toad as an endangered species. In that rule, we stated that assessments of the economic impacts that may occur due to a critical habitat designation were not yet complete. See the April 7, 2022, emergency rule and December 2, 2022, final rule for more information on previous Federal actions concerning the Dixie Valley toad.

Peer Review

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we solicited independent scientific review of the information contained in the Dixie Valley toad SSA report (Service 2022, entire). We sent the SSA report to four independent peer reviewers and received three responses; we incorporated the results of these reviews, as appropriate, into the SSA report, which is the foundation for this proposed rule. Results of this structured peer review process can be found at *https://www.regulations.gov.* For a summary of peer reviewer comments, please refer to the December 2, 2022, final listing rule (87 FR 73971).

Background

It is our intent to discuss in this proposed rule only those topics directly relevant to the designation of critical habitat for the Dixie Valley toad. For more information on the taxonomy, life history, habitat, population descriptions, and factors affecting the species, please refer to the April 7, 2022, emergency listing rule (87 FR 20336) and proposed listing rule (87 FR 20374), as well as the December 2, 2022, final listing rule (87 FR 73971).

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that each Federal action agency ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of designated critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Rather, designation requires that, where a landowner requests Federal agency funding or authorization for an action that may affect an area designated as critical habitat, the Federal agency consult with the Service under section 7(a)(2) of the Act. If the action may affect the listed species itself (such as for occupied critical habitat), the Federal agency would have already been required to consult with the Service even absent the designation because of the requirement to ensure that the action is not likely to jeopardize the continued existence of the species. Even if the Service were to conclude after consultation that the proposed activity is likely to result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat).

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. The regulations at 50 CFR 424.02 define

''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or absence of a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, we may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

The following is a summary of the key information describing the physical and biological features essential to the conservation of the Dixie Valley toad. More information on species ecology and resource needs is available in chapter 3 of the SSA report (Service 2022, pp. 14–26), which is available on *https://www.regulations.gov* at Docket No. FWS–R8–ES–2023–0188, and on the Service's Environmental Conservation Online System (ECOS) website at *https://ecos.fws.gov/ServCat/DownloadFile/215829.*

Space for Individual and Population Growth and for Normal Behavior

Dixie Valley toads need enough wetland habitat to maintain population dynamics and life-history functions. Wetland habitat needs to include enough wetted area and have the natural range of variability of water extent to support the vegetation Dixie Valley toads use for brumation (periods of inactivity during cold temperatures) and shelter; open, ephemeral wetted areas for breeding; as well as the prey items the species relies upon.

There is little information on Dixie Valley toad dispersal capacity, besides the fact that they cannot disperse outside of the Dixie Meadows wetlands because they are surrounded by a dry landscape. However, we assume Dixie Valley toads can disperse among the wetlands, via upland corridors, during wet periods or rain. Maintaining the upland dispersal corridors between wetlands is important to maintain genetic diversity within the population and species.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

Dixie Meadows contains 122 known spring and seep sources (McGinley and Associates 2021, pp. 1–2) that distribute water across the landscape. Dixie Valley toads are completely reliant on the wetlands produced by the Dixie Meadows springs, as the species is highly aquatic and individuals are rarely found more than 14 meters (m) (46 feet (ft)) away from water (Halstead et al. 2021, pp. 28, 30).

Not only is the water itself necessary for the Dixie Valley toad, but the warm water temperatures produced by the springs are necessary for the species. The Dixie Meadows springs are thermal springs, providing relatively stable, warm temperatures to the wetlands. Dixie Valley toads select areas that are warmer than other surrounding available habitat, particularly in spring, fall, and winter months (Halstead et al. 2021, pp. 30, 33–34). In the spring, Dixie Valley toads select areas with warmer water for breeding (oviposition sites), which allows for faster egg hatching and time to metamorphosis. In the fall, Dixie Valley toads select different areas (closer to thermal springs with dense vegetation) to satisfy their thermal preferences as nighttime temperatures decrease. As they enter winter months, toads find areas with consistent warm temperatures during brumation (periods of inactivity during cold temperatures) so that they do not freeze (Halstead et al. 2021, pp. 30, 33–34). Dixie Valley toads are reliant on warm water temperatures, with Dixie Valley toad tadpoles found most often between 20 °C–28 °C (68 °F–82 °F), in wetland habitat for all life-history stages (Rose et al. 2023, p. 560).

The exact water quality parameters preferred by the Dixie Valley toad are unknown; however, this species has evolved only in Dixie Meadows and is presumed to thrive in the existing complex mix of water emanating from both the basin-fill aquifer and the deep geothermal reservoir. Temperature, dissolved oxygen, pH, salinity and water conductivity, and excessive nutrient concentrations (among others) have all been shown to have direct and indirect impacts to amphibian species when found to be outside of naturally occurring levels for any particular location (Sparling 2010, pp. 105–117). The natural variation of water quality parameters found in Dixie Meadows is considered a need for the species.

There is no published information on the feeding habits of the Dixie Valley toad. It is assumed that adult Dixie Valley toads are opportunistic feeders, similar to other toad species (*e.g.,* Muths and Nanjappa 2005, p. 395), and their diet most likely consists of the available aquatic and terrestrial invertebrates found in Dixie Meadows. Toad tadpoles are assumed to feed on algae and detritus (*e.g.,* Fellers 2005, p. 407).

Cover or Shelter

Dixie Valley toads need sufficient wetland vegetation to use as shelter. The species uses dense stands of bulrush (*Schoenoplectus* spp.) for shelter from predators and as brumation sites during cold winter months. Dixie Valley toads use other types of vegetation for shelter as well, so the natural heterogeneity of the wetland vegetation found in Dixie Meadows is a need for the species (*e.g., Juncus balticus* (Baltic rush), *Schoenoplectus* spp. (bulrushes), *Phragmites australis* (common reed), *Eleocharis* spp. (spikerushes), *Carex* spp. (sedges), and *Distichlis spicata* (saltgrass)) (Halstead et al. 2021, p. 34).

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Dixie Valley toad breeding occurs annually from March through May (Forrest et al. 2013, p. 76). Breeding appears protracted due to the thermal nature of the habitat and can last for months, with toads breeding early in the year in habitats closer to the thermal spring sources and then moving downstream into habitats as they warm throughout the spring and early

summer, which is not typical of other toad species that have a much more contracted breeding season of 3 to 4 weeks (*e.g.,* Sherman 1980, pp. 18–19, 72–73). Dixie Valley toads prefer to breed in open, ephemerally wetted areas adjacent to vegetated areas (Rose et al. 2023, p. 560).

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of the Dixie Valley toad from studies of the species' habitat, ecology, and life history as described below. Additional information can be found in the SSA report (Service 2022, pp. 14–27; available on *https://www.regulations.gov* under Docket No. FWS–R8–ES–2022–0024). We have determined that the following physical or biological features are essential to the conservation of the Dixie Valley toad:

(1) Wetlands within Dixie Valley that are composed of some combination of the following characteristics:

(a) Diverse wetland vegetation that includes, but is not limited to, native phreatophyte (deep-rooted) species found within the Dixie Meadows wetlands (*e.g., Juncus balticus* (Baltic rush), *Schoenoplectus* spp. (bulrushes), *Phragmites australis* (common reed), *Eleocharis* spp. (spikerushes), *Carex* spp. (sedges), and *Distichlis spicata* (saltgrass)).

(b) Dense bulrush stands for brumation and shelter.

(c) Open, ephemerally wetted areas adjacent to vegetated areas for breeding.

(d) The natural range of variability of water temperatures found throughout each wetland.

(e) The natural range of variability of water extent found throughout each wetland.

(f) Water quality necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages.

(g) A variety of aquatic and terrestrial invertebrates, detritus, and algae for feeding.

(2) Upland habitat between wetlands through which Dixie Valley toads can disperse when conditions permit.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. The features essential to the conservation of the Dixie Valley toad may require special management considerations or protection to reduce the following threats: (1) groundwater pumping activities, such as those associated with geothermal energy development and production; and (2) cattle grazing. Geothermal development is considered the primary threat to the Dixie Valley toad. Specifically, the Dixie Meadows Geothermal Utilization Project could have significant, detrimental impacts to the water flow and temperature emanating from the thermal springs the Dixie Valley toad relies on (Service 2022, pp. 39–41, 80–84, 113–119; Tetra Tech 2023a, pp. 3–7; Tetra Tech 2023b, pp. 2–3). A decrease in water flow would reduce habitat in the wetlands, and water temperatures in the wetlands could be reduced to a degree that the species cannot survive through cold winter months. Cattle can step on Dixie Valley toads while grazing, causing direct mortality and grazing may have impacts on water quality due to defecation and urination in the water.

Management activities that could ameliorate these threats include, but are not limited to, development and use of best management practices designed to maintain natural spring flows, spring temperatures, and water quality; use of best management practices designed to control or minimize the level of grazing in order to maintain the desired condition of Dixie Valley toad habitat; and restoration of disturbed features to their pre-disturbance, natural state.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat. We are not currently proposing to designate any areas outside the geographical area occupied by the species because we have not identified any unoccupied areas that meet the Act's definition of critical habitat. There are no unoccupied areas that have the unique characteristics and physical and biological features necessary to support the Dixie Valley toad.

Sources of data for the Dixie Valley toad and its habitat needs include peer-reviewed articles on the species and related species, satellite imagery analysis done by the U.S. Geological Survey (USGS), and communication with species experts.

To determine which areas to propose as critical habitat, we used the Dixie Meadows wetlands as a starting point. All of the wetlands are considered occupied by the Dixie Valley toad (Rose et al. 2023, entire) and are proposed as critical habitat.

We then used USGS's satellite imagery analysis on the extent of land cover vegetation and soil wetness from October 2015 through January 2022 (Bransky et al. 2023, entire), to determine the upland habitat that could be used by Dixie Valley toads to disperse between wetlands. We delineated all areas of habitat classified by USGS with at least a class two landcover class (apparent moist soil and sparse or short vegetation) at some time during the analysis period, using the Green Normalized Difference Vegetation Index (gNDVI; Gitelson et al. 1996, entire), as suitable upland dispersal habitat for inclusion in the proposed critical habitat. Although upland habitat is not occupied year-round, it is assumed to be used during wet periods each year, playing a vital role in maintaining genetic diversity throughout the single population of the species.

In summary, for areas within the geographic area occupied by the species at the time of listing, we delineated critical habitat unit boundaries using the following criteria:

(1) We identified the wetlands occupied by the Dixie Valley toad.

(2) We then delineated the upland habitat between wetlands that included all areas that could be used for dispersal. Upland habitat was considered dispersal habitat if it has been classified by USGS at some time from October 2015 through January 2022 as at least a gNDVI class two land cover class based on satellite imagery analysis.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the Dixie Valley toad. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat.

Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

The proposed critical habitat designation is defined by the map, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which the map is based available to the public on *https://www.regulations.gov* at Docket No. FWS–R8–ES–2023–0188.

Proposed Critical Habitat Designation

We are proposing to designate approximately 930 acres (ac) (376 hectares (ha)) in one unit as critical habitat for the Dixie Valley toad. The critical habitat area we describe below as Dixie Meadows is occupied by the species and constitutes our current best assessment of the area that meets the definition of critical habitat for the Dixie Valley toad. Table 1 shows the land ownership and approximate areas of the proposed critical habitat unit for the Dixie Valley toad.

TABLE 1—PROPOSED CRITICAL HABITAT UNIT FOR THE DIXIE VALLEY TOAD

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Land ownership by type	Size of unit in acres (hectares)	Occupied?
Dixie Meadows	Department of Defense (DoD)	588 (238)	Yes.
	BLM	342 (138)	
	Total	*930 (376)*	

We present a brief description and map of the proposed unit, and reasons why it meets the definition of critical habitat for the Dixie Valley toad, below.

Dixie Meadows Unit

The Dixie Meadows Unit consists of 930 ac (376 ha) of occupied wetland and upland habitat in Dixie Meadows, Churchill County, Nevada. This unit encompasses the entire range of the Dixie Valley toad and contains all of the physical or biological features essential to the conservation of the species. This unit is essential to the recovery of Dixie Valley toad because it includes all the habitat that is occupied by the species across its range. Special management considerations or protection may be required to protect against impacts from threats that are anticipated: to reduce water flow, temperature, and quality emanating from the springs; and to reduce water quality, water temperature, the amount of wetted area, and vegetation on the landscape. Sources of these threats include geothermal development and production, groundwater pumping activities, and grazing (see Special Management Considerations or Protection, above). Special management considerations related to geothermal development and production, groundwater pumping, and grazing include, but are not limited to: development and use of best management practices designed to maintain natural spring flows, spring temperatures, and water quality; use of best management practices designed to control or minimize the level of grazing in order to maintain the desired condition of Dixie Valley toad habitat; and restoration of disturbed features back to their pre-disturbance, natural state.

Roughly 63 percent (588 ac (238 ha)) of the Unit is part of the Air Station's lands and 37 percent (342 ac (138 ha)) is Bureau of Land Management (BLM) land. The 588 ac (238 ha) of Air Station lands are being considered for exemption from the critical habitat designation (see Exemptions, below).

A map of the proposed unit, showing areas of wetlands, the Air Station's lands, and BLM land appears below. Please note that the BLM lands are those areas within the proposed unit's boundaries that are not labeled as Department of Defense lands:

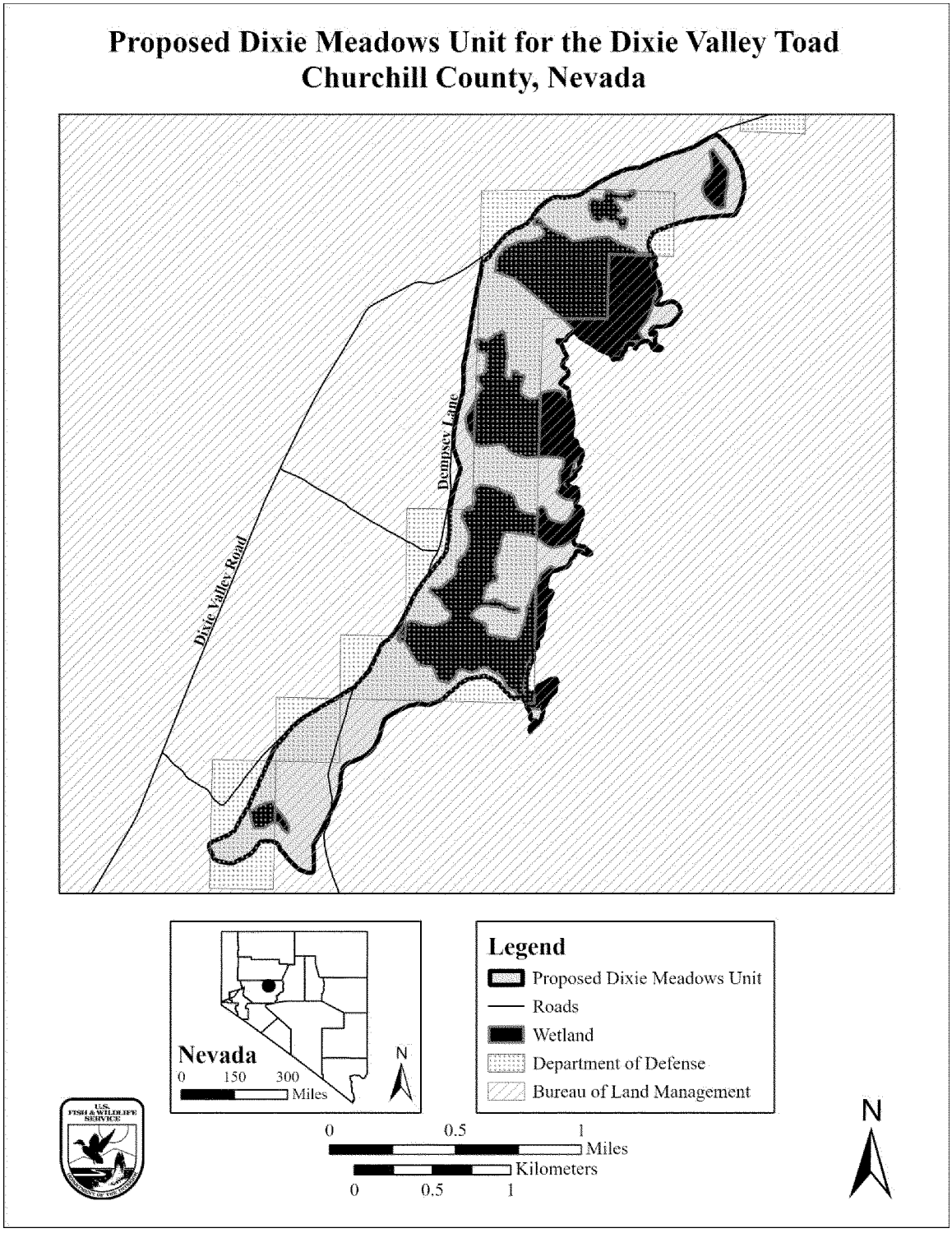


Figure 1. Proposed Dixie Meadows Unit for the Dixie Valley Toad

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species (50 CFR 402.02).

Compliance with the requirements of section 7(a)(2) is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate consultation. Reinitiation of consultation is required and shall be requested by the Federal agency, where discretionary Federal involvement or control over the action has been retained or is authorized by law and: (1) if the amount or extent of taking specified in the incidental take statement is exceeded; (2) if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion or written concurrence; or (4) if a new species is listed or critical habitat designated that may be affected by the identified action. As provided in 50 CFR 402.16, the requirement to reinitiate consultations for new species listings or critical habitat designation does not apply to certain agency actions (*e.g.,* land management plans issued by the Bureau of Land Management in certain circumstances).

Destruction or Adverse Modification of Critical Habitat

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat for the conservation of the listed species. As discussed above, the role of critical habitat is to support the physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires that our **Federal Register** notices ''shall, to the maximum extent practicable also include a brief description and evaluation of those activities (whether public or private) which, in the opinion of the Secretary, if undertaken may adversely modify [critical] habitat, or may be affected by such designation.'' Activities that may be affected by designation of critical habitat for the Dixie Valley toad include those that may affect the physical or biological features of the Dixie Valley toads' critical habitat (see Physical or Biological Features Essential to the Conservation of the Species).

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the DoD, or designated for its use, that are subject to an integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act Improvement Act of 1997 (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.

An INRMP was completed by the Air Station in 2014, prior to the Dixie Valley toad being described as a species and before the toad was listed as an endangered species. The Air Station is in the process of amending its INRMP to incorporate the DoD's National Strategic Plan for amphibian and reptile conservation and management (Lovich et al. 2015, entire), which will include specific management for Dixie Meadows and the Dixie Valley toad (Schofield 2023, in litt.). After we receive the INRMP amendment, we will assess its conservation benefit to the toad under 50 CFR 424.12(h) before the final critical habitat designation. If we determine the Air Station lands qualify for exemption from critical habitat designation, then the 588 ac (238 ha) of Air Station land would be exempted from the final designation, which is 63 percent of the proposed critical habitat designation.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. Exclusion decisions are governed by the regulations at 50 CFR 424.19 and the Policy Regarding Implementation of Section 4(b)(2) of the Endangered Species Act (hereafter, the ''2016 Policy''; 81 FR 7226, February 11, 2016), both of which were developed jointly with the National Marine Fisheries Service (NMFS). We also refer to a 2008 Department of the Interior Solicitor's opinion entitled, ''The Secretary's Authority to Exclude Areas from a Critical Habitat Designation under Section 4(b)(2) of the Endangered Species Act'' (M–37016).

In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise discretion to exclude the area only if such exclusion would not result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor. In our final rules, we explain any decision to exclude areas, as well as decisions not to exclude, to make clear the rational basis for our decision. We describe below the process that we use for taking into consideration each

category of impacts and any initial analyses of the relevant impacts.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and its habitat within the areas proposed. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for this particular species. The probable economic impact of a proposed critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.''

The ''without critical habitat'' scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (*e.g.,* under the Federal listing as well as other Federal, State, and local regulations). Therefore, the baseline represents the costs of all efforts attributable to the listing of the species under the Act (*i.e.,* conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts would not be expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat should we choose to conduct a discretionary section 4(b)(2) exclusion analysis.

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Executive Order 14094 reaffirms the principles of E.O.s 12866 and 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Consistent with the E.O. regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities. Section 3(f) of E.O. 12866 identifies four criteria when a regulation is considered a ''significant regulatory action'' and requires additional analysis, review, and approval if met. The criterion relevant here is whether the designation of critical habitat may have an economic effect of $200 million or more in any given year (section 3(f)(1), as amended by E.O. 14094). Therefore, our consideration of economic impacts uses a screening analysis to assess whether a designation of critical habitat for the Dixie Valley toad is likely to exceed the economically significant threshold.

For this particular designation, we developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this proposed designation of critical habitat. The information contained in our IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the Dixie Valley toad (Industrial Economics (IEc) 2023, entire). We began by conducting a screening analysis of the proposed designation of critical habitat in order to focus our analysis on the key factors that are likely to result in incremental economic impacts. The purpose of the screening analysis is to filter out particular geographical areas of critical habitat that are already subject to such protections and are, therefore, unlikely to incur incremental economic impacts. In particular, the screening analysis considers baseline costs (*i.e.,* absent critical habitat designation) and includes any probable incremental economic impacts where land and water use may already be subject to conservation plans, land management plans, best management practices, or regulations that protect the habitat area as a result of the Federal listing status of the species.

Ultimately, the screening analysis allows us to focus our analysis on evaluating the specific areas or sectors that may incur probable incremental economic impacts as a result of the designation. The presence of the listed species in occupied areas of critical habitat means that any destruction or adverse modification of those areas is also likely to jeopardize the continued existence of the species. Therefore, designating occupied areas as critical habitat typically causes little if any incremental impacts above and beyond the impacts of listing the species. As a result, we generally focus the screening analysis on areas of unoccupied critical habitat (unoccupied units or unoccupied areas within occupied units). Overall, the screening analysis assesses whether designation of critical habitat is likely to result in any additional management or conservation efforts that may incur incremental economic impacts. This screening analysis combined with the information contained in our IEM constitute what we consider to be our draft economic analysis (DEA) of the proposed critical habitat designation for the Dixie Valley toad; our DEA is summarized in the narrative below.

As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation. In our evaluation of the probable incremental economic impacts that may result from the proposed designation of critical habitat for the Dixie Valley toad, first we identified, in the IEM dated April 10, 2023, probable incremental economic impacts associated with the following categories of activities: (1) geothermal development and production (BLM, DoD); (2) groundwater withdrawal; and (3) grazing (BLM). We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. In the area where the Dixie Valley toad is present, Federal agencies are required to consult with the Service under section 7 of the Act on activities they authorize, fund, or carry out that may affect the species. If we finalize this proposed critical habitat designation, Federal agencies would be required to consider the effects of their actions on the designated habitat, and if the Federal action may affect critical habitat, our consultations would include an evaluation of measures to avoid the

destruction or adverse modification of critical habitat.

In our IEM, we attempted to clarify the distinction between the effects that result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for the Dixie Valley toad's critical habitat. It has been our experience that it is difficult to discern which conservation efforts are attributable to the species being listed and those which will result solely from the designation of critical habitat. However, the following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that would likely adversely affect the essential physical or biological features of occupied critical habitat are also likely to adversely affect the species itself. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this proposed designation of critical habitat.

The proposed critical habitat designation for the Dixie Valley toad includes 930 ac (376 ha) of wetland and upland habitat in one occupied unit. The Air Station manages 588 ac (238 ha), and the BLM manages the remaining 342 ac (138 ha). Any actions that may affect the species or its habitat would also affect designated critical habitat, and it is unlikely that any additional conservation efforts would be recommended to address the adverse modification standard over and above those recommended as necessary to avoid jeopardizing the continued existence of the Dixie Valley toad. Therefore, only administrative costs are expected to result from the proposed critical habitat designation. While this additional analysis will require time and resources by both the Federal action agency and the Service, it is believed that, in most circumstances, these costs would predominantly be administrative in nature and would not be significant.

The probable incremental costs of designating critical habitat for the Dixie Valley toad are likely to be limited to additional administrative efforts to consider adverse modification in section 7 consultations. This limitation is because all of the proposed critical habitat designation is occupied by the Dixie Valley toad. The incremental administrative burden resulting from the designation of critical habitat for the Dixie Valley toad is not anticipated to reach $200 million in any given year based on the anticipated annual number of consultations and associated consultation costs, which are not expected to exceed $7,000 per year (2023 dollars). If Air Station lands are determined to be exempt from the critical habitat designation for the Dixie Valley toad, the anticipated annual consultations costs are not expected to exceed $4,000 per year. The designation is unlikely to trigger additional requirements under State or local regulations. Thus, the annual administrative burden is relatively low.

We are soliciting data and comments from the public on the DEA discussed above. During the development of a final designation, we will consider the information presented in the DEA and any additional information on economic impacts we receive during the public comment period to determine whether any specific areas should be excluded from the final critical habitat designation under the authority of section 4(b)(2) of the Act, our implementing regulations at 50 CFR 424.19, and the 2016 Policy. We may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of this species.

Consideration of National Security Impacts

Section 4(a)(3)(B)(i) of the Act may not cover all DoD lands or areas that pose potential national-security concerns (*e.g.,* a DoD installation that is in the process of revising its INRMP for a newly listed species or a species previously not covered). If a particular area is not covered under section 4(a)(3)(B)(i), then national-security or homeland-security concerns are not a factor in the process of determining what areas meet the definition of ''critical habitat.'' However, we must still consider impacts on national security, including homeland security, on those lands or areas not covered by section 4(a)(3)(B)(i) because section 4(b)(2) requires the Service to consider those impacts whenever it designates critical habitat. Accordingly, if DoD, Department of Homeland Security (DHS), or another Federal agency has requested exclusion based on an assertion of national-security or homeland-security concerns, or we have otherwise identified national-security or homeland-security impacts from designating particular areas as critical habitat, we generally have reason to consider excluding those areas.

However, we cannot automatically exclude requested areas. When DoD, DHS, or another Federal agency requests exclusion from critical habitat on the basis of national-security or homeland-security impacts, we must conduct an exclusion analysis if the Federal requester provides information, including a reasonably specific justification of an incremental impact on national security that would result from the designation of that specific area as critical habitat. That justification could include demonstration of probable impacts, such as impacts to ongoing border-security patrols and surveillance activities, or a delay in training or facility construction, as a result of compliance with section 7(a)(2) of the Act. If the agency requesting the exclusion does not provide us with a reasonably specific justification, we will contact the agency to recommend that it provide a specific justification or clarification of its concerns relative to the probable incremental impact that could result from the designation. If we conduct an exclusion analysis because the agency provides a reasonably specific justification or because we decide to exercise the discretion to conduct an exclusion analysis, we will defer to the expert judgment of DoD, DHS, or another Federal agency as to: (1) Whether activities on its lands or waters, or its activities on other lands or waters, have national-security or homeland-security implications; (2) the importance of those implications; and (3) the degree to which the cited implications would be adversely affected in the absence of an exclusion. In that circumstance, in conducting a discretionary section 4(b)(2) exclusion analysis, we will give great weight to national-security and homeland-security concerns in analyzing the benefits of exclusion.

Under section 4(b)(2) of the Act, we also consider whether a national security or homeland security impact might exist on lands owned or managed by DoD or DHS. The Air Station may request exclusion on the basis of national-security or homeland-security impacts. The only DoD or DHS lands within the proposed critical habitat designation are the 588 ac (238 ha) of Air Station lands, which is 63 percent of the proposed critical habitat designation, that are being considered for exemption under section 4(a)(3)(B)(i) of the Act (see Exemptions, above). The Air Station has not requested exclusion based on national security impacts.

Consideration of Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security discussed above. To identify other relevant impacts that may affect the exclusion analysis, we consider a number of factors, including whether there are approved and permitted conservation agreements or plans covering the species in the area—such as safe harbor agreements (SHAs), candidate conservation agreements with assurances (CCAAs) or ''conservation benefit agreement'' or ''conservation agreement'' (''CBAs'') (CBAs are a new type of agreement replacing SHAs and CCAAs in use after April 2024 (89 FR 26070; April 12, 2024)) or HCPs—or whether there are non-permitted conservation agreements and partnerships that may be impaired by designation of, or exclusion from, critical habitat. In addition, we look at whether Tribal conservation plans or partnerships, Tribal resources, or government-to-government relationships of the United States with Tribal entities may be affected by the designation. We also consider any State, local, social, or other impacts that might occur because of the designation.

Summary of Exclusions Considered Under 4(b)(2) of the Act

In preparing this proposal, we have determined that no HCPs or other management plans for Dixie Valley toad currently exist, and the proposed designation does not include any Tribal lands or trust resources or any lands for which designation would have any economic impacts. We note that this land is a sacred site to the Fallon Paiute-Shoshone Tribe and that they supported the listing of the Dixie Valley toad in their comments on the April 7, 2022, proposed listing rule (87 FR 20374). Therefore, we anticipate no other relevant impacts to Tribal lands, partnerships, or HCPs from this proposed critical habitat designation, and, thus, as described above, we are not considering excluding any particular areas on the basis of the presence of conservation agreements or impacts to trust resources. We will consider exclusion of the Air Station lands if the Air Station requests an exclusion based on national-security impacts.

However, if through the public comment period we receive information that we determine indicates that there are economic, national security, or other relevant impacts from designating particular areas as critical habitat, then as part of developing the final designation of critical habitat, we will evaluate that information and may conduct a discretionary exclusion analysis to determine whether to exclude those areas under authority of section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19. If we receive a request for exclusion of a particular area and after evaluation of supporting information we do not exclude, we will fully describe our decision in the final rule for this action. (Please see **ADDRESSES**, above, for instructions on how to submit comments).

Required Determinations

Clarity of the Rule

We are required by E.O.s 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Regulatory Planning and Review (Executive Orders 12866, 13563, and 14094)

Executive Order (E.O.) 12866, as reaffirmed by E.O. 13563 and E.O. 14094, provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 14094 reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine whether potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies would be directly regulated if we adopt the proposed critical habitat designation. The RFA does not require evaluation of the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities would be directly regulated by this rulemaking, the Service certifies that, if made final as proposed, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the proposed designation would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if made final, the proposed critical habitat designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare statements of energy effects ''to the extent permitted by law'' when undertaking actions identified as significant energy actions (66 FR 28355; May 22, 2001). E.O. 13211 defines a ''significant energy action'' as an action that (i) is a significant regulatory action under E.O. 12866 (or any successor order, including, most recently, E.O. 14094 (88 FR 21879; April 11, 2023)); and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule is not a significant regulatory action under E.O. 12866 or 14094. Therefore, this action is not a significant energy action, and there is no requirement to prepare a statement of energy effects for this action.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following finding:

(1) This proposed rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or Tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or Tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions are not likely to destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments. The lands being proposed for critical habitat designation are owned by the DoD and BLM. Neither of these government entities fit the definition of ''small governmental jurisdiction.'' Therefore, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the Dixie Valley toad in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed for the proposed designation of critical habitat for the Dixie Valley toad, and it concludes that, if adopted, this designation of critical habitat does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this proposed critical habitat designation with, appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the proposed rule does not have substantial direct effects either on the States, or on the relationship between the Federal Government and the States, or on the distribution of powers and responsibilities among the various levels of government. The proposed designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary for the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist State and local governments in long-range planning because they no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with E.O. 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this proposed rule identifies the physical or biological features essential to the conservation of the species. The proposed area of critical habitat is presented on a map, and the proposed rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

Regulations adopted pursuant to section 4(a) of the Act are exempt from the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) and do not require an environmental analysis under NEPA. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This includes listing, delisting, and reclassification rules, as well as critical habitat designations. In a line of cases starting with *Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), the courts have upheld this position.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), E.O. 13175 (Consultation and Coordination with Indian Tribal Governments), the President's memorandum of November 30, 2022 (Uniform Standards for Tribal Consultation; 87 FR 74479, December 5, 2022), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes on a government-to-government basis. In accordance with Secretaries' Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We requested information from the Fallon Paiute-Shoshone Tribe during the SSA and proposed listing processes and responded to comments the Tribe made on the proposed listing rule. The Fallon Paiute-Shoshone Tribe commented that they support the listing of the Dixie Valley toad and that the Dixie Meadows hot springs are one of the most sacred sites in their Tribe's culture. The Service met with the Fallon Paiute-Shoshone Tribe for government-to-government consultation in March 2023 at the Tribe's request. During this consultation, the Service emphasized our commitment to incorporating the Tribe's traditional ecological knowledge, to the extent to which the Tribe is comfortable, into the proposed critical habitat designation process, and we stated that we welcome further conversations to facilitate this. We will continue to work with Tribal entities during the development of a final rule for the designation of critical habitat for the Dixie Valley toad.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Reno Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Reno Fish and Wildlife Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.11, in paragraph (h), amend the List of Endangered and Threatened Wildlife by revising the entry for ''Toad,

Dixie Valley'' under AMPHIBIANS to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
		AMPHIBIANS		
*	*	*	*	*
Toad, Dixie Valley	*Anaxyrus williamsi*	Wherever found	E	87 FR 73971, 12/2/2022; 50 CFR 17.95(d).CH
*	*	*	*	*

■ 3. In § 17.95, amend paragraph (d) by adding an entry for ''Dixie Valley Toad (*Anaxyrus williamsi*)'' after the entry for ''Arroyo Toad (*Anaxyrus californicus*)'', to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(d) *Amphibians.*

* * * * *

Dixie Valley Toad (*Anaxyrus williamsi*)

(1) The critical habitat unit for the Dixie Valley toad in Churchill County, Nevada, is depicted on the map in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of the Dixie Valley toad consist of the following components:

(i) Wetlands within Dixie Valley that are composed of some combination of the following characteristics:

(A) Diverse wetland vegetation that includes, but is not limited to, native phreatophyte (deep-rooted) species found within the Dixie Meadows wetlands (*e.g., Juncus balticus* (Baltic rush), *Schoenoplectus* spp. (bulrushes), *Phragmites australis* (common reed), *Eleocharis* spp. (spikerushes), *Carex* spp. (sedges), and *Distichlis spicata* (saltgrass)).

(B) Dense bulrush stands for brumation and shelter.

(C) Open, ephemerally wetted areas adjacent to vegetated areas for breeding.

(D) The natural range of variability of water temperatures found throughout each wetland.

(E) The natural range of variability of water extent found throughout each wetland.

(F) Water quality necessary to sustain natural physiological processes for normal behavior, growth, and viability of all life stages.

(G) A variety of aquatic and terrestrial invertebrates, detritus, and algae for feeding.

(ii) Upland habitat between wetlands through which Dixie Valley toads can disperse when conditions permit.

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of the final rule.

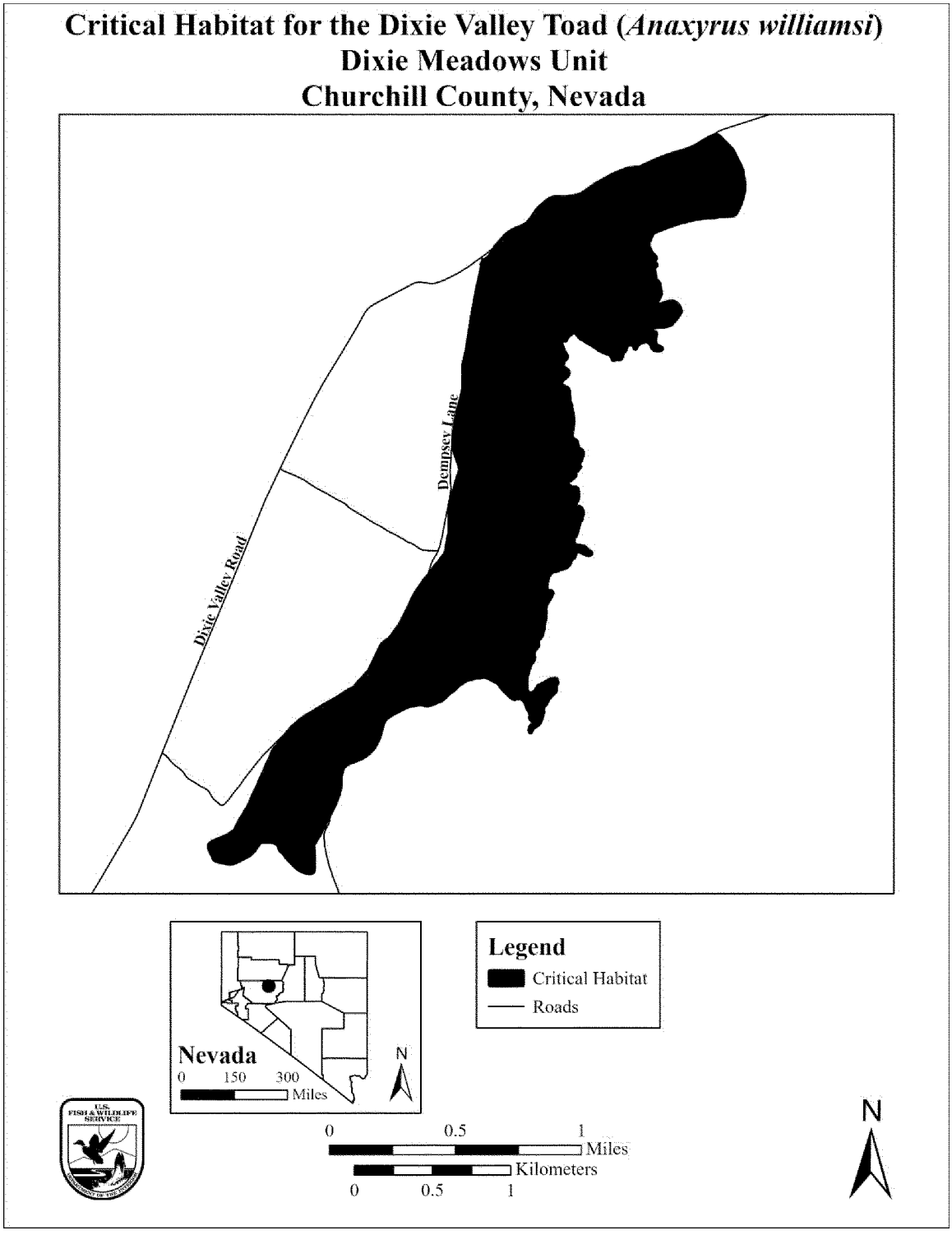
(4) Data layers defining the map unit were created by the Service, and the critical habitat unit was then mapped using Universal Transverse Mercator Zone 11N coordinates. The map in this entry, as modified by any accompanying regulatory text, establishes the boundaries of the critical habitat designation. The coordinates or plot points or both on which this map is based are available to the public at the Service's internet site at *https://www.regulations.gov* at Docket No. FWS–R8–ES–2023–0188, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Dixie Meadows Unit; Churchill County, Nevada.

(i) The unit consists of 930 acres (ac) (376 hectares (ha)) in Churchill County and is composed of Federal lands owned by the Department of Defense (588 ac (238 ha)) and Bureau of Land Management (342 ac (138 ha)).

(ii) Map follows:

Figure 1 to Dixie Valley Toad (*Anaxyrus williamsi*) Paragraph (5)(ii)



Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2024–11847 Filed 5–29–24; 8:45 am]

BILLING CODE 4333–15–P

Notices

Federal Register
Vol. 89, No. 105
Thursday, May 30, 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.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Agency Information Collection Activities; Outreach and Assistance to Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers Program (2501 Program) Application and Performance Reporting

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, this notice announces the Office of Partnerships and Public Engagement's intention to request a new information collection titled ''*Outreach and Assistance to Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers Program (2501 Program) Application and Performance Reporting.*''

DATES: We will consider comments we receive by July 29, 2024.

ADDRESSES: We invite you to submit comments on this notice.

Electronic Submission of Comments. You may submit comments electronically through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions provided on that site to submit comments electronically.

Submission of Comments by Mail, Hand delivery, or Courier. You may submit comments to the USDA, Office of Partnerships and Public Engagement, Jamie L. Whitten Building, Room 524A, Mail Stop 0601, 1400 Independence Ave. SW, Washington, DC 20250. USDA strongly encourages commenters to submit comments electronically. Electronic submission of comments allows you maximum time to prepare and submit a comment and ensures timely receipt by USDA.

FOR FURTHER INFORMATION CONTACT: Kim Okahara, Performance Improvement Officer, 202–720–6350, *kim.okahara@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Outreach and Assistance to Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers Program (2501 Program) Application and Performance Reporting.

OMB Control Number: 0503–New.

Type of Request: Notice of intent to request a new information collection entitled ''*Outreach and Assistance to Socially Disadvantaged Farmers and Ranchers and Veteran Farmers and Ranchers Program (2501 Program) Application and Performance Reporting.*''

Abstract: The 2501 program at the U.S. Department of Agriculture (USDA) makes competitively awarded grants to community-based and non-profit organizations, institutions of higher education, and Tribal entities to provide education and training in agriculture, agribusiness, forestry, agricultural-related services, and USDA programs, develop underserved youths' interest in agriculture, and conduct outreach initiatives.

The objectives of the 2501 Program are to support socially disadvantaged farmers and ranchers, military veteran farmers and ranchers, and beginning farmers and ranchers with owning and operating successful farms and ranches and participating equitably in the full range of agricultural, forestry, and related programs offered by USDA. The Agriculture Improvement Act of 2018 (2018 Farm Bill) authorizes grants to enhance coordination of the outreach, technical assistance, and education efforts authorized under agriculture programs; and to assist the Secretary in reaching current and prospective socially disadvantaged farmers and ranchers and veteran farmers and ranchers in a linguistically appropriate manner; and improving the participation of those farmers and ranchers in Department programs (7 U.S.C. 2279).

Applications: The application package required for eligible entities includes the following: Standard Form (SF) 424; Application for Federal Assistance; Project/Performance Site Location(s); Project Abstract Summary; Project Narrative; Standard Form (SF) 424A; Budget Information—Non-Construction Programs; Budget Narrative; Key Contacts (list names of all key personnel expected to work on the project); *Grants.gov* Lobbying Form; Resumes of all key personnel working on the project; and related documentation (*e.g.,* Articles of Incorporation for all nonprofit organizations, 501(c)3 status documentation).

Performance Reports: Grant recipients are required to submit semi-annual progress reports on their activities and a final performance report at the end of the award period. Under 7 U.S.C. 2279(c)(4)(D), USDA must submit to Congress an annual report that includes the following:

- The recipients of funds made available under the program;
- The activities undertaken and services provided;
- The number of current and prospective socially disadvantaged farmers or ranchers served and outcomes of such service;
- The problems and barriers identified by entities in trying to increase participation by current and prospective socially disadvantaged farmers or ranchers;
- The number of farms or ranches started, maintained, or improved as a result of funds made available under the program; and
- Actions taken by the Secretary in partnership with eligible entities to enhance participation in agricultural programs by veteran farmers or ranchers and socially disadvantaged farmers or ranchers and the effectiveness of those actions.

USDA will use the information collected to:

1. Assess program eligibility and compliance with program requirements;
2. Complete the annual report to Congress as required by 7 U.S.C. 2279(c)(4)(D);
3. Comply with the newly revised guidance on the collection of demographic information, per OMB Statistical Policy Directive No. 15;
4. Comply with the reporting requirements under the Government Performance and Results Modernization Act and Foundations of Evidence-based Policymaking Act; and
5. Assess the progress of grant recipients regarding measurable goals.

Data collected from the grantees will provide a nationwide description of

activities funded under the 2501 Program to reach current and prospective socially disadvantaged farmers and ranchers and veteran farmers and ranchers in a linguistically appropriate manner and improve the participation of those farmers and ranchers in Department programs. Data collected from grantees will also provide information for usage by Congress, the Department, and the public. In addition, USDA will use this data to inform program management, monitoring, and technical assistance efforts. Grantees will be able to use the data for internal management and program improvement.

Estimated Program Burden: USDA estimates the burden of this collection of information as follows. The information collection has three parts:

(A) *Grants.gov* collects data from applicants. Applicants submit their application package to USDA using grants.gov. The estimated average amount of time required to complete the application package is 160 hours annually. The estimated response burden includes time to review instructions, gather existing data, and complete and review the application. These estimates are based on the experience of former grantees who have previously applied to the program.

(B) A web-based system that collects data from grantees. Grantees report to USDA using a web-based data collection system. The estimated average amount of time required to complete all responses to the data collection instrument is 20 hours per report, or 40 hours annually. We anticipate an additional 10 burden hours for those completing a final report, which is approximately ⅓ of grantee organizations each year. All grantees will complete two semiannual reports, regardless of whether or not they are completing a final report, as the semiannual report serves to provide data on the preceding six-month period, while the final report covers the entire grant period. Additionally, the estimated number of respondents per year is higher than the total number of grantees funded over three years, to account for no-cost extensions to existing grant agreements. The estimated response burden includes time to review the instructions, gather existing data, and complete and review the data entries. These estimates are based on the current time reported by grantees to respond to reports, as well as efficiencies in the new web-based system anticipated by the staff who implement these programs.

(C) A follow-up survey that grantees collect from program participants. Many grantees currently ask program participants to complete surveys after attending a program offering or at the completion of a training program to assess the effectiveness and relevance of the training content to the needs of the participant. In this case, we are proposing that OPPE will survey program participants directly in order fulfill reporting requirements to Congress on the success of the program in meeting its performance measures. This information will be used by USDA to measure the program's overall performance from the perspective of program participants. Historical data from grantees regarding burden hours is helpful, but not especially relevant here, as currently grantees create their own feedback surveys that are not consistent across different grantee organizations. We have estimated the number of burden hours for this item based on the number of questions and whether they are multiple choice, short answer, or paragraph responses requested. In this estimate, we also anticipate administering the survey longitudinally by requesting responses from participants at 3 different time intervals.

Respondent/data collection activity	Estimated number of respondents	Responses per respondent	Hours per response	Annual burden hours
Application	120	1	160	19,200
Semiannual performance report	150	2	20	6,000
Final performance report	50	1	30	1,500
Follow-up survey (or course evaluation) (ArcGIS Survey 123)	5,000	3	.5	7,500
Total	.....	.....	.....	34,200

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden 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 those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

USDA will consider the comments received and amend the Information Collection Request (ICR) as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, USDA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Lisa Ramirez,

Director, Office of Partnerships and Public Engagement, U.S. Department of Agriculture.

[FR Doc. 2024–11906 Filed 5–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Business and Professional Classification Report

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information

collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on March 8, 2024 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Department of Commerce.

Title: Business and Professional Classification Report.

OMB Control Number: 0607–0189.

Form Number(s): SQ–CLASS.

Type of Request: Regular submission, Request for an Extension, without Change, of a Currently Approved Collection.

Number of Respondents: 60,000.

Average Hours per Response: 13 minutes.

Burden Hours: 13,000.

Needs and Uses: This request is for continued clearance of the Business and Professional Classification Report (SQ–CLASS Report). The primary purpose of the SQ–CLASS Report is to meet the ongoing sample needs of the Census Bureau's current business surveys of the retail trade, wholesale trade, and services portions of the economy as defined by the North American Industry Classification System (NAICS). The data collected by the SQ–CLASS Report are used to update the samples in our current business surveys to reflect newly opened establishments.

Additionally, establishments in the five-year economic census will receive data collection instruments specifically tailored to their industry based on the classification information obtained by the SQ–CLASS Report. Businesses in Support Activities for Crop Production (NAICS 1151) and Support Activities for Animal Production (NAICS 1152) are included in the scope and collection of the Economic Census. To ensure that businesses are properly classified, the scope of the SQ–CLASS Report includes businesses in the Agriculture Sector (NAICS Sector 11) that are not fully classified. This accounts for approximately 600 cases in the SQ–CLASS Report's sample each year.

To keep current with rapid changes in the marketplace caused by new businesses (a.k.a. births) the Census Bureau samples newly assigned Employer Identification Numbers (EINs) obtained from the Internal Revenue Service (IRS). Each EIN can only be selected once for the SQ–CLASS Report. EINs selected for the SQ–CLASS Report sample are asked to provide data about the establishment(s) associated with the new EIN including a more reliable measure of size, consisting of sales in two recent months, company affiliation information, a new or more detailed industry classification code, and other key information needed to maintain proper coverage of the business universe on the Business Register (BR) for the current business surveys.

Based on information collected on the SQ–CLASS Report form, EINs meeting the criteria for inclusion in the Census Bureau's current business surveys are eligible for a second phase of sampling. The retail, wholesale, and services EINs selected in this second sampling are asked to report monthly for the retail and wholesale surveys and quarterly for the services survey.

The Economic Census and the current business surveys represent the primary source of facts about the structure and function of the U.S. economy, providing essential information to government and the business community in making sound decisions. This information helps build the foundation for the calculation of Gross Domestic Product (GDP) and other economic indicators. Crucial to its success are the accuracy and reliability of the BR data, which provides the Economic Census and current business surveys with their establishment lists. Critical to the quality of information housed in the BR is that each of the statistical units has an accurate industry classification, measure of size, activity status, and physical address. The vital information obtained from the SQ–CLASS Report is fed back to the BR to represent changes in industries and confirm coverage between the years of the Economic Census.

We are not proposing any major changes to the collection. Minimal changes are being made to the economic activity descriptions in the primary business activity question on the SQ–CLASS Report. Respondents will continue to choose the economic sector of their business and then select their type of business from a list of business activities based on their response to the economic sector question. If the respondent does not see their business activity listed, then they will provide a brief description of their business activity. This is the same methodology that the Census Bureau uses in the Economic Census to assign industry classification.

Frequency: One time.

Respondent's Obligation: Mandatory.

Legal Authority: The Census Bureau conducts this survey under the authority of an Act of Congress, Title 13, U.S.C., Sections 131, 182, and 193.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0189.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–11836 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; School District Review Program

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on December 6, 2023, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Department of Commerce.

Title: School District Review Program.

OMB Control Number: 0607–0987.

Form Number(s): None.

Type of Request: Regular submission, Request for a Revision of a Currently Approved Collection.

Number of Respondents: 156.

- *Annotation Phase:* 52.
- *Verification Phase:* 52.
- *Feedback:* 52.

Average Hours per Response: 41 hours.

- *Annotation Phase:* 30 hours.
- *Verification Phase:* 10 hours.
- *Feedback:* 1 hour.

Burden Hours: 2,132 hours.

- *Annotation Phase:* 1,560 hours.
- *Verification Phase:* 520 hours.
- *Feedback:* 52 hours.

Needs and Uses: The School District Review Program (SDRP) is a U.S. Department of Education National Center for Education Statistics (NCES) sponsored program conducted annually by the U.S. Census Bureau. It is of vital importance for each state's allocation of federal funding under Title I of the Elementary and Secondary Education Act as amended by the Every Student Succeeds Act of 2015, Public Law 114–95. School district information submitted through this program, along with the decennial census population, Small Area Income and Poverty Estimates, and current population estimates, are used in forming the Census Bureau's estimates of the number of children ages 5 through 17 in families in poverty for each school district. The U.S Department of Education uses these estimates to allocate more than $17 billion annually in Title I funds.

The SDRP encompasses the review of Type 1, Type 2, and Type 3 school districts as defined by the NCES. Type 1 is a local school district that is not a component of a supervisory union. Type 2 is a local school district component of a supervisory union sharing a superintendent and administrative services with other local school districts. Type 3 is an education agency that performs administrative services for more than one school district, providing a common superintendent for participating districts.

Respondents to the SDRP are the mapping coordinators and Title I Coordinators from the fifty states and the District of Columbia. The NCES also anticipates the inclusion of the Commonwealth of Puerto Rico within the next three years. Mapping coordinators are designated by the state departments of education and are tasked with reviewing and providing updates for school district boundaries, federally assigned school district local education agency codes, names, grade ranges, and levels to the Census Bureau. Title I Coordinators are responsible for overseeing the SDRP and reviewing all materials.

There are two phases to the SDRP: the Annotation Phase and Verification Phase. During the Annotation Phase, the Census Bureau provides mapping coordinators with materials containing the latest school district boundaries and school district information that the Census Bureau has on file for their state. Mapping coordinators review the data and submit any changes to the Census Bureau. The Census Bureau reviews and processes the information submitted by the mapping coordinator and updates the Master Address File/Topologically Integrated Geographic Encoding and Referencing (MAF/TIGER) System. During the Verification Phase, mapping coordinators verify that the Census Bureau updated the MAF/TIGER System accurately and completely with updates submitted during the Annotation Phase.

The Census Bureau is adding a feedback component to allow for the solicitation of feedback from respondents to improve the administration of the program and potentially reduce the future burden. Respondents may be asked to provide their feedback on materials, method(s) of data collection, manner of communications, and the usability of program applications and tools.

Affected Public: All fifty states, the District of Columbia, and the Commonwealth of Puerto Rico.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. 16, 141, and 193. *NCES Legal Authority:* Title I of the Elementary and Secondary Education Act as amended by the Every Student Succeeds Act of 2015, Public Law 114–95.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0987.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–11828 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–64–2024]

Approval of Subzone Expansion; Swagelok Company; Cleveland, Ohio

On April 5, 2024, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Cleveland Cuyahoga County Port Authority, grantee of FTZ 40, requesting expansion of Subzone 40I subject to the existing activation limit of FTZ 40, on behalf of Swagelok Company, in Wickliffe, Ohio.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (89 FR 25232, April 10, 2024). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval. Pursuant to the authority delegated to the FTZ Board Executive Secretary (15 CFR 400.36(f)), the application to expand Subzone 40I to include a new site located at 1400 Worden Road, in Wickliffe (Site 13) was approved on May 23, 2024, subject to the FTZ Act and the Board's regulations, including section 400.13, and further subject to FTZ 40's 2,000—acre activation limit.

Dated: May 23, 2024.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2024–11833 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–27–2024]

Foreign-Trade Zone (FTZ) 22, Notification of Proposed Production Activity; Gotion Inc.; (Lithium Battery Packs and Lithium Battery Systems); Manteno, Illinois

Gotion Inc. submitted a notification of proposed production activity to the FTZ Board (the Board) for its facility in Manteno, Illinois within Subzone 22AF. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on May 22, 2024.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via *www.trade.gov/ftz.*

The proposed finished products include high voltage lithium battery systems, high voltage battery system control cabinets, and liquid cooled

battery packs (duty rate ranges from 2.7 to 3.4%).

The proposed foreign-status materials/components include: structural glue; thermal conductive glue; high voltage warning signs; polyurethane foam strips; glass fiber resin sheets/pads; waterproof blinds; plastic fittings/industrial handles; plug-in panel; wire tie rack; fuse plastic cover; plastic sheath seat; plastic sheath cover; plastic panels; plastic buckles; module brackets; plastic pressure seals/plates; plastic casings; plastic covers; plastic rail fasteners; rubber seals/pads; pan-head screws; hex head combination bolts; hex nuts; steel rivets; electrical switch plates; rail jam (irregular shape); control box body cover/panels; insulating pillar; electrical connectors; copper bars; relief valve; power supply switch; lead acid storage battery; lithium-ion energy storage box/battery; storage battery parts; displays; indicator lights; pre-charge 100 watt resistors; main circuit on/off switches; pre-charge on/off switches; surge protectors; fuses; solenoid valve control modules; isolating switches; power switch buttons; high voltage sockets (positive/negative poles); electrical screw terminals; electrical base control panels; three-level battery management systems; switchgear assemblies; insulated copper winding wire; high voltage wiring harnesses; electricity meters; and electrical current sensors (duty rate ranges from duty-free to 6.6%). The request indicates that certain materials/components may be subject to duties under section 301 of the Trade Act of 1974 (section 301), depending on the country of origin. The applicable section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov*. The closing period for their receipt is July 9, 2024.

A copy of the notification will be available for public inspection in the ''Online FTZ Information System'' section of the Board's website.

For further information, contact Kolade Osho at *Kolade.Osho@trade.gov*.

Dated: May 23, 2024.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2024–11835 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 90–9A007]

Export Trade Certificate of Review

ACTION: Notice of issuance of an amended Export Trade Certificate of Review to United States Surimi Commission (USSC), Application No. 90–9A007.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (OTEA), issued an amended Export Trade Certificate of Review to USSC on May 13, 2024.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov*.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4011–21) (the Act) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Conduct

USSC amended its Certificate as follows:

1. Added the following entities as Members of the Certificate within the meaning of section 325.2(l) of the Regulations (15 CFR 325.2(l)):

- Arctic Fjord II LLC
- Arctic Storm Holding Company LLC
- Coastal Alaska Premier Seafoods, LLC
- F/V Neahkahnie LLC
- Fishery Investments, Ltd.
- Phoenix Processor Limited Partnership

2. Removed the following entities as Members of the Certificate:

- AF International, Inc.
- Aleutian Spray Fisheries, Inc
- Fjord Seafoods LLC
- Fjord Fisheries General Partnership
- NWPI, Inc.
- Starbound LLC

List of Members, as amended:

1. American Seafoods Company LLC, Seattle, WA
2. American Seafoods Japan, Ltd., Seattle, WA
3. AS Europe ApS, Seattle, WA
4. American Seafoods China (Dalian) Ltd., Seattle, WA
5. Arctic Storm, Inc., Seattle, WA
6. Arctic Storm International, Inc., Seattle, WA
7. Arctic Fjord, Inc., Seattle, WA
8. Arctic Fjord II LLC, Seattle, WA
9. F/V Neahkahnie LLC, Seattle, WA
10. Arctic Storm Management Group LLC, Seattle, WA
11. Arctic Storm Holding Company LLC, Seattle, WA
12. Glacier Fish Company LLC, Seattle, WA
13. ASM Export Co., Seattle, WA
14. Coastal Alaska Premier Seafoods, LLC, Anchorage, AK
15. Phoenix Processor Limited Partnership, Seattle, WA
16. Fishery Investments, Ltd., Seattle, WA

The effective date of the amended certificate is February 13, 2024, the date on which USSC's application to amend was deemed submitted.

Dated: May 23, 2024.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2024–11814 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–331–805]

Frozen Warmwater Shrimp From Ecuador: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily finds that frozen warmwater shrimp (shrimp) from Ecuador is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2022,

through September 30, 2023. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Kyle Clahane, Matthew Palmer, or Megan Goins, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5449, (202) 482–1678, and (202) 482–0884, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 21, 2023.[1] On March 7, 2024, Commerce postponed the preliminary determination of this investigation until May 22, 2024.[2]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is shrimp from Ecuador. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice.* Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Constructed export prices have been calculated in accordance with section 772(b) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted-average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act. In this investigation, Commerce preliminarily calculated a *de minimis* rate for Industrial Pesquera Santa Priscila S.A. (Santa Priscila)/Tropical Packing Ecuador Tropack S.A.(Tropack) (Santa Priscila/Tropack).[6] Therefore, the only rate that is not zero, *de minimis* or based entirely on facts otherwise available is the rate calculated for Sociedad Nacional de Galápagos C.A./Marina del Rey (SONGA/Marina del Ray).[7] Consequently, the preliminary rate calculated for SONGA/Marina del Ray is also the preliminary rate assigned to all other producers and exporters.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offset(s)) (percent)
Sociedad Nacional de Galápagos C.A./Marina del Rey	10.58	10.58
Industrial Pesquera Santa Priscila S.A./Tropical Packing Ecuador Tropack S.A	* 1.54	N/A
All Others	10.58	10.18

* (*de minimis*).

Consistent with section 733(b)(3) of the Act, Commerce disregards *de minimis* rates and preliminarily determines that individually examined respondents with *de minimis* rates have not made sales of subject merchandise at LTFV.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted average dumping margin or the estimated all-others rate, as follows: (1) the cash deposit rate for the respondents listed

[1] *See Frozen Warmwater Shrimp from Ecuador and Indonesia: Initiation of Less-Than-Fair-Value Investigations,* 88 FR 81043 (November 21, 2023) (*Initiation Notice*).

[2] *See Frozen Warmwater Shrimp from Ecuador and Indonesia: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 89 FR 16535 (March 7, 2024).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Frozen Warmwater Shrimp from Ecuador,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice,* 88 FR at 81043.

[6] Commerce preliminarily determines that these companies are a single entity. *See* Preliminary Decision Memorandum; *see also* Memorandum, ''Preliminary Affiliation and Collapsing Memorandum,'' dated concurrently with this notice (Preliminary Affiliation and Collapsing Memorandum).

[7] Commerce preliminarily determines that these companies are a single entity. *See* Preliminary Decision Memorandum; *see also* Preliminary Affiliation and Collapsing Memorandum.

above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise, except as explained below; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Because the estimated weighted-average dumping margin for Santa Priscila/Tropack is *de minimis,* entries of shipments of subject merchandise from Santa Priscila/Tropack will not be subject to suspension of liquidation or cash deposit requirements. In such situations, Commerce applies the exclusion to the provisional measures to the producer/exporter combination that was examined in the investigation. Accordingly, Commerce is directing CBP not to suspend liquidation of entries of subject merchandise from Santa Priscila/Tropack. Entries of shipments of subject merchandise from these companies in any other producer/exporter combination, or by third parties that sourced subject merchandise from the excluded producer/exporter combination, are subject to the provisional measures at the all-others rate.

Should the final estimated weighted-average dumping margin be zero or *de minimis* for the producer/exporter combination identified above, entries of shipments of subject merchandise from this producer/exporter combination will be excluded from the potential antidumping duty order. Such exclusions are not applicable to merchandise exported to the United States by these respondents in any other producer/exporter combinations or by third parties that sourced subject merchandise from the excluded producer/exporter combination.

Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce preliminarily made an affirmative determination for countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted cash deposit rate may be found in the ''Preliminary Determination'' section above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting estimated antidumping duty cash deposits unadjusted for countervailed export subsidies at the time that the provisional CVD measures expire. These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose to interested parties the calculations performed in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case brief.[8] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[9]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[10] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[11]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2)(B) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final

[8] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[9] *See* 19 CFR 351.309(c)(2) and (d)(2).

[10] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[11] *See APO and Service Final Rule.*

determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On April 17, 2024 and May 20, 2024, pursuant to 19 CFR 351.210(e), American Shrimp Processors Association (ASPA, or the petitioner), and Santa Priscila/Tropack and SONGA, respectively, requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[12] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce's final determination will be issued no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: May 22, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation includes certain frozen warmwater shrimp and prawns whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off, deveined or not deveined, cooked or raw, or otherwise processed in frozen form. ''Tails'' in this context means the tail fan, which includes the telson and the uropods.

The frozen warmwater shrimp and prawn products included in the scope, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the Penaeidae family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (Penaeus vannemei), banana prawn (Penaeus merguiensis), fleshy prawn (Penaeus chinensis), giant river prawn (Macrobrachium rosenbergii), giant tiger prawn (Penaeus monodon), redspotted shrimp (Penaeus brasiliensis), southern brown shrimp (Penaeus subtilis), southern pink shrimp (Penaeus notialis), southern rough shrimp (Trachypenaeus curvirostris), southern white shrimp (Penaeus schmitti), blue shrimp (Penaeus stylirostris), western white shrimp (Penaeus occidentalis), and Indian white prawn (Penaeus indicus).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope. In addition, food preparations, which are not ''prepared meals,'' that contain more than 20 percent by weight of shrimp or prawn are also included in the scope.

Excluded from the scope are: (1) breaded shrimp and prawns (HTSUS subheading 1605.21.1020); (2) shrimp and prawns generally classified in the Pandalidae family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTSUS subheadings 0306.36.0020 and 0306.36.0040); (4) shrimp and prawns in prepared meals (HTSUS subheadings 1605.21.0500 and 1605.29.0500); (5) dried shrimp and prawns; (6) canned warmwater shrimp and prawns (HTSUS subheading 1605.29.1040); and (7) certain battered shrimp. Battered shrimp is a shrimp-based product: (1) that is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a ''dusting'' layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the non-shrimp content of the end product constituting between four and ten percent of the product's total weight after being dusted, but prior to being frozen; and (5) that is subjected to individually quick frozen (IQF) freezing immediately after application of the dusting layer. When dusted in accordance with the definition of dusting above, the battered shrimp product is also coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the scope are currently classified under the following HTSUS subheadings: 0306.17.0004, 0306.17.0005, 0306.17.0007, 0306.17.0008, 0306.17.0010, 0306.17.0011, 0306.17.0013, 0306.17.0014, 0306.17.0016, 0306.17.0017, 0306.17.0019, 0306.17.0020, 0306.17.0022, 0306.17.0023, 0306.17.0025, 0306.17.0026, 0306.17.0028, 0306.17.0029, 0306.17.0041, 0306.17.0042, 1605.21.1030, and 1605.29.1010. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2024–11898 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–DS–P

[12] *See* Petitioner's Letter, ''Warmwater Shrimp from Ecuador and Indonesia: Petitioner's Requests to Postpone Final Determinations,'' dated April 17, 2024; *see also* Santa Priscila and SONGA's Letter, ''Request to Extend the Deadline for the Final Determination,'' dated May 20, 2024.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–351–861, C–834–813, C–557–829]

Ferrosilicon From Brazil, Kazakhstan, and Malaysia: Postponement of Preliminary Determinations in the Countervailing Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Bob Palmer or Laurel Smalley (Brazil), Peter Shaw (Kazakhstan), and Suresh Maniam (Malaysia), AD/CVD Operations, Offices I, VII, and VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9068, (202) 482–3456, (202) 482–0697, or (202) 482–1603, respectively.

SUPPLEMENTARY INFORMATION:

Background

On April 17, 2024, the U.S. Department of Commerce (Commerce) initiated countervailing duty (CVD) investigations of imports of ferrosilicon from Brazil, Kazakhstan, Malaysia and the Russian Federation (Russia).[1]

[1] *See Ferrosilicon from Brazil, Kazakhstan, Malaysia, and the Russian Federation: Initiation of Countervailing Duty Investigations,* 89 FR 31133 (April 24, 2024).

Currently, the preliminary determinations are due no later than June 21, 2024.

Postponement of Preliminary Determinations

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.

On May 17, 2024, the petitioners [2] submitted a timely request that Commerce postpone the preliminary CVD determinations with respect to Brazil, Kazakhstan, and Malaysia.[3] The petitioners stated that they request postponement because, due to the number and nature of the subsidy programs, the normal 65-day deadline for the preliminary determinations would not provide sufficient time for Commerce to adequately examine the amount of subsidies that producers and exporters of subject merchandise in Brazil, Kazakhstan, and Malaysia may have received.[4]

In accordance with 19 CFR 351.205(e), the petitioners stated the reasons for requesting a postponement of the preliminary determination, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determinations to no later than 130 days after the date on which these investigations were initiated, *i.e.,* August 26, 2024.[5] Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations of these investigations will continue to be 75 days after the date of the preliminary determinations.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: May 23, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–11908 Filed 5–29–24; 8:45 am]

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[2] The petitioners are CC Metals and Alloys, LLC and Ferroglobe USA, Inc.

[3] *See* Petitioners' Letter, ''Petitioner's Request to Postpone the Deadline for the Preliminary Determination,'' dated May 17, 2024. The petitioners did not request a postponement of the CVD investigation with respect to ferrosilicon from Russia.

[4] *Id.* at 2.

[5] Postponing the preliminary determination to 130 days after initiation would place the deadline on Sunday, August 25, 2024. Commerce's practice dictates that where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–560–842]

Frozen Warmwater Shrimp From Indonesia: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that frozen warmwater shrimp (shrimp) from Indonesia is being, or likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is October 1, 2022, through September 30, 2023. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Rachel Jennings or Miranda Bourdeau, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1110 or (202) 482–2021, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on November 21, 2023.[1] On March 7, 2024, Commerce postponed the preliminary determination of this investigation until May 22, 2024.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is shrimp from Indonesia. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] No interested party commented on the scope of the investigation as it appeared in the *Initiation Notice.* Commerce is not preliminarily modifying the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice.

Methodology

Commerce is conducting this investigation in accordance with section

[1] *See Frozen Warmwater Shrimp from Ecuador and Indonesia: Initiation of Less-Than-Fair-Value Investigations,* 88 FR 81043 (November 21, 2023) (*Initiation Notice*).

[2] *See Frozen Warmwater Shrimp from Ecuador and Indonesia: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigations,* 89 FR 16535 (March 7, 2024).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination in the Less-Than-Fair-Value Investigation of Frozen Warmwater Shrimp from Indonesia'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Normal value is calculated in accordance with section 773 of the Act. In addition, Commerce has relied on partial facts available under section 776(a)(1) of the Act for PT First Marine Seafoods and PT Khom Foods (collectively, First Marine/Khom Foods).[6] For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act. In this investigation, Commerce preliminarily calculated a zero rate for PT Bahari Makmur Sejati (BMS). Therefore, the only rate that is not zero, *de minimis* or based entirely on facts otherwise available is the rate calculated for First Marine/Khom Foods. Consequently, the rate calculated for First Marine/Khom Foods is also assigned as the rate for all other producers and exporters.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Weighted-average dumping margin (percent) [7]
PT Bahari Makmur Sejati	0.00
PT First Marine Seafoods; PT Khom Foods	6.30
All Others	6.30

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise except as explained below; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Because the estimated weighted-average dumping margin for BMS is zero or *de minimis,* entries of shipments of subject merchandise from BMS will not be subject to suspension of liquidation or cash deposit requirements during the provisional measures period. In such situations, Commerce applies the exclusion to the provisional measures to the producer/exporter combination that was examined in the investigation. Accordingly, Commerce is directing CBP not to suspend liquidation of entries of subject merchandise produced and exported by BMS. Entries of shipments of subject merchandise from these companies in any other producer/exporter combination, or by third parties that sourced subject merchandise from the excluded producer/exporter combination, are subject to the provisional measures at the all-others rate.

Should the final estimated weighted-average dumping margin be zero or *de minimis* for the producer/exporter combination identified above, entries of shipments of subject merchandise from this producer/exporter combination will be excluded from the potential antidumping duty order. Such exclusions are not applicable to merchandise exported to the United States by these respondents in any other producer/exporter combinations or by third parties that sourced subject merchandise from the excluded producer/exporter.

Disclosure

Commerce intends to disclose to interested parties its calculations performed in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Consistent with 19 CFR 351.224(e), Commerce will analyze and, if appropriate, correct any timely allegations of significant ministerial errors by amending the preliminary determination. However, consistent with 19 CFR 351.224(d), Commerce will not consider incomplete allegations that do not address the significance standard under 19 CFR 351.224(g) following the preliminary determination. Instead, Commerce will address such allegations in the final determination together with issues raised in the case briefs or other written comments.

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation.[8] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[9] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[10]

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this investigation, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised

[6] Commerce preliminarily determines that PT First Marine Seafoods and PT Khom Foods are a single entity. *See* Preliminary Decision Memorandum.

[7] Commerce preliminarily determined that countervailable subsidies are not being provided to producers and exporters of shrimp from Indonesia. *See Frozen Warmwater Shrimp from Indonesia: Preliminary Negative Countervailing Duty Determination, and Alignment of Final Determination With the Final Antidumping Duty Determination,* 89 FR 22383 (April 1, 2024), and accompanying Preliminary Decision Memorandum.

[8] *See* 19 CFR 351.309(c)(1)(i); *see also* 19 CFR 351.303 (for general filing requirements).

[9] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Final Rule*).

[10] *See* 19 351.309(c)(2) and (d)(2).

in their briefs.[11] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in this investigation. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[12]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On April 16, and 18, 2024, pursuant to 19 CFR 351.210(e), BMS and First Marine requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months, respectively.[13] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporters account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: May 22, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation includes certain frozen warmwater shrimp and prawns whether wild-caught (ocean harvested) or farm-raised (produced by aquaculture), head-on or head-off, shell-on or peeled, tail-on or tail-off, deveined or not deveined, cooked or raw, or otherwise processed in frozen form. ''Tails'' in this context means the tail fan, which includes the telson and the uropods.

The frozen warmwater shrimp and prawn products included in the scope, regardless of definitions in the Harmonized Tariff Schedule of the United States (HTSUS), are products which are processed from warmwater shrimp and prawns through freezing and which are sold in any count size.

The products described above may be processed from any species of warmwater shrimp and prawns. Warmwater shrimp and prawns are generally classified in, but are not limited to, the Penaeidae family. Some examples of the farmed and wild-caught warmwater species include, but are not limited to, whiteleg shrimp (Penaeus vannemei), banana prawn (Penaeus merguiensis), fleshy prawn (Penaeus chinensis), giant river prawn (Macrobrachium rosenbergii), giant tiger prawn (Penaeus monodon), redspotted shrimp (Penaeus brasiliensis), southern brown shrimp (Penaeus subtilis), southern pink shrimp (Penaeus notialis), southern rough shrimp (Trachypenaeus curvirostris), southern white shrimp (Penaeus schmitti), blue shrimp (Penaeus stylirostris), western white shrimp (Penaeus occidentalis), and Indian white prawn (Penaeus indicus).

Frozen shrimp and prawns that are packed with marinade, spices or sauce are included in the scope. In addition, food preparations, which are not ''prepared meals,'' that contain more than 20 percent by weight of shrimp or prawn are also included in the scope.

Excluded from the scope are: (1) breaded shrimp and prawns (HTSUS subheading 1605.21.10.20); (2) shrimp and prawns generally classified in the Pandalidae family and commonly referred to as coldwater shrimp, in any state of processing; (3) fresh shrimp and prawns whether shell-on or peeled (HTSUS subheadings 0306.36.0020 and 0306.36.0040); (4) shrimp and prawns in prepared meals (HTSUS subheading 1605.21.05.00 and 1605.29.05.00); (5) dried shrimp and prawns; (6) canned warmwater shrimp and prawns (HTSUS subheading 1605.29.10.40); and (7) certain battered shrimp. Battered shrimp is a shrimp-based product: (1) that is produced from fresh (or thawed-from-frozen) and peeled shrimp; (2) to which a ''dusting'' layer of rice or wheat flour of at least 95 percent purity has been applied; (3) with the entire surface of the shrimp flesh thoroughly and evenly coated with the flour; (4) with the non-shrimp content of the end product constituting between four and ten percent of the product's total weight after being dusted, but prior to being frozen; and (5) that is subjected to IQF freezing immediately after application of the dusting layer. When dusted in accordance with the definition of dusting above, the battered shrimp product is also coated with a wet viscous layer containing egg and/or milk, and par-fried.

The products covered by the scope are currently classified under the following HTSUS subheadings: 0306.17.0004, 0306.17.0005, 0306.17.0007, 0306.17.0008, 0306.17.0010, 0306.17.0011, 0306.17.0013, 0306.17.0014, 0306.17.0016, 0306.17.0017, 0306.17.0019, 0306.17.0020, 0306.17.0022, 0306.17.0023, 0306.17.0025, 0306.17.0026, 0306.17.0028, 0306.17.0029, 0306.17.0041, 0306.17.0042, 1605.21.1030, and 1605.29.1010. These HTSUS subheadings are provided for convenience and for customs purposes only and are not dispositive, but rather the written description of the scope is dispositive.

[11] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[12] *See APO and Service Final Rule,* 88 FR at 67070–73, 67076.

[13] *See* BMS's Letter, ''Request to Extend Final Determination,'' dated April 16,2024; *see also* First Marine's Letter, ''Request to Extend Final Determination,'' dated April 18, 2024.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Affiliation/Single Entity Treatment
V. Discussion of the Methodology
  A. Comparisons to Normal Value
  B. Product Comparisons
  C. Date of Sale
  D. Export Price
  E. Normal Value
VI. Currency Conversion
VII. Recommendation

[FR Doc. 2024–11899 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–902]

Organic Soybean Meal From India: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to certain producers/exporters of organic soybean meal from India. The period of review (POR) is September 3, 2021, through December 31, 2022. Interested parties are invited to comment on these preliminary results.

DATES: Applicable May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Peter Shaw or Tylar Lewis, AD/CVD Operations, Office OVII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0697 or (202) 482–6009, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 12, 2023, Commerce published in the **Federal Register** the notice of initiation of an administrative review of the *Order* with respect to 38 companies.[1] On August 11, 2023, Commerce selected Delight Lifelike Products Private Ltd. and Vinod Kumar Ranjeet Singh Bafna.[2] Subsequently, on October 24, 2023, we selected Shri Sumati Industries Private Limited (Shri Sumati) and Shanti Worldwide (Shanti), the only two companies for which an administrative review was requested and not withdrawn, as the mandatory respondents.[3] Pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), Commerce extended the deadline for the preliminary results until May 23, 2024.[4]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5] A list of topics discussed in the Preliminary Decision Memorandum is included in Appendix I. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order

The products covered by this *Order* is organic soybean meal from India. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. A list of the 35 companies Commerce received timely-filed withdrawal requests from is provided below in Appendix II. Because the withdrawal requests were timely filed and no other parties requested a review of these companies, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* with respect to these 35 companies.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Act. For each of the subsidy programs found to be countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[6] For a full description of the methodology underlying our conclusions, including our reliance on adverse facts available pursuant to sections 776(a) and (b) of the Act, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, we preliminarily determine that for 2021 and 2022, the following estimated countervailable subsidy rates exist:

Company	Subsidy rate 2021 (percent *ad valorem*)	Subsidy rate 2022 (percent *ad valorem*)
Shri Sumati Industries Private Limited	7.99	4.08
Shanti Worldwide	261.80	261.80

Disclosure

Commerce intends to disclose its calculations and analysis performed in connection with the preliminary results to interested parties within five days of its public announcement, or if there is no public announcement, within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Public Comment

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs to Commerce no later than 30 days after the publication of these preliminary results of review in the **Federal**

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 44262 (July 12, 2023); *see also Organic Soybean Meal from India: Countervailing Duty Order,* 87 FR 29735 (May 16, 2022) (*Order*).

[2] *See* Memorandum, ''Respondent Selection,'' dated August 11, 2023.

[3] *See* Memorandum, ''Respondent Selection,'' dated October 24, 2023.

[4] *See* Memorandum, ''Extension of Deadline for Preliminary Results,'' dated January 9, 2024.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Countervailing Duty Order on Organic Soybean Meal from India; 2021–2022,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

Register. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline for filing case briefs.[7] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[8] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In this review, we instead request that interested parties provide at the beginning of their briefs a public, executive summary for each issue raised in their briefs.[9] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[10]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.[11]

[7] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[8] *See* 19 CFR 351.309(c)(2) and (d)(2).

[9] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[10] *See APO and Service Procedures.*

[11] *See* 19 CFR 351.310(d).

Cash Deposit Requirements

Pursuant to section 751(a)(2)(C) of the Act, Commerce intends, upon publication of the final results, to instruct U.S. Customs and Border Protection (CBP) to collect cash deposits of estimated countervailing duties in the amounts shown for the year 2022 for Shri Sumati and Shanti, except where the rate calculated in the final results is zero or *de minimis,* no cash deposit will be required on shipments of the subject merchandise entered or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Assessment Rates

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily assigned subsidy rates in the amounts shown above for the producers/exporters shown above. Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

For the companies for which this review is rescinded with these preliminary results, we will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period September 3, 2021, through December 31, 2022, in accordance with 19 CFR 351.212(c)(1)(i).

Final Results

Unless the deadline is extended pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2), Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised by parties in their comments, within 120 days after the date of publication of these preliminary results in the **Federal Register**.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: May 23, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the Non-exclusive Functions and Duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

Appendix II

List of Companies for Which Commerce Is Rescinding Its Review

1. Abhay Oil Industries
2. Agrawal Oil & Biocheam
3. Bergwerff Organic India Pvt., Ltd.; Suminter India Organics Pvt., Ltd.
4. Bio Treasure Overseas
5. Delight Lifelike Products Private Ltd.
6. Delight Sustainable Products Llp
7. Eco Gold Nutri & Organics Llp
8. Eco Gold Nutri And Organics Llp
9. Ecopure Specialties Limited
10. Jay Shree Agro Products
11. Kaj Traders
12. Kanishka Organics Llp
13. Keshav Proteins and Organic LLP
14. Kiesriya Agro Exim Pvt., Ltd.
15. Mani Loni
16. Navjyot International
17. Prasad Cotton Industries Pvt., Ltd.
18. Radha Krishna Oil Product
19. Raj Foods International
20. Raj Natural Food Pvt., Ltd.
21. Rajat Agro Commodities Pvt., Ltd.
22. Reindeer Organics Llp
23. Sai Smaran Foods Ltd.
24. Satguru Agro Resources Private Ltd.
25. Satguru Organics Pvt., Ltd.
26. Seasons International Pvt., Ltd.
27. Shanti Overseas
28. Shemach Impex
29. Shivam Enterprises
30. Shri Narayani Mfg. Co.
31. Tejawat Organic Foods
32. Unique Organics Ltd.
33. Vimala Food Products
34. Vinod Kumar Ranjeet Singh Bafna

35. We Organic Nature Pvt. Ltd.

[FR Doc. 2024–11909 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Board of Overseers of the Malcolm Baldrige National Quality Award

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The Board of Overseers of the Malcolm Baldrige National Quality Award (Board of Overseers) will meet in open session on Thursday, June 13, 2024, from 11:00 a.m. to 4:00 p.m. Eastern time. The Board of Overseers, appointed by the Secretary of Commerce, reports the results of the Malcolm Baldrige National Quality Award (Award) activities to the Director of the National Institute of Standards and Technology (NIST) each year, along with its recommendations for the improvement of the Award process. The purpose of this meeting is to discuss and review information received from the National Institute of Standards and Technology. The agenda will include: Baldrige Program Update, Baldrige Foundation Update, Ethics Review, Alliance for Performance Excellence Update, Communities of Excellence Update, and New Business/Public Comment.

DATES: The meeting will be held on Thursday, June 13, 2024, from 11:00 a.m. Eastern Time until 4:00 p.m. Eastern Time. The meeting will be open to the public.

ADDRESSES: The meeting will be virtual via webinar. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Robert Fangmeyer, Director, Baldrige Performance Excellence Program, phone: 301–975–2361, email *robert.fangmeyer@nist.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. 1000 *et seq.,* notice is hereby given that the Board of Overseers will meet in open session on the date(s) and at the time(s) set forth in the **DATES** section of this notice. The Board of Overseers (Board), composed of approximately twelve members preeminent in the field of organizational performance excellence and appointed by the Secretary of Commerce, makes an annual report on the results of Award activities to the Director of the National Institute of Standards and Technology (NIST), along with its recommendations for improvement of the Award process.

The purpose of this meeting is to discuss and review information received from NIST. The agenda will include: Baldrige Program Update, Baldrige Foundation Update, Ethics Review, Alliance for Performance Excellence Update, Communities of Excellence Update, and New Business/Public Comment. The agenda may change to accommodate the Board of Overseers business. The final agenda will be posted on the NIST Baldrige Performance Excellence website at *http://www.nist.gov/baldrige/community/overseers.cfm.* The meeting is open to the public.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Board's affairs and/or the Judges Panel's general process are invited to request a place on the agenda. Approximately one-half hour will be reserved in the afternoon for public comments, and speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received but is likely to be about 3 minutes each. The exact time for public comments will be included in the final agenda that will be posted on the Baldrige Performance Excellence Program website at *http://www.nist.gov/baldrige/community/overseers.cfm.* Questions from the public will not be considered during this period. Requests must be submitted by email to Robyn Decker at *robyn@nist.gov* and must be received by 4:00 p.m. Eastern Time, June 6, 2024, to be considered. Speakers who wish to expand upon their oral statements, those who had wished to speak, but could not be accommodated on the agenda, and those who were unable to attend in person are invited to submit written statements by email to *robyn@nist.gov.*

Pursuant to 41 CFR § 102–3.150(a)(6), Admittance instructions: All participants will be attending virtually via webinar and need to pre-register to be admitted. Please contact Mrs. Robyn Decker by email at *robyn@nist.gov;* Mailing Address: NIST c/o Robyn Decker 100 Bureau Drive, MS 1020, Gaithersburg, MD 20899; or 301–975–2361, please provide her with your name, email, and phone number; and she will provide you with instructions for admittance. All requests to attend must be received by 4:00 p.m. Eastern Time, June 6, 2024.

Authority: 15 U.S.C. 3711a(d)(1), 15 U.S.C. 3711a(d)(2)(B) and the Federal Advisory Committee Act, as amended, 5 U.S.C. 1000 *et seq.*

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2024–11876 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XV200]

Solicitation of Nominations for Membership on the Space Weather Advisory Group (SWAG)

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of solicitation of nominations for membership.

SUMMARY: Pursuant to the Promoting Research and Observations of Space Weather to Improve the Forecasting of Tomorrow (PROSWIFT) Act of and the Federal Advisory Committee Act (FACA), the Space Weather Interagency Working Group (interagency working group), requests nominations for membership on the SWAG.

DATES: Nominations should be sent to the web address specified below and must be received on or before June 30, 2024.

ADDRESSES: Nominations and applications should be submitted electronically to the Designated Federal Officer (DFO), SWAG, NOAA, Amy Macpherson via email: *amy.macpherson@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Amy Macpherson, DFO, SWAG, and Acting National Space Weather Program Manager, National Weather Service, NOAA, at *amy.macpherson@noaa.gov* and William Murtagh, Program Coordinator, Space Weather Prediction Center, NOAA, at *william.murtagh@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Authority

Establishment of the SWAG implements a statutory requirement of the PROSWIFT Act 2020 (Pub. L. 116–181), 51 U.S.C. 60601 *et seq.* The SWAG is governed by the FACA, as amended, 5 U.S.C. App., which sets forth standards for the formation and use of advisory committees. The mission of the SWAG is to receive advice from the academic community, the commercial space weather sector, and nongovernmental space weather end

users to advise the Space Weather Interagency Working Group (interagency working group) established by the National Science and Technology Council pursuant to 51 U.S.C. 60601(c). Duties include advising the interagency working group on the following: facilitating advances in the space weather enterprise of the United States; improving the ability of the United States to prepare for, mitigate, respond to, and recover from space weather phenomena; enabling the coordination and facilitation of research to operations and operations to research, as described in section 60604(d) of title 51, United States Code; and developing and implementing the integrated strategy under 51 U.S.C. 60601(c), including subsequent updates and reevaluations. The SWAG shall also conduct a recurring, comprehensive survey of the needs of users of space weather products to identify the space weather research, observations, forecasting, prediction, and modeling advances required to improve space weather products, as required by 51 U.S.C. 60601(d)(3).

II. Structure

The SWAG shall consist of not more than 15 members, including a chair, of whom: 5 members shall be representatives of the academic community; 5 members shall be representatives of the commercial space weather sector; and 5 members shall be nongovernmental representatives of the space weather end-user community. Members will be chosen to provide an appropriate range of views that represent the span of the space weather community and end-user sectors. Members shall serve in a representative capacity; they are, therefore, not Special Government Employees. As such, members are not subject to the ethics rules applicable to Government employees, except that they must not misuse Government resources or their affiliation with the Committee for personal purposes. All members of the SWAG will be appointed by the interagency working group for a 3-year term, with one member appointed by NOAA as the Chair. Members may not serve on the SWAG for more than two consecutive terms. A member of the SWAG may not serve as the Chair of the SWAG for more than two terms, regardless of whether the terms are consecutive. The SWAG will meet approximately three times each year, which may be conducted in person or by teleconference, webinar, or other means. Additional meetings may be called as appropriate, with approval by the Administrator of NOAA. Members are reimbursed for actual and reasonable travel in accordance with Federal per diem expenses incurred in performing such duties but will not be reimbursed for their time. As a Federal Advisory Committee, the SWAG's membership is required to be balanced in terms of viewpoints represented and the functions to be performed as well as appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, or cultural, religious, or socioeconomic status.

III. Nominations

Interested persons may nominate themselves or third parties. An application is required to be considered for SWAG membership, regardless of whether a person is nominated by a third party or self-nominated. The application package must include: (1) the nominee's full name, title, institutional affiliation, and contact information; (2) identification of the nominee's area(s) of industry perspective—academia, commercial service provider, or end-user; (3) a short description of his/her qualifications relative to the kinds of advice being solicited by NOAA in this Notice; and (4) a current resume (maximum length four pages). All nomination information should be provided in a single, complete package, and should be sent to the Designated Federal Officer of the SWAG at the electronic address provided above.

Dated: May 23, 2024.

Michael Farrar,

Director, National Centers for Environmental Prediction, National Weather Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2024–11827 Filed 5–29–24; 8:45 am]

BILLING CODE 3510–KE–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Women in the Services; Notice of Federal Advisory Committee Meeting

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Advisory Committee on Women in the Services (DACOWITS) will take place.

DATES: DACOWITS will hold an open to the public meeting—Tuesday, June 25, 2024, from 8:00 a.m. to 2:30 p.m. (EST).

ADDRESSES: The meeting will take place at the Association of the United States Army Conference Center, located at 2425 Wilson Boulevard, Arlington, Virginia 22201. The meeting will also be streamed virtually. To participate in the meeting, see the Meeting Accessibility section for instructions.

FOR FURTHER INFORMATION CONTACT: Colonel Samantha Frazier, Designated Federal Officer (DFO), (202) 650–2943 (voice), *Samantha.j.frazier11.mil@mail.mil* (email). The most up-to-date changes to the meeting agenda can be found on the website: *https://dacowits.defense.gov.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 CFR 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available at the DACOWITS website, *https://dacowits.defense.gov/.* Materials presented in the meeting may also be obtained on the DACOWITS website.

Purpose of the Meeting: The purpose of the meeting is for the DACOWITS to receive briefings and have discussions on topics related to the recruitment, retention, employment, integration, well-being, and treatment of women in the Armed Forces of the United States.

Agenda: Tuesday, June 25, 2024, from 8:00 a.m. to 2:30 p.m.—Welcome; Introductions; Announcements; Request for Information Status Update; Briefings from United States Military Entrance Processing (MEPS) Command and the Military Services' Medical Waiver Review Authorities on MEPS processes and medical waivers; Briefings from the Military Services' on recruiting barriers and challenges; Briefings from Military Community Advocacy Directorate, Military Criminal Investigative Organization, Defense Health Agency, and the Military Services on domestic abuse and intimate partner violence; DACOWITS discussion; and a Public Comment Period from 2:00 p.m. to 2:15 p.m.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to availability of space, from 8:00 a.m. to 2:30 p.m. on June 25, 2024. The meeting will also be

streamed by videoconference. The number of participants is limited and is on a first-come basis. Any member of the public who wishes to participate via videoconference must register by contacting DACOWITS at *osd.pentagon.ousd-p-r.mbx.dacowits@mail.mil* or by contacting Mr. Robert Bowling at (703) 380–0116 no later than Monday, June 17, 2024. Once registered, the videoconference information will be provided.

Special Accommodations: Individuals requiring special physical or electronic accommodations to access the public meeting should contact Mr. Robert Bowling no later than Monday, June 17, 2024, so appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102–3.140 and section 10(a)(3) of the FACA, interested persons may submit a written statement to the DACOWITS pertaining to its overall mission/scope or in response to the approved meeting agenda announced in this notice. Individuals submitting a written statement must submit their statement no later than 5:00 p.m., Monday, June 17, 2024, to Mr. Robert Bowling, (703) 380–0116 (voice), or to *osd.pentagon.ousd-p-r.mbx.dacowits@mail.mil.* Mailing address is 4800 Mark Center Drive, Suite 06E22, Alexandria, VA 22350. Members of the public interested in making an oral statement must submit a written statement of their comments. If a statement is not received by Monday, June 17, 2024, it may not be provided to or considered by the Committee during this quarterly business meeting. After reviewing the written statements, the Chair and the DFO will determine if the requesting persons are permitted to make an oral presentation. Oral presentations will be limited to two minutes. The DFO will review all timely submissions with the DACOWITS Chair and will provide to all members of the Committee.

Dated: May 23, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–11824 Filed 5–29–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Adoption of National Oceanographic and Atmospheric Administration Categorical Exclusion Pursuant to a Section of the National Environmental Policy Act (NEPA)

AGENCY: Defense Advanced Research Projects Agency (DARPA), Department of Defense (DoD).

ACTION: Notice of adoption of the National Oceanic and Atmospheric Administration (NOAA) categorical exclusion for habitat restoration.

SUMMARY: DARPA is adopting the NOAA categorical exclusion C1 for the restoration of coral reefs in south Florida. This notice describes the proposed action for which DARPA intends to use the NOAA categorical exclusion and details the consultation between the agencies.

DATES: This action is effective May 30, 2024.

FOR FURTHER INFORMATION CONTACT: Dr. Catherine Campbell, 703–526–2044 (Voice), *Catherine.Campbell@darpa.mil* (Email).

SUPPLEMENTARY INFORMATION:

I. Background

National Environmental Policy Act and Categorical Exclusions

NEPA, 42 U.S.C. 4321–4347 requires all Federal agencies to assess the environmental impacts of their actions. Congress enacted NEPA to encourage productive and enjoyable harmony between humans and the environment, recognizing the profound impact of human activity and the critical importance of restoring and maintaining environmental quality to the overall welfare of humankind. NEPA seeks to ensure agencies consider the environmental effects of their proposed actions in their decision-making processes and inform and involve the public in that process. NEPA created the Council on Environmental Quality (CEQ), which promulgated NEPA implementing regulations, 40 Code of Federal Regulations (CFR) parts 1500 through 1508 (CEQ regulations).

To comply with NEPA, agencies determine the appropriate level of review—an Environmental Impact Statement (EIS), Environmental Assessment (EA), or categorical exclusion. (42 U.S.C. 4336). If a proposed action is likely to have significant environmental effects, the agency must prepare an EIS and document its decision in a record of decision. Id. If the proposed action is not likely to have significant environmental effects or the effects are unknown, the agency may instead prepare an EA, which involves a more concise analysis and process than an EIS. Id.

Following the EA, the agency may conclude the process with a finding of no significant impact if the analysis shows that the action will have no significant effects. If the analysis in the EA finds that the action is likely to have significant effects, however, then an EIS is required.

Under NEPA and the CEQ regulations, a Federal agency may establish in its NEPA implementing procedures categorical exclusions, which are categories of actions the agency has determined normally do not significantly affect the quality of the human environment. (40 CFR 1501.4, 1507.3(e)(2)(ii), 1508.1(d)). If an agency determines that a categorical exclusion covers a proposed action, it then evaluates the proposed action for extraordinary circumstances in which a normally excluded action may have a significant effect. (40 CFR 1501.4(b)). If no extraordinary circumstances are present or if further analysis determines that the extraordinary circumstances do not involve the potential for significant environmental impacts, the agency may apply the categorical exclusion to the proposed action without preparing an EA or EIS. (40 CFR 1501.4). If the extraordinary circumstances have the potential to result in significant effects, the agency is required to prepare an EA or EIS.

Section 109 of NEPA, enacted as part of the Fiscal Responsibility Act of 2023, allows a Federal agency to adopt a categorical exclusion listed in another agency's NEPA procedures for a category of proposed agency actions for which the categorical exclusion was established (42 U.S.C. 4336(c)). To adopt another agency's categorical exclusion under Section 109, an agency must identify the relevant categorical exclusion listed in that agency's (''establishing agency'') NEPA procedures that cover its category of proposed actions or related actions; consult with the establishing agency to ensure that the proposed adoption of the categorical exclusion to a category of actions is appropriate; identify to the public the categorical exclusion that the agency plans to use for its proposed actions; and document adoption of the categorical exclusion. *Id.* This notice documents DARPA's adoption of NOAA's categorical exclusion under Section 109 of NEPA.

II. Identification of the Categorical Exclusion

NOAA's categorical exclusion, C1, for habitat restoration actions is codified in NOAA's procedures for implementing NEPA (*https://www.noaa.gov/sites/default/files/2021-10/NOAA-NAO-216-6A-Companion-Manual-03012018%20%281%29.pdf*) and related authorities, as contained in the Companion Manual to NOAA Administrative Order NAO 2–16–6A. The text of categorical exclusion C–1 is as follows, ''Habitat restoration actions, provided that such action: (1) transplants only organisms currently or formerly present at the site or in its immediate vicinity (if transplant is a component of the action); (2) does not require substantial placement of fill or dredging; (3) does not involve any removal of debris, excavation, or conditioning of soils unless such removal of debris, excavation, or conditioning of soils is geographically limited to the impact area such that site conditions will not impede or negatively alter natural processes, is in compliance with all permit and disposal requirements, and will not impact critical aquifers or recharge areas; and (4) does not involve an added risk of human or environmental exposure to toxic or hazardous substances, pathogens, or radioactive materials. *Notes:* If applicable, limitations and mitigation measures identified in the NOAA Restoration Center Programmatic Environmental Impact Statement for Habitat Restoration Actions must be followed. This CE includes, but is not limited to, response or restoration actions under CERLCA, OPA, or NMSA, if such actions help to restore an ecosystem, habitat, biotic community, or population of living resources to a determinable pre-impact condition prior to the incident leading to the response or restoration.''

Proposed Action

DARPA proposes to deploy and field test ecological engineering and biological adaptation strategies for corals in south Florida that have been tested in laboratory settings. The need to field test these strategies is to determine the best methods for coral translocation that will maximize wave attenuation, promote coral growth, mimic natural reef building and self-repair, increase the adaptive capacity of coral, and provide for long-term resiliency of the artificial reef that will be a part of DARPA's Reefense program in south Florida.

III. Consideration of Extraordinary Circumstances

If an agency determines that a categorical exclusion covers a proposed action, the agency must evaluate the proposed action for extraordinary circumstances in which a normally excluded action may have a significant effect. (40 CFR 1501.4(b)). DARPA does not currently have its own NEPA implementing procedures to guide its application of extraordinary circumstances. Until DARPA establishes NEPA implementing procedures, for purposes of considering extraordinary circumstances in connection with the NOAA categorical exclusion discussed in this notice, DARPA has considered whether the proposed action has the potential to result in significant effects. DARPA has assessed extraordinary circumstances and determined they are not present.

IV. Consultation With NOAA and Determination of Appropriateness

DARPA and NOAA consulted on the appropriateness of DARPA's adoption of the categorical exclusion. This consultation included a review of NOAA's experience applying the categorical exclusion and the proposed action for which DARPA plans to utilize it. Following this consultation and review, DARPA has determined that the impacts of the proposed action to deploy and field test ecological engineering and biological adaptation strategies for corals that have been tested in laboratory settings are similar to the impacts, which are not significant, of projects for which NOAA may apply the categorical exclusion. Additionally, DARPA determined that there are no extraordinary circumstances. Therefore, DARPA has determined that its proposed use of NOAA's categorical exclusion C1, as described within this notice, would be appropriate.

Notice to the Public and Documentation of Adoption

This notice documents adoption of the NOAA categorical exclusion listed above and is available for use by DARPA, effective immediately.

Dated: May 22, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–11865 Filed 5–29–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0077]

Agency Information Collection Activities; Comment Request; Maintenance-of-Effort Requirements and Waiver Requests Under the Elementary and Secondary School Emergency Relief (ESSER) Fund and the Governor's Emergency Education Relief (GEER) Fund

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before July 29, 2024.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number Docket Search Results ED–2024–SCC–0077. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, the Department will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Andrew Brake, (202) 453–6136.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on

proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Maintenance-of-Effort Requirements and Waiver Requests under the Elementary and Secondary School Emergency Relief (ESSER) Fund and the Governor's Emergency Education Relief (GEER) Fund.

OMB Control Number: 1810–0745.

Type of Review: Extension without change of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 81.

Total Estimated Number of Annual Burden Hours: 358.

Abstract: This is a request for an extension without change of an existing information collection, 1810–0745. This collection solicits from States, Outlying Areas, and State educational agencies (SEAs) maintenance of effort (MOE) data under section 18008 of the CARES Act. Under four programs the Governors Emergency Education Relief Fund (GEER Fund, section 18002) and the Elementary and Secondary School Emergency Relief Fund (ESSER Fund, section 18003) and two formula grant programs to the Outlying Areas authorized under section 18001(a)(1),Education Stabilization Fund-State Educational Agencies (ESF–SEA) and Education Stabilization Fund-Governors (ESF-Governor) States are required to maintain fiscal effort on behalf of elementary, secondary and postsecondary education. Recipients of the resources from the ESSER Fund, the GEER Fund, the ESF–SEA Fund, and the ESF-Governor Fund have signed Certifications and Agreements, in which they agree to abide by the provisions of the CARES Act, including MOE requirement.

Dated: May 23, 2024.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–11815 Filed 5–29–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2024–FSA–0070]

Privacy Act of 1974; System of Records

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the U.S. Department of Education (Department) publishes this notice of a modified system of records entitled ''Aid Awareness and Application Processing'' (18–11–21). This system maintains information necessary for the Department to process applications for Federal student financial program assistance under title IV of the Higher Education Act of 1965, as amended (HEA); to perform the responsibilities of the Federal Student Aid (FSA) Ombudsman; to provide Federal student loan repayment relief including under the borrower defense to repayment regulations; to notify aid applicants and aid recipients of aid program opportunities and updates under title IV of the HEA via digital communication channels; and to maintain the *StudentAid.gov* website as the front end for assisting customers with all of their Federal student financial aid needs throughout the student aid lifecycle. The Department's Digital and Customer Care (DCC) Information Technology (IT) system collects the electronic records maintained in the Aid Awareness and Application Processing (AAAP) system.

DATES: Submit your comments on this modified system of records notice on or before July 1, 2024.

This modified system of records notice will become applicable upon publication in the **Federal Register** on May 30, 2024, except for the new and modified routine uses (1)(p), (1)(q), and 1(s) that are outlined in the section entitled ''ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES,'' which will be applicable July 1, 2024, unless they need to be changed as a result of public comment. The Department will publish any changes to the modified system of records notice resulting from public comment.

ADDRESSES: Comments must be submitted via the Federal eRulemaking Portal at *regulations.gov.* However, if you require an accommodation or cannot otherwise submit your comments via *regulations.gov*, please contact one of the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**. The Department will not accept comments submitted by fax or by email, or comments submitted after the comment period closes. To ensure that the Department does not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ''.

Privacy Note: The Department's policy is to make comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or aid, please contact one of the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT:

Rachel Coghlan, Central Processing System (CPS) System Manager, Student Experience and Aid Delivery, Federal Student Aid (FSA), U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454. Telephone: (202) 377–3205. Email: *Rachel.Coghlan@ed.gov.*

Corey Johnson, FAFSA® Processing System (FPS) Information System Owner, Federal Student Aid, U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454. Telephone: (202) 377–3898. Email: *Corey.Johnson@ed.gov.*

Bonnie Latreille, Ombudsman/Director, Ombudsman Group, Federal Student Aid (FSA), U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454. Telephone: (202) 377–3726. Email: *Bonnie.J.Latreille@ed.gov.*

Pardu Ponnapalli, Information System Owner, Technology Directorate, Federal Student Aid, U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454. Telephone: (240) 382–5825. Email: *Pardu.Ponnapalli@ed.gov.*

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act, the Department proposes to modify the system of records notice entitled ''Aid Awareness and Application Processing'' (18–11–21), which was last published in full in the **Federal Register** on February 2, 2024 (89 FR 7381).

The Department is modifying the section entitled ''PURPOSE(S) OF THE SYSTEM'' for the purposes related to applying for Federal student financial assistance and administering title IV, HEA programs to add purpose (18) to enable institutions of higher education (IHEs) and State higher education agencies to provide aid applicants and aid recipients with information about certain Federal means-tested benefits for which they may qualify and to enable IHEs and State higher education agencies, with the explicit written consent of aid applicants or aid recipients, and parents of dependent aid applicants or aid recipients and spouses of married aid applicants or aid recipients if necessary, to share non-Federal Tax Information (FTI) Free Application for Federal Student Aid (FAFSA) information directly with Federal, State, or local government agencies or tribal organizations to assist such applicants or recipients, in applying for or receiving Federal, State, or local government assistance, or tribal assistance for any component of the applicants' or recipients' cost of attendances that may include financial assistance or non-monetary assistance.

The Department is modifying the second sentence in the first paragraph in the section entitled ''CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM'' to remove the category of individuals that includes those who are students in attendance at a secondary school or local educational agency for which State grant agencies and other eligible requesting entities submit information to the Department in order for the Department to provide such entities with the student's FAFSA Filing Status Information. The Department is removing this category of individuals because the Department is no longer collecting this information and permits FAFSA filing status to be redisclosed by State higher education agencies to such entities, as described in the modification of routine use 1(p).

The Department is modifying the note in Category (1) in the section entitled ''CATEGORIES OF RECORDS IN THE SYSTEM'' to clarify that the ''FUTURE Act System (FAS)'' (18–11–23) system of records notice was published in the **Federal Register**.

The Department is modifying the section entitled ''ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES'' as follows:

(i) In the first paragraph, the Department is deleting the last sentence (which reads, ''Until June 30, 2024, Section 483(a)(3)(E) of the HEA (20 U.S.C. 1090(a)(3)(E)) restricts the use of the information gathered from the electronic version of the FAFSA to the application, award, and administration of aid awarded under title IV of the HEA, aid awarded by States, aid awarded by eligible institutions, or aid awarded by such entities as the Secretary of Education may designate'') because Section 483(a)(3)(E) of the HEA will not be in effect after June 30, 2024;

(ii) Routine use (1)(p) is modified to revise and limit the entities to which the Department may disclose a student's FAFSA filing status for the purpose of encouraging a student to complete a FAFSA that they started but did not submit and assisting a student with the completion of a FAFSA to a State higher education agency in order for such agency to redisclose such information to a local educational agency; a secondary school where the student is or was enrolled; grantees of the Department; American Indian and Alaska Native educational entities; and nonprofit college access organizations with an established relationship with the student;

(iii) Routine use (1)(q) is modified to remove and replace ''Through June 30, 2024, the Department may disclose records from this system to State higher education agencies, eligible IHEs, and other entities that the Secretary of Education has designated under section 483(a)(3)(E) of the HEA (20 U.S.C. 1090(a)(3)(E)) that award and administer aid to students, to determine an applicant's eligibility for the award of aid by State higher education agencies, eligible IHEs, or by other entities the Secretary of Education has designated. (Beginning July 1, 2024, under amendments to the HEA made by the FAFSA Simplification Act and the FAFSA Simplification Technical Corrections Act, the Department will no longer rely on this authority to disclose records from this system to State higher education agencies, eligible IHEs, and other entities that the Secretary of Education has designated under section 483(a)(3)(E) of the HEA (20 U.S.C. 1090(a)(3)(E))'' with ''The Department may disclose records under Sections 483(a)(2)(D)(i), 483(a)(2)(E)(ii), and 483(a)(3)(B)(i) of the HEA (20 U.S.C. 1090(a)(2)(D)(i), 1090(a)(2)(E)(ii), and 1090(a)(3)(B)(i)) from this system to State higher education agencies, eligible IHEs, and scholarship organizations that were designated prior to the date of enactment (December 19, 2019) of the FUTURE Act (Pub. L. 116–91, 133 Stat. 1189) that award and administer aid to students, to determine an applicant's eligibility for aid awarded by State higher education agencies, eligible IHEs, or designated scholarship organizations, and to administer Federal aid or aid awarded by State higher education agencies, eligible IHEs, or designated scholarship organizations.''; and

(iv) Routine use (1)(s) is added to permit disclosures of records from an applicant's FAFSA to IHEs and State higher education agencies to provide aid applicants and aid recipients with information about certain Federal means-tested benefits for which they may qualify.

Accessible Format: On request to any of the program contact persons listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in

text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Richard Cordray,

Chief Operating Officer, Federal Student Aid.

For the reasons discussed in the preamble, the Chief Operating Officer, Federal Student Aid (FSA) of the U.S. Department of Education (Department) publishes a modified system of records notice to read as follows:

SYSTEM NAME AND NUMBER:

Aid Awareness and Application Processing (18–11–21).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

U.S. Department of Education, 830 First Street NE, Washington, DC 20202.

The following locations are for the Central Processing System (CPS):

Lee's Summit Federal Records Center, National Archives and Records Administration (NARA), 200 Space Center Drive, Lee's Summit, MO 6464–1182 (*Note:* This is where paper applications are stored);

General Dynamics Information Technology (GDIT) Image and Data Capture (IDC) Center, 1084 South Laurel Road, Building 1, London, KY 40744 (*Note:* The IDC scans paper financial aid documents and correspondence, key-enters the data and electronically transmits the data and related images to the CPS for processing);

Next Generation Data Center (NGDC), 250 Burlington Drive, Clarksville, VA 23927 (*Note:* NGDC hosts the infrastructure that supports CPS applications including backend application processing); and

CPS Print Facility, 327 Columbia Pike, Rensselaer, NY 12144 (*Note:* This facility handles print operations).

The following locations are for the Free Application for Federal Student Aid (FAFSA®) Processing System (FPS):

Perspecta/Peraton, 15052 Conference Center Drive, Chantilly, VA 20151 (*Note:* Perspecta supports the FSA-provided development, security, and operations (DevSecOps) toolchain configuration; coordinates environment building; and supports technical operations activities and application modernization);

Information Capture Solutions (ICS), 25 Air Park Drive, London, KY 40744 (*Note:* ICS provides image and data capture, print/mailing operational services, and builds and operates the IDC);

iWorks, 1889 Preston White Drive, Suite 100, Reston, VA 20191 (*Note:* iWorks provides quality control managers (key personnel); develops and updates the quality control plan; oversees/validates service level measures; supports internal Capability Maturity Model Integration (CMMI) audits; supports Project Management Office (PMO) activities; and provides application development support using Agile methodologies);

Red Cedar Consultancy, LLC, 161 Fort Evans Road NE, Suite 200, Leesburg, VA 20176 (*Note:* Red Cedar provides application development support using Agile methodologies);

Windsor Group, LLC, 6820 Wisconsin Avenue, Unit 4004, Chevy Chase, MD 20815 (*Note:* Windsor Group provides quality resources in system security, database administration, and technical writing); and

Jazz Solutions, LLC, 20745 Williamsport Place, Suite 320, Ashburn, VA 20147 (*Note:* Jazz Solutions provides application development support using Agile methodologies and supports application programming interface (API) management solutions, including designing, building, and operating services).

The following locations are for the Digital and Customer Care (DCC) Information Technology (IT) System:

Salesforce Government Cloud, 415 Mission Street, 3rd Floor, San Francisco, CA 94105 (*Note:* The system is accessible via the internet to different categories of users, including Department personnel, customers, and designated agents of the Department at any location where they have internet access. This site is the location where customer interactions with contact center support via all inbound and outbound channels (phone, email, chat, webform, email, customer satisfaction survey, fax, physical mail, and controlled correspondence) and customer-provided feedback (complaints, suspicious activities, positive feedback, and dispute cases) are tracked and worked by contractors and the Department. This site also contains workflow management for processing tasks including, but not limited to: credit appeals, borrower defense to repayment, commingled Social Security numbers (SSNs), and archived document retrieval in the Common Origination and Disbursement (COD) System, and the FAFSA special correction application process. This site stores customer-provided documentation to support the interactions and processing tasks, as needed. This site will also be used by the Department for determining employer eligibility to support Public Service Loan Forgiveness (PSLF), and Office of Inspector General (OIG) fraud referrals);

Amazon Web Services (AWS) GovCloud (East/West), 410 Terry Avenue, North Seattle, WA 98109–5210 (*Note:* The DCC IT system is hosted at this location. This site is the location where the Shado (Dynamo) application collects, processes, stores, and makes available user activity events from across the DCC IT system to provide a complete view of the customer to the Department and its contractors. This site is also the location where the Adobe Marketing Campaign application delivers strategic and real-time personalized email and short message service (SMS) communications); and

Contact Center Fulfillment Center (Senture facility), 4255 W Highway 90, Monticello, KY 42633 (*Note:* This facility handles mail fulfillment and imaging operations).

The following 10 listings are the locations of the Aid Awareness and Application Processing Customer Contact Centers: Jacksonville Contact Center, One Imeson Park Boulevard, Jacksonville, FL 32118; Knoxville, TN Servicing Center, 120 N Seven Oaks Drive, Knoxville, TN 37922; 1600 Osgood Street, Suite 2–120, North Andover, MA 01845; 11499 Chester Road, Suite 101, Sharonville, OH 45246; 100 Domain Drive, Suite 200, Exeter, NH 03833; 221 N Kansas Street, Suite 700, El Paso, TX 79901; 4255 W Highway 90, Monticello, KY 42633; 555 Vandiver Drive, Columbia, MO 65202; 633 Spirit Drive, Chesterfield, MO 63005; and 820 First Street, NE, Washington, DC 20002.

SYSTEM MANAGER(S):

CPS—System Manager, Student Experience and Aid Delivery, FSA, U.S. Department of Education, Union Center Plaza (UCP), 830 First Street NE, Washington, DC 20202–5454.

FPS—Information System Owner, Technology Directorate, Federal Student Aid, U.S. Department of Education, Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454.

Ombudsman, FSA, U.S. Department of Education, UCP, 830 First Street NE, Washington, DC 20202–5454.

DCC—Information System Owner, Technology Directorate, Federal Student Aid, U.S. Department of Education,

Union Center Plaza, 830 First Street NE, Washington, DC 20202–5454.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authorities are title IV of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1070 *et seq.*); 20 U.S.C. 1018(f); and the Higher Education Relief Opportunities for Students Act of 2003 (20 U.S.C. 1098bb) (including any waivers or modifications that the Secretary of Education deems necessary to make to any statutory or regulatory provision applicable to the Federal student financial assistance programs under title IV of the HEA to achieve specific purposes listed in the section in connection with a war, other military operation, or a national emergency). The collection of SSNs of individuals, and parents of dependent students, who apply for or receive Federal student financial assistance under programs authorized by title IV of the HEA is also authorized by 31 U.S.C. 7701 and Executive Order 9397, as amended by Executive Order 13478 (November 18, 2008).

PURPOSE(S) OF THE SYSTEM:

The information contained in this system is maintained for the following purposes related to applying for Federal student financial assistance and administering title IV, HEA programs: (*Note:* Different parts of the HEA use the terms ''discharge,'' ''cancellation,'' or ''forgiveness'' to describe when a borrower's loan amount is reduced in whole or in part by the Department. To reduce complexity, this system of records notice uses the term ''discharge'' to include all three terms (''discharge,'' ''cancellation,'' and ''forgiveness''), including but not limited to discharges of student loans made pursuant to specific benefit programs. At times, the system of records notice may refer by name to a specific benefit program, such as the ''Public Service Loan Forgiveness'' program; such specific references are not intended to exclude any such program benefits from more general references to loan discharges.)

(1) Assisting with the determination, correction, processing, tracking, and reporting of program eligibility and benefits for the Federal student financial assistance programs authorized by title IV of the HEA, including, but not limited to, discharge of eligible loans under title IV, HEA programs;

(2) Making a loan or grant;

(3) Verifying the identity of the applicant for Federal financial assistance under title IV of the HEA, the spouse of a married applicant, the parent(s) of a dependent applicant, and, until CPS is decommissioned after September 30, 2024, an individual who applies for an FSA ID; and verifying the accuracy of the information in this system;

(4) Reporting the results of the need analysis and Federal Pell Grant eligibility determination to applicants, institutions of higher education (IHEs), third-party servicers, State agencies designated by the applicant, and Departmental and investigative components;

(5) Reporting the results of duly authorized matching programs between the Department and other Federal agencies and between the Department and State or local governments, or agencies thereof, to applicants, IHEs, third-party servicers, State agencies designated by the applicant, and Departmental and investigative components where the Department is required by law to do so or where it would be essential to the conduct of the matching program to report, such as for the imposition of criminal, civil, or administrative sanctions;

(6) Enforcing the terms and conditions of a title IV, HEA loan or grant;

(7) Servicing and collecting a delinquent title IV, HEA loan or grant;

(8) Initiating enforcement action against individuals, IHEs, or other entities involved in program fraud, abuse, or noncompliance;

(9) Locating a debtor or recipient of a grant overpayment;

(10) Maintaining a record of the data supplied by those requesting title IV, HEA program assistance;

(11) Ensuring compliance with and enforcing title IV, HEA programmatic requirements and various consumer protection laws;

(12) Acting as a repository and source for information necessary to fulfill the requirements of title IV of the HEA;

(13) Evaluating title IV, HEA program effectiveness;

(14) Enabling IHEs and State grant agencies designated by the applicant to review and analyze the financial aid data of their applicant population;

(15) Enabling IHEs and State grant agencies to assist applicants with the completion of the application for the Federal student financial assistance programs authorized by title IV of the HEA;

(16) Assisting State agencies, eligible IHEs, and other entities that award aid to students and that are designated by the Secretary of Education with making eligibility determinations for the award of aid and with administering these awards;

(17) Promoting and encouraging applications for title IV, HEA program assistance, State assistance, and aid awarded by eligible IHEs or by other entities designated by the Secretary of Education; and

(18) Enabling IHEs and State higher education agencies to provide aid applicants and aid recipients with information about certain Federal means-tested benefits for which they may qualify and to enable IHEs and State higher education agencies, with the explicit written consent of aid applicants or aid recipients, and parents of dependent aid applicants or aid recipients and spouses of married aid applicants or aid recipients if necessary, to share non-FTI FAFSA information directly with Federal, State, or local government agencies or tribal organizations to assist such applicants or recipients, in applying for or receiving Federal, State, or local government assistance, or tribal assistance for any component of the applicants' or recipients' cost of attendances that may include financial assistance or non-monetary assistance.

The information contained in this system is also maintained for the following purposes related to managing customer engagement:

(1) Carrying out the duties and responsibilities of the FSA Ombudsman, including investigating and resolving complaints, inquiries, and requests for assistance, updating borrower account records, correcting errors, analyzing complaint trends, and making appropriate recommendations pursuant to 20 U.S.C. 1018(f);

(2) Carrying out the duties and responsibilities of the Department to provide Federal student loan repayment relief under Federal law;

(3) Verifying the identity of FSA customers;

(4) Recording complaints, suspicious activities, positive feedback, and comments as provided by customer interactions with contact center support via inbound and outbound channels (phone, chat, webform, email, customer satisfaction survey, fax, physical mail, social media platforms, digital engagement platforms, and controlled correspondence);

(5) Tracking individual cases, including complaints, borrower defense submissions, general inquiries, and chat sessions, through final resolution, reporting trends, and analyzing the data to recommend improvements in Federal student financial assistance programs;

(6) Assisting in the informal resolution of disputes submitted by aid applicants or aid recipients about issues related to title IV, HEA program assistance;

(7) Carrying out the duties and responsibilities of the Department under

the borrower defense to repayment regulations at 34 CFR 685.206 and 685.222 and 34 CFR part 685, subpart D, including receiving, reviewing, evaluating, and processing requests for relief under the borrower defense to repayment regulations; and

(8) Initiating proceedings, where appropriate, to recover liabilities from an IHE for losses incurred as a result of the act or omission of the IHE participating in the Federal student loan programs.

The information contained in this system is also maintained for the following purposes related to assisting aid applicants and recipients with Federal student financial assistance programs authorized by title IV of the HEA, and managing customer relationships for marketing and improving customer service:

(1) Determining employer qualification for borrowers to receive discharge under the PSLF Program;

(2) Collecting, processing, storing, and making available user activity events and user-submitted documentation from across the DCC IT system to provide a complete view of the customer to the Department and its contractors;

(3) Sending aid applicants and aid recipients strategic and real-time, personalized communications via email, and SMS ''text messages'' via mobile phone communications to inform them of title IV, HEA aid marketing campaigns (such as encouraging completion of their FAFSA), and sending transactional communication to customers (such as confirmation emails when a user completes an action);

(4) Measuring customer satisfaction and analyzing results; and

(5) Promoting and encouraging the repayment of title IV, HEA program loans in a timely manner.

The information in this system is also maintained for the following purposes relating to the Department's administration and oversight of title IV, HEA programs:

(1) To support the investigation of possible fraud and abuse and to detect and prevent fraud and abuse in the title IV, HEA Federal grant and loan programs;

(2) To support compliance with title IV, HEA statutory and regulatory requirements;

(3) To provide an aid recipient's financial aid history, including information about the recipient's title IV, HEA loan defaults, title IV, HEA aid receipt, and title IV, HEA grant program overpayments;

(4) To facilitate receiving and correcting application data, processing Federal Pell Grants and Direct Loans, and reporting Federal Perkins Loan Program expenditures to the Department's processing and reporting systems;

(5) To support pre-claims/supplemental pre-claims assistance;

(6) To assist in locating holders of title IV, HEA loan(s);

(7) To assist in assessing the administration of title IV, HEA program funds by guaranty agencies, lenders and loan holders, IHEs, and third-party servicers;

(8) To initiate or support a limitation, suspension, or termination action, an emergency action, or a debarment or suspension action;

(9) To inform the parent(s) of a dependent applicant of information about the parent(s), or the spouse of a married applicant of information about the spouse, in an application for title IV, HEA funds;

(10) To disclose applicant records to the parent(s) of a dependent applicant applying for a PLUS loan (to be used on behalf of a student), to identify the student as the correct beneficiary of the PLUS loan funds, and to allow the processing of the PLUS loan application and promissory note;

(11) To expedite the application process;

(12) To enable an applicant, at the applicant's written request, to obtain income information about the applicant from the Internal Revenue Service (IRS) using the Data Retrieval Tool, until CPS is decommissioned after September 30, 2024;

(13) To identify, prevent, reduce, and recoup improper payments, prevent fraud, and conduct at-risk campaigns, including protecting customers from Third-Party Debt Relief firms;

(14) To help Federal, State, Tribal, and local government entities exercise their supervisory and administrative powers (including, but not limited to licensure, examination, discipline, regulation, or oversight of educational institutions, Department contractors, guaranty agencies, lenders and loan holders, and third-party servicers) or to respond to individual aid applicant or recipient complaints submitted regarding the practices or processes of the Department and/or the Department's contractors, or to update information or correct errors contained in Department records regarding the aid applicant's or recipient's title IV, HEA program funds;

(15) To provide eligible applicants for title IV, HEA aid, and when necessary, the spouse or parents of an applicant, with information about certain Federal means-tested benefits and services for which they may qualify;

(16) To collect, track, and process Office of Inspector General (OIG) fraud referrals;

(17) To support research, analysis, and development, and the implementation and evaluation of educational policies in relation to title IV, HEA programs; and

(18) To conduct testing, analysis, or take other administrative actions needed to prepare for or execute programs under title IV of the HEA.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains records on individuals who are, were, or may be participants in any of the Federal student financial assistance programs under title IV of the HEA who request assistance from the Department, directly or through State requestors and legal assistance organizations (''third-party requestors'') who may request that the Secretary of Education form a group of Federal student loan borrowers for borrower defense relief.

This system also maintains records on student and parent applicants (and their third-party preparers), as well as the spouse of a married applicant and the parent(s) of a dependent applicant, who apply for Federal student financial assistance under one of the programs authorized under title IV of the HEA, including, but not limited to the: (1) Federal Pell Grant Program; (2) Federal Perkins Loans Program; (3) Academic Competitiveness Grant (ACG) Program; (4) National Science and Mathematics Access to Retain Talent (National SMART) Grant Program; (5) Teacher Education Assistance for College and Higher Education (TEACH) Grant Program; (6) Iraq and Afghanistan Service Grant (IASG) Program; (7) Direct Loan Program, which includes Federal Direct Stafford/Ford Loans, Federal Direct Unsubsidized Stafford/Ford Loans, Federal Direct PLUS Loans, and Federal Direct Consolidation Loans; (8) Federal Family Education Loan (FFEL) Program; and (9) Federal Insured Student Loan (FISL) Program.

This system also maintains records on individuals who apply for an FSA ID in the Department's Person Authentication Service (PAS) system because the Department uses CPS, which maintains records that are part of this system, as a pass-through to send these individuals' records from the PAS system to the Social Security Administration (SSA) for computer matching in order to assist the Department in verifying their identities. This pass-through will be terminated when CPS is decommissioned after September 30, 2024.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains records that contain the following information:

(1) Information provided by applicants for title IV, HEA program assistance on an incomplete or completed FAFSA, including, but not limited to, the applicant's name, address, SSN, DOB, telephone number, driver's license number (which will not be collected on the FAFSA for award year 2024–2025 and onward, and will not be collected by FPS), email address, citizenship status, marital status, legal residence, status as a veteran, educational status, and financial information (including asset and income information). (*Note:* The Federal Tax Information (FTI) that the Department obtains directly from the IRS under the Fostering Undergraduate Talent by Unlocking Resources for Education (FUTURE) Act, Pub. L. 116–91, is maintained in a separate system of records entitled ''FUTURE Act System (FAS)'' (18–11–23), the notice for which was published in the **Federal Register** on June 29, 2023 (88 FR 42220));

(2) Information provided about the parent(s) of a dependent applicant, including, but not limited to, the parent's highest level of schooling completed (which will not be collected on the FAFSA starting with award year 2024–2025 and will not be collected by FPS; after which point the Department will instead collect on the FAFSA the parent's college attendance status), marital status, SSN, last name and first initial, DOB, email address, number of people in the household supported by the parent, and asset and income information.

(3) Information about the spouse of a married applicant including, but not limited to: the spouse's name, address, SSN, DOB, telephone number, email address, citizenship status, marital status, legal residence, status as a veteran, and financial information (including asset and income information that is needed for CPS processing until September 30, 2024);

(4) Information provided by IHEs on behalf of student and parent applicants, including, but not limited to, verification results, dependency overrides, and resolution of comment codes or reject codes;

(5) Information calculated by CPS through the 2023–24 award year on the applicant's expected family contribution (EFC);

(6) Information on the applicant's Institutional Student Information Record (ISIR), and Student Aid Report (SAR) or the renamed FAFSA Submission Summary (FSS). The Department uses the ISIR and SAR or FSS to report, among other things, the EFC, or the SAI results that are calculated during FPS processing, to IHEs, State grant agencies, and applicants. The EFC or SAI is available to, and used by, IHEs to determine the applicant's eligibility for Federal and institutional program assistance and the amount of assistance, and State grant agencies to determine the applicant's eligibility for State grants and the amount of grant assistance. The Department notifies the applicant of the results of their application via the SAR or FSS. The Department provides the IHEs identified on the applicant's FAFSA with the ISIR, which indicates whether there are discrepant or insufficient information, school adjustments, or CPS assumptions that affect processing of the FAFSA. Other information in the system includes, but is not limited to: Secondary EFC (an EFC that is calculated from the full EFC formula and is printed in the Financial Aid Administrator's (FAA) Information section of the ISIR), dependency status, Federal Pell Grant eligibility, duplicate SSN (an indicator that is set to alert ISIR recipients that two applications were processed with the same SSN, Incarcerated Student Indicator Flag (an indicator that will be used to identify an aid applicant as an incarcerated student), selection for verification, Simplified Needs Test (SNT) or Automatic Zero EFC (used for extremely low family income), CPS and FPS processing comments, reject codes (explanation for applicant's FAFSA not computing EFC), assumptions made with regard to the student's information due to incomplete or inconsistent FAFSA information, FAA adjustments including dependency status overrides, and CPS and FPS record processing information (application receipt date, transaction number, transaction process date, SAR Serial Number, Compute Number, Data Release Number (DRN), a four-digit number assigned to each application), National Student Loan Database System (NSLDS) match results, a bar code, and transaction source);

(7) Information that identifies aid applicant or aid recipient complaints, positive feedback, reports of suspicious activity, requests for assistance, requests for borrower defense relief, requests for PSLF reconsideration, or other inquiries. Such information includes, but is not limited to: written documentation of an aid applicant or aid recipient's complaint, request for assistance, request for relief under the borrower defense to repayment regulations, case tracking number, case appeal identifier, or other comment or inquiry; and information pertaining to the aid recipient's or the aid recipient's parent's student financial assistance program account(s) under title IV of the HEA, such as the aid recipient's and the aid recipient's parent's names and Federal Student Aid IDs (FSA IDs). Information may include the name, address, and phone numbers of the aid recipient's counsel or representative, IHE(s), lender(s), secondary holder(s) or lender(s), guaranty agency(ies), servicer(s), private collection agency(ies), and third-party requestor(s), as this term is defined in 34 CFR 685.401(a), if applicable, and may contain other loan-level information;

(8) Information provided and generated through customer interactions with contact center support via inbound and outbound channels (phone, chat, webform, email, customer satisfaction survey, fax, physical mail, social media platforms, digital engagement platforms, and controlled correspondence). Information includes, but is not limited to: chat transcripts, email communications, audio recordings of customer calls, and screen recordings of contact center support desktop during customer interactions;

(9) Loan discharge eligibility and verification information for use in determining whether a title IV, HEA debt/loan qualifies for discharge;

(10) Aid recipient's employer information to determine employer qualification for borrowers to receive discharge under PSLF; OIG fraud referral information; and customer support interactions including phone, chat, webform, email, fax, physical mail, and controlled correspondence;

(11) Information for collecting, processing, and storing user activity events from across the DCC IT system: campaign details, delivery details, email/SMS sent timestamp, transaction ID, Federal Account Number (FAN) ID, activity details, activity date, pages/URL accessed, user IP address, user-submitted materials, and user request details;

(12) Information needed to aid in the delivery of strategic and real-time communication to customers, including, but not limited to, first name, last name, DOB, state of residence, email, phone number, mobile device ID, device data, FAFSA transaction data, uniform resource locator (URL), computer-related data, and customer communication preferences and user activity (open or clicks) for email and SMS communications;

(13) Information provided on third-party preparers, including, but not limited to, first name, last name, SSN or employer identification number,

affiliation, address or employer's address, signature, and signature date.

Note: This system of records also maintains information that is collected in this system and stored in other systems of records. The following information about individuals who apply for or receive a Federal grant or loan under one of the programs authorized under title IV of the HEA is collected in this system and stored in the ''Common Origination and Disbursement (COD) System'' (18–11–02) system of records: applicant identifiers including applicant's name, SSN, and DOB; demographic information, including asset and income information (tax return status, adjusted gross income, Internal Revenue Service exemptions, and tax year), and enrollment information; borrower's loan(s) information, including information about recipients of Direct Loans, FFEL Program loans, Perkins Loans, and FISL Program loans, such as the period from the origination of the loan through final payment, and milestones, including, but not limited to, consolidation, discharge, or other final disposition including details such as loan amount, disbursements, balances, loan status, repayment plan and related information, collections, claims, deferments, forbearances, and refunds; information about students receiving Federal grants, including recipients of Pell Grants, ACG, National SMART Grants, TEACH Grants, Iraq and Afghanistan Service Grants, and including grant amounts, grant awards, verification status, lifetime eligibility used (LEU), IASG eligible veteran's dependent indicator, Children of Fallen Heroes Scholarship eligibility indicator, and the Pell Grant additional eligibility indicator; Pell Grant collection status indicator and overpayment collection information; promissory notes, Direct Loan Entrance Counseling forms, Federal Student Loan Exit Counseling forms, PLUS Loan Counseling forms, the Annual School Loan Acknowledgement (ASLA), Direct PLUS Loan Requests, endorser addendums, and counseling in the Direct Loan and TEACH Grant programs, such as the date that applicant completed counseling; PLUS Loan credit report information; applicant identifier information for an electronic request to repay a Direct Loan under an income-driven repayment plan and endorser/spouse information, such as the SSN, date that applicant completed the income-driven repayment plan application, and current loan balances; Electronic Direct Consolidation Loan borrower identifier information, such as the borrower's SSN, the date that borrower completed the Federal Direct Consolidation Loan application and promissory note, and current loan balances; and credit check decisions, credit appeals, credit appeal identifiers, and credit history information to support the credit appeal process. Further, information from the ''Enterprise Data Management and Analytics Platform Services (EDMAPS)'' (18–11–22) system of records is accessible in the DCC IT system to: allow real-time updates to a customer's identifiers, demographic attributes, address, phone, and email contact details; update customer preference for receiving marketing information via text message; allow the Department and its contractors to identify customers who have completed a customer satisfaction survey; and enable the Department to contact borrowers who have been identified by the Department as potentially having fraudulent activity from a Third-Party Debt Relief (TPDR) company and are at risk of loan default. The following information is modifiable by the customer through *StudentAid.gov*: name, DOB, address, phone number, and email address. The DCC IT system also sends the following information to the EDMAPS system for analytics and reporting: case information including complaints, and OIG fraud referral data. Information includes, but is not limited to: SSN, DOB, address, phone, and email. Additionally, some information from Federal Loan Servicers' systems (covered by the ''Common Services for Borrowers (CSB)'' (18–11–16) system of records) is accessible on *StudentAid.gov* to allow customers to view their payment information, loan information, and to make payments on *StudentAid.gov* as they would on the various Federal Loan Servicer websites. Further, customers can use *StudentAid.gov* to update their contact information and access financial aid history that is stored in the ''National Student Loan Data System (NSLDS)'' (18–11–06) system of records. Additionally, until CPS is decommissioned after September 30, 2024, CPS is also used as a pass-through to send information that is stored in the ''Person Authentication Service (PAS)'' (18–11–12) system of records to SSA for computer matching on individuals who apply for an FSA ID in PAS in order to assist the Department in verifying their identities. The information includes, but is not limited to: SSN, name, and DOB. Finally, beginning with the 2024–25 award year application cycle, the IRS will disclose directly to the Department FTI for FAFSA application processing and aid eligibility determination; that FTI will not be maintained in this system. Beginning July 30, 2023, the IRS will also disclose directly to the Department FTI to determine eligibility and monthly payment amounts under Income-Driven Repayment (IDR) plans; that FTI also will not be maintained in this system. All FTI that the Department will obtain directly from the IRS under the FUTURE Act will be maintained within the FTI Module (FTIM) system that will be compliant with the IRS Publication 1075, ''Tax Information Security Guidelines for Federal, State and Local Agencies, Safeguards for Protecting Federal Tax Returns and Return Information,'' and that will be covered under the Department's system of records notice entitled ''FUTURE Act System (FAS)'' (18–11–23). This system will continue to maintain both historical income information (obtained from the IRS until CPS is decommissioned) and applicant-provided income information (either through a manual FAFSA entry or submission of alternative documentation of income (ADOI) through the IDR process). Any reference to income throughout this system of records notice refers explicitly to income information that the Department did not obtain directly from the IRS but obtained from the applicant or from another source.

RECORD SOURCE CATEGORIES:

Information maintained in this system of records is obtained from applicants, the parents of dependent applicants, third-party preparers, and the spouse of married applicants for title IV, HEA program assistance, on the paper FAFSA, Portable Document Format (PDF) FAFSA, the online FAFSA form, and FAFSA by phone; the authorized employees or representatives of authorized entities (namely, IHEs, institutional third-party servicers, FFEL Program lenders, FFEL Program guaranty agencies, Federal loan servicers, State grant agencies, other Federal agencies, and research agencies); and from other persons or entities from which information is obtained following a disclosure under the routine uses set forth below.

The Financial Aid Administrators at IHEs designated by the applicant and IHEs' third-party servicers may correct the records in this system as a result of documentation provided by the applicant or by a dependent applicant's parents, such as Federal income return(s) (IRS Form 1040), Social Security card(s), and Department of Homeland Security I–551 Permanent Resident Card.

This system maintains information added during CPS processing and that will be added during FPS processing and information received from other Department systems, including the NSLDS, the COD System, and the SAIG Participation Management System. The results of matching programs with Federal agencies or State or local governments, or agencies thereof, are added to the student's record during CPS processing and will be added to the student's record during FPS processing. The Department's matching programs at the time of the publication of this system of records notice are with the SSA to verify the SSNs of applicants, dependent applicants' parent(s), and spouses of married applicants, as well as of individuals who apply for an FSA ID, and to confirm the U.S. citizenship status of applicants as recorded in SSA records and date of death (if applicable) of applicants, and dependent applicants' parents, pursuant to title IV of the HEA, including sections 428B(f)(2), 483(a)(12) (which under the FAFSA Simplification Act will be section 483(a)(2)(B)), and 484(g) and (p) (which the FAFSA Simplification Act redesignates as section 484(o)) of the HEA (20 U.S.C. 1078–2(f)(2), 1090(a)(12) (which the FAFSA Simplification Act amends to be 1090(a)(2)(B)), and 1091(g) and (p) (which the FAFSA Simplification Act redesignates as 1091(o)); with the Department of Veterans Affairs (VA) to verify the status of applicants who claim to be veterans, pursuant to section 480(c) and (d)(1)(D) of the HEA (20 U.S.C. 1087vv(c) and (d)(1)(D)); with the U.S. Department of Homeland Security (DHS) to confirm the immigration status of applicants for assistance as authorized by section 484(g) of the HEA (20 U.S.C. 1091(g)); with the U.S. Department of Justice (DOJ) to enforce any requirement imposed at the discretion of a court, pursuant to section 5301 of the Anti-Drug Abuse Act of 1988, Public Law 100–690, as amended by section 1002(d) of the Crime Control Act of 1990, Public Law 101–647 (21 U.S.C. 862), denying Federal benefits under the programs established by title IV of the HEA to any individual convicted of a State or Federal offense for the distribution or possession of a controlled substance; and, through award year 2023–2024 following the implementation of the FAFSA Simplification Act on July 1, 2024, with the U.S. Department of Defense (DoD) to identify dependents of U.S. military personnel who died in service in Iraq and Afghanistan after September 11, 2001, to determine if they are eligible for increased amounts of title IV, HEA program assistance, pursuant to sections 420R and 473(b) of the HEA (20 U.S.C. 1070h and 1087mm(b)), which will be replaced by Section 401(c) under the FAFSA Simplification Act.

During CPS and FPS processing, the Department's COD System sends information to these systems for students who have received a Federal Pell Grant. CPS and FPS use this information for verification analysis and for end-of-year reporting. These data elements include, but are not limited to: Verification Selection and Status, Potential Over-award Project (POP) indicator, Institutional Cost of Attendance, Reporting and Attended Campus Pell ID and Enrollment Date, and Federal Pell Grant Program information (Scheduled Federal Pell Grant Award, Origination Award Amount, Total Accepted Disbursement Amount, Number of Disbursements Accepted, Percentage of Eligibility Used At This Attended Campus Institution, and Date of Last Activity from the Origination or Disbursement table).

CPS and FPS also receive applicant information from the Department's NSLDS system each time an application is processed or corrected. This process assesses student aid eligibility, updates financial aid history, and ensures compliance with title IV, HEA regulations. Some of this information appears on the applicant's SAR or FSS and ISIR. Title IV, HEA award information is provided to NSLDS from several different sources. Federal Perkins Loan information and Federal Supplemental Educational Opportunity Grant (FSEOG) overpayment information is sent from IHEs or their third-party servicers; the Department's COD System provides Federal Pell Grant and Direct Loan data; and State and guaranty agencies provide information on FFEL loans received from lending institutions participating in the FFEL programs. Financial aid transcript information reported by NSLDS provides aid recipients, IHEs, and third-party servicers with information about the type(s), amount(s), dates, and overpayment status of prior and current title IV, HEA funds the aid recipient has received. FFEL and William D. Ford Federal Direct Student Loan data information reported by NSLDS includes, but is not limited to: (1) Aggregate Loan Data, such as Subsidized, Unsubsidized; Combined Outstanding Principal Balances; Unallocated Consolidated Outstanding Principal Balances, Subsidized, Unsubsidized; Combined Pending Disbursements, Subsidized, Unsubsidized; Combined Totals; and Unallocated Consolidated Totals; (2) Detailed Loan Data, such as Loan Sequence Number; Loan Type Code; Loan Change Flag; Loan Program Code; Current Status Code and Date; Outstanding Principal Balance and Date; Net Loan Amount; Loan Begin and End Dates; Amount and Date of Last Disbursement; Guaranty Agency Code; School Code; Contact Code; and Institution Type and Grade Level; and (3) system flags for Additional Unsubsidized Loan; Capitalized Interest; Defaulted Loan Change; Discharged Loan Change; Loan Satisfactory Repayment Change; Active Bankruptcy Change; Overpayments Change; Aggregate Loan Change; Defaulted Loan; Discharged Loan; Loan Satisfactory Repayment; Active Bankruptcy; Additional Loans; Direct Loan Master Promissory Note; Direct PLUS Loan Master Promissory Note; Subsidized Loan Limit; and the Combined Loan Limit. Federal Perkins Loan information reported by NSLDS includes, but is not limited to: Cumulative and Current Year Disbursement Amounts; flags for Perkins Loan Change; Defaulted Loan; Discharged Loan; Loan Satisfactory Repayment; Active Bankruptcy; Additional Loans; and Perkins Overpayment Flag and Contact (School or Region). Federal Pell Grant payment information reported includes, but is not limited to: Pell Sequence Number; Pell Attended School Code; Pell Transaction Number; Last Update Date; Scheduled Amount; Award Amount; Amount Paid to Date; Percent Scheduled Award Used; Pell Payment EFC; Flags for Pell Verification; and Pell Payment Change. TEACH Grant Program information includes, but is not limited to: TEACH Grant Overpayment Contact; TEACH Grant Overpayment Flag; TEACH Grant Loan Principal Balance; TEACH Grant Total; and TEACH Grant Change Flag. Iraq and Afghanistan Service Grants information includes, but is not limited to, Total Award Amount. The Department obtains from and exchanges information that is included in this system of records with IHEs, third-party servicers, and State agencies. These eligible entities register with the SAIG system to participate in the information exchanges specified for their business processes.

During FPS processing, this system will receive the SAI information from the Department's FAS. The SAI is calculated using FTI that the IRS will provide directly to the Department under the FUTURE Act that will not be maintained in this system, but instead the system of records entitled ''FUTURE Act System (FAS)'' (18–11–23).

Additionally, for individuals who request assistance from the Department, directly or through State requestors and legal assistance organizations (''third-party requestors''), as these terms are defined in 34 CFR 685.401(a), who may request that the Secretary of Education form a group of Federal student loan borrowers for borrower defense relief, information is obtained from individuals (*e.g.,* borrowers), their counsel or representatives, or students or their parents (when the individual is a borrower and depending on whether the individual is a parent or student), Federal agencies, State agencies, IHEs, lenders, private collection agencies, guaranty agencies, accreditors, and from other persons or entities from whom or from which data is obtained following a disclosure under routine uses set forth below.

Note: Some customer information that is retrieved from Federal Loan Servicers' IT systems (covered by the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16)) is accessible through *StudentAid.gov* to provide customers with payment and loan information and to enable customers to make loan payments as they would on the various Federal Loan Servicer websites. Information that is collected in this system is stored in and retrieved from the COD System (covered by the system of records notice entitled ''Common Origination and Disbursement (COD) System'' (18–11–02)) to allow: applicants and borrowers to submit Counseling (Entrance, Exit, Financial Awareness Counseling, PLUS, TEACH Grant Initial and Subsequent, TEACH Grant Exit, TEACH Grant Conversion), Master Promissory Note (MPN), Endorser Addendum, TEACH Grant Agreement to Serve or Repay (Agreement), Loan Consolidation, Income-Driven Repayment, PLUS Loan Request, and Annual Student Loan Acknowledgement (ASLA) applications through *StudentAid.gov;* credit check decision, credit appeal, and credit history information to be viewable on *StudentAid.gov* to support credit appeal processing; users to view and search the PSLF employer database as retrieved from the COD System and provide updates to employers' information; and the PDF version of the PSLF/Temporary Expanded PSLF (TEPSLF) certification and application form that is generated from the PSLF Help Tool to be accessible. Information is also retrieved from the COD System to provide *StudentAid.gov* functionality for creating and updating customer records. The following information from the EDMAPS system is accessible in the DCC IT system: customer information that is retrieved to allow real-time updates to a customer's identifiers, demographic attributes, address, phone, and email contact details; SMS opt-in/out information for customer communication preferences to opt-in/out of receiving marketing information via text message; information for customers who have been identified by the Department and its contractors as having completed a customer satisfaction survey; information for borrowers who will be contacted by the Department because they have been identified by the Department as having potentially fraudulent activity from a TPDR company; and information on borrowers who have been identified by the Department and its contractors as being at risk for loan default.

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

The Department may disclose information maintained in a record in this system of records under the routine uses listed in this system of records notice without the consent of the individual if the disclosure is compatible with the purposes for which the record was collected. These disclosures may be made on a case-by-case basis or pursuant to a computer matching agreement that meets the requirements of the Privacy Act of 1974, as amended (Privacy Act) (5 U.S.C. 552a).

(1) *Program Disclosures.* The Department may disclose records from the system of records for the following program purposes:

(a) To verify the identity of the applicant, the spouse of a married applicant, and the parent(s) of a dependent applicant, to verify, until CPS is decommissioned after September 30, 2024, the identities of individuals who apply for a FSA ID, to determine the accuracy of the information contained in the record, to support compliance with title IV, HEA statutory and regulatory requirements, and to assist with the determination, correction, processing, tracking, and reporting of program eligibility and benefits, the Department may disclose records to applicants, guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, local, or Tribal agencies;

(b) To provide an applicant's financial aid history to IHEs, guaranty agencies and State agencies, lenders and loan holders participating in the FFEL Program, and third-party servicers, including information about the applicant's title IV, HEA loan defaults, and title IV, HEA grant program overpayments, the Department may disclose records to IHEs, guaranty agencies and State agencies, lenders and loan holders participating in the FFEL Program, and third-party servicers;

(c) To facilitate receiving and correcting application information, processing Federal Pell Grants and Direct Loans, and reporting Federal Perkins Loan Program expenditures to the Department's processing and reporting systems, the Department may disclose records to IHEs, State agencies, and third-party servicers;

(d) To assist loan holders with the collection and servicing of title IV, HEA loans, to support pre-claims/supplemental pre-claims assistance, to assist in locating borrowers, and to assist in locating students who owe grant overpayments, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, local, and Tribal agencies;

(e) To facilitate assessments of title IV, HEA program compliance, the Department may disclose records to guaranty agencies and IHEs, third-party servicers, and Federal, State, and local agencies;

(f) To assist in locating holders of loans, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, and local agencies;

(g) To assist in assessing the administration of title IV, HEA program funds by guaranty agencies, lenders and loan holders in the FFEL Program, IHEs, and third-party servicers, the Department may disclose records to Federal and State agencies;

(h) To enforce the terms of a loan or grant or to assist in the collection of loan or grant overpayments, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, and local agencies;

(i) To assist borrowers in repayment, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, and local agencies;

(j) To determine the relief that is appropriate if the Secretary of Education grants a borrower defense to repayment discharge application, as well as to pursue the recovery of liabilities of such discharges against the IHE, the

Department may disclose records to Federal, State, and Tribal agencies, accreditors, IHEs, lenders and loan holders, guaranty agencies, third-party servicers, and private collection agencies;

(k) To initiate legal action against an individual or entity involved in an illegal or unauthorized title IV, HEA program expenditure or activity, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, local, and Tribal agencies;

(l) To initiate or support a limitation, suspension, or termination action, an emergency action, or a debarment or suspension action, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, IHEs, third-party servicers, and Federal, State, local, and Tribal agencies;

(m) To investigate and resolve complaints, inquiries, requests for assistance, requests for Federal student loan repayment relief and other relief under the borrower defense to repayment regulations, and to update borrower account records and to correct errors, the Department may disclose records to guaranty agencies, lenders and loan holders participating in the FFEL Program, accreditors, IHEs, third-party requestors, third-party servicers, private collection agencies, and Federal, State, and local agencies;

(n) To inform the parent(s) of a dependent applicant of information about the parent(s), or the spouse of a married applicant of information about the spouse, in an application for title IV, HEA funds, the Department may disclose records to the parent(s), or spouse, respectively;

(o) To identify the student as the correct beneficiary of the PLUS loan funds, and to allow the processing of the PLUS loan application and promissory note, the Department may disclose records to the parent(s) applying for the parent PLUS loan;

(p) To encourage a student to complete a FAFSA that they started but did not submit or to assist a student with the completion of a FAFSA, the Department may disclose a student's FAFSA filing status to a State higher education agency so that the agency may redisclose that information to a local educational agency; a secondary school where the student is or was enrolled; grantees of the Department; American Indian and Alaska Native educational entities; and nonprofit college access organizations with an established relationship with the student;

(q) The Department may disclose records under Sections 483(a)(2)(D)(i), 483(a)(2)(E)(ii), and 483(a)(3)(B)(i) of the HEA (20 U.S.C. 1090(a)(2)(D)(i), 1090(a)(2)(E)(ii), and 1090(a)(3)(B)(i)) from this system to State higher education agencies, eligible IHEs, and scholarship organizations that were designated prior to the date of enactment (December 19, 2019) of the FUTURE Act (Pub. L. 116–91, 133 Stat. 1189) that award and administer aid to students, to determine an applicant's eligibility for aid awarded by State higher education agencies, eligible IHEs, or designated scholarship organizations, and to administer Federal aid or aid awarded by State higher education agencies, eligible IHEs, or designated scholarship organizations.;

(r) To help Federal, State, Tribal, and local government entities exercise their supervisory and administrative powers (including, but not limited to licensure, examination, discipline, regulation, or oversight of IHEs, Department contractors, guaranty agencies, lenders and loan holders, and third-party servicers) or to respond to aid applicant or recipient complaints submitted regarding the practices or processes of the Department and/or the Department's contractors, or to update information or correct errors contained in Department records regarding the aid applicant's or recipient's title IV, HEA program funds, the Department may disclose records to governmental entities at the Federal, State, Tribal, and local levels. These records may include all aspects of loans and grants made under title IV of the HEA to permit these governmental entities to verify compliance with applicable debt collection, consumer protection, financial, and other applicable statutory, regulatory, or local requirements. Before making a disclosure to these Federal, State, local, or Tribal governmental entities, the Department will require them to maintain safeguards consistent with the Privacy Act to protect the security and confidentiality of the disclosed records; and

(s) The Department may disclose records from an applicant's FAFSA to IHEs and State higher education agencies to provide aid applicants and aid recipients with information about certain Federal means-tested benefits for which they may qualify.

Note: Some information that is maintained in this system of records is also maintained in other Department systems of records and, therefore, may be disclosed pursuant to the routine uses published in those other systems' system of records notices, including the ''Common Origination and Disbursement (COD) System'' (18–11–02), ''National Student Loan Data System (NSLDS)'' (18–11–06), and ''Common Services for Borrowers (CSB)'' (18–11–16).

(2) *Enforcement Disclosure.* In the event that information in this system of records indicates, either on its face or in connection with other information, a violation or potential violation of any applicable statute, regulations, or order of a competent authority, the Department may disclose the relevant records to the appropriate agency, whether Federal, State, Tribal, or local, charged with the responsibility of investigating or prosecuting that violation or charged with enforcing or implementing the statute, Executive Order, rule, regulation, or order issued pursuant thereto.

(3) *Litigation and Alternative Dispute Resolution (ADR) Disclosure.*

(a) *Introduction.* In the event that one of the parties listed in sub-paragraphs (i) through (v) of this routine use is involved in judicial or administrative litigation or ADR, or has an interest in judicial or administrative litigation or ADR, the Department may disclose certain records to the parties described in paragraphs (b), (c), and (d) of this routine use under the conditions specified in those paragraphs:

(i) The Department or any of its components;

(ii) Any Department employee in their official capacity;

(iii) Any Department employee in their individual capacity where the U.S. Department of Justice (DOJ) agrees to or has been requested to provide or arrange for representation of the employee;

(iv) Any Department employee in their individual capacity where the Department has agreed to represent the employee; and

(v) The United States, where the Department determines that the litigation is likely to affect the Department or any of its components.

(b) *Disclosure to the DOJ.* If the Department determines that disclosure of certain records to the DOJ is relevant and necessary to judicial or administrative litigation or ADR, the Department may disclose those records as a routine use to the DOJ.

(c) *Adjudicative Disclosure.* If the Department determines that it is relevant and necessary to judicial or administrative litigation or ADR to disclose certain records to an adjudicative body before which the Department is authorized to appear or to a person or entity designated by the Department or otherwise empowered to

resolve or mediate disputes, the Department may disclose those records as a routine use to the adjudicative body, person, or entity.

(d) *Disclosure to Parties, Counsel, Representatives, and Witnesses.* If the Department determines that disclosure of certain records is relevant and necessary to judicial or administrative litigation or ADR, the Department may disclose those records as a routine use to the party, counsel, representative, or witness.

(4) *Freedom of Information Act (FOIA) and Privacy Act Advice Disclosure.* The Department may disclose records to the DOJ or to the Office of Management and Budget (OMB) if the Department determines that disclosure is desirable or necessary in determining whether records are required to be disclosed under the FOIA or the Privacy Act.

(5) *Contract Disclosure.* If the Department contracts with an entity to perform any function that requires disclosing records in this system of records to the contractor's employees, the Department may disclose the records to those employees. As part of such a contract, the Department shall require the contractor to agree to establish and maintain safeguards to protect the security and confidentiality of the disclosed records.

(6) *Congressional Member Disclosure.* The Department may disclose the records of an individual to a member of Congress or the member's staff when necessary to respond to an inquiry from the member made at the written request of and on behalf of the individual whose records are being disclosed. The member's right to the information is no greater than the right of the individual who requested it.

(7) *Employment, Benefit, and Contracting Disclosure.*

(a) *For Decisions by the Department.* The Department may disclose a record to a Federal, State, or local agency, or to another public agency or professional organization, maintaining civil, criminal, or other relevant enforcement or other pertinent records, if necessary to obtain information relevant to a Department decision concerning the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

(b) *For Decisions by Other Public Agencies and Professional Organizations.* The Department may disclose a record to a Federal, State, local, or other public agency or professional organization, or the Department's contractor in connection with the hiring or retention of an employee or other personnel action, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit, to the extent that the record is relevant and necessary to the receiving entity's decision on the matter.

(8) *Employee Grievance, Complaint, or Conduct Disclosure.* If a record is relevant and necessary to an employee grievance, complaint, or disciplinary action involving a present or former employee of the Department, the Department may disclose a record from this system of records in the course of investigation, fact-finding, or adjudication to any party to the grievance, complaint, or action; to the party's counsel or representative; to a witness; or to a designated fact-finder, mediator, or other person designated to resolve issues or decide the matter.

(9) *Labor Organization Disclosure.* The Department may disclose records from this system of records to an arbitrator to resolve disputes under a negotiated grievance procedure or to officials of labor organizations recognized under 5 U.S.C. chapter 71 when relevant and necessary to their duties of exclusive representation.

(10) *Disclosure to the DOJ.* The Department may disclose records to the DOJ to the extent necessary for obtaining DOJ advice on any matter relevant to an audit, inspection, or other inquiry related to the programs covered by this system.

(11) *Research Disclosure.* The Department may disclose records to a researcher if the Department determines that the individual or organization to which the disclosure would be made is qualified to carry out specific research related to functions or purposes of this system of records. The Department may disclose records from this system of records to that researcher solely for the purpose of carrying out that research related to the functions or purposes of this system of records. The researcher must agree to establish and maintain safeguards to protect the security and confidentiality of the disclosed records.

(12) *Disclosure to the OMB and Congressional Budget Office (CBO) for Federal Credit Reform Act (FCRA) Support.* The Department may disclose records to OMB and CBO as necessary to fulfill FCRA requirements in accordance with 2 U.S.C. 661b.

(13) *Disclosure in the Course of Responding to Breach of Data.* The Department may disclose records to appropriate agencies, entities, and persons when (a) the Department suspects or has confirmed that there has been a breach of the system of records; (b) the Department has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Department (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(14) *Disclosure in Assisting another Agency in Responding to a Breach of Data.* The Department may disclose records from this system of records to another Federal agency or Federal entity, when the Department determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach, or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(15) *Disclosure of Information to State and Federal Agencies.* The Department may disclose records from this system of records to (a) a Federal or State agency, its employees, agents (including contractors of its agents), or contractors, or (b) a fiscal or financial agent designated by the U.S. Department of the Treasury, including employees, agents, or contractors of such agent, for the purpose of identifying, preventing, or recouping improper payments to an applicant for, or recipient of, Federal funds.

(16) *Disclosure to the National Archives and Records Administration (NARA).* The Department may disclose records from this system of records to NARA for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

(17) *Disclosure to Consumer Reporting Agencies.* Disclosures pursuant to 5 U.S.C. 552a(b)(12): The Department may disclose the following information to a consumer reporting agency regarding a valid, overdue claim of the Department: (a) the name, address, taxpayer identification number, and other information necessary to establish the identity of the individual responsible for the claim; (b) the amount, status, and history of the claim; and (c) the program under which the claim arose. The Department may disclose the information specified in

this paragraph under 5 U.S.C. 552a(b)(12) and the procedures contained in subsection 31 U.S.C. 3711(e). A consumer reporting agency to which these disclosures may be made is defined at 15 U.S.C. 1681a(f) and 31 U.S.C. 3701(a)(3).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

System records are paper-based and stored in locked rooms or electronic and stored on secured computer systems and in the cloud.

Fully processed paper applications and supporting paper documentation that are received on or before June 30, 2024, are stored for applicable periods in standard Federal Records Center boxes in locked storage rooms at the contractor facilities in London, Kentucky. Fully processed paper applications and supporting paper documentation requiring retention and received on or after July 1, 2024, will be stored in a private records storage facility, as applicable. The records storage facilities currently utilized are listed in the ''System Location'' section above.

Digitized paper applicant records, which include optically imaged documents, are stored on DADS (disks) in a virtual disk library, which is also electronic, in the computer facilities controlled by the Next Generation Data Center (NGDC) in Clarksville, VA.

Records that are collected in this system for applicants of Federal grants or loans are stored in the COD System for individuals who apply under one of the programs authorized under title IV of the HEA, including, but not limited to the: (1) Federal Pell Grant Program; (2) Federal Perkins Loans Program; (3) ACG Program; (4) National SMART Grant Program; (5) TEACH Grant Program; (6) Iraq and Afghanistan Service Grant Program; (7) Direct Loan Program, which includes Federal Direct Stafford/Ford Loans, Federal Direct Unsubsidized Stafford/Ford Loans and Federal Direct PLUS Loans and Federal Direct Consolidation Loans; (8) FFEL Program; and (9) FISL Program.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records in this system pertaining to a title IV, HEA loan applicant, borrower, or grant recipient are indexed and retrieved by a single data element, or a combination of the following data elements, to include SSN, name, DOB, the award year in which the applicant applied for title IV, HEA program assistance, and case tracking number. These data elements are also used to retrieve information of title IV, HEA program applicants for and recipients of Federal grants or loans from the COD System (applicant information is collected in this system of records and stored in the COD System).

This system also uses a credit appeal identifier to retrieve credit appeal information from the COD System to support the credit appeal process.

Additionally, this system uses a combination of SSN, DOB, and name data elements to retrieve some records from Federal Loan Servicers' systems (covered by the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16)) to allow customers to access their payment information, loan information and to make payments on *StudentAid.gov* as they would on the various Federal Loan Servicer websites.

This system also uses customer identifiers to retrieve customer information data from the EDMAPS system (covered by the system of records noticed entitled ''Enterprise Data Management and Analytics Platform Services (EDMAPS) System'' (18–11–22)) to allow real-time updates to customer information and communication preferences; and for the Department and its contractors to identify customers who have completed a customer satisfaction survey in the DCC system; who may have potential fraudulent activity from a TPDR company; and who may be at risk for loan default.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records maintained in this system are primarily retained and disposed of in accordance with the records schedules listed below. The Department has submitted amendments to these records schedules to NARA for its review and approval.

(a) Department Records Schedule 051: FSA National Student Loan Data System (NSLDS) (DAA–0441–2017–0004) (ED 051). (Records covered by ED 051 will not be destroyed until NARA-approved amendments to ED 051 are in effect, as applicable.)

(b) Department Records Schedule 052: Ombudsman Case Files (N1–441–09–21) (ED 052). (Records covered by ED 052 will not be destroyed until NARA-approved amendments to ED 052 are in effect, as applicable.)

(c) Department Records Schedule 072: FSA Application, Origination, and Disbursement Records (DAA–0441–2013–0002) (ED 072). (Records covered by ED 072 will not be destroyed until NARA-approved amendments to ED 072 are in effect, as applicable.)

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All users of the system will have a unique user ID with a password. All physical access to the data housed at system locations is controlled and monitored by security personnel who check each individual entering the building for their employee or visitor badge. The IT systems employed by the Department offers a high degree of resistance to tampering and circumvention with firewalls, encryption, and password protection. This security system limits data access to Department and contract staff on a ''need-to-know'' basis and controls individual users' ability to access and alter records within the system. All interactions by users of the system are recorded.

In accordance with the Federal Information Security Management Act of 2002 (FISMA), as amended by the Federal Information Security Modernization Act of 2014, every Department system must receive a signed Authorization to Operate (ATO) from a designated Department official. The ATO process includes a rigorous assessment of security and privacy controls, a plan of actions and milestones to remediate any identified deficiencies, and a continuous monitoring program.

FISMA controls implemented are comprised of a combination of management, operational, and technical controls, and include the following control families: access control, awareness and training, audit and accountability, security assessment and authorization, configuration management, contingency planning, identification and authentication, incident response, maintenance, media protection, physical and environmental protection, planning, personnel security, privacy, risk assessment, system and services acquisition, system and communications protection, system and information integrity, and program management.

RECORD ACCESS PROCEDURES:

If you wish to gain access to a record in this system, contact the respective system manager at the address listed above. You must provide necessary particulars such as your name, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals with the same name.

Alternatively, to gain access to a record in the system, you may make a Privacy Act request through the U.S. Department of Education, FOIA Service

Center at *https://www2.ed.gov/policy/gen/leg/foia/request_privacy.html* by completing the applicable request forms. Requests by an individual for access to a record must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

Borrowers are able to access their financial aid history from NSLDS in this system. If you wish to gain access to other records in the NSLDS, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''National Student Loan Data System (NSLDS)'' (18–11–06).

For title IV, HEA program applicants and recipients of Federal grants or loans, if you wish to gain access to such information about you from the COD System, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''Common Origination and Disbursement (COD) System'' (18–11–02).

If you wish to gain access to the EDMAPS system information that is about you and accessible in this system, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''Enterprise Data Management and Analytics Platform Services (EDMAPS) System'' (18–11–22).

If you wish to gain access to the PAS system information about you that is maintained in this system until CPS is decommissioned after September 30, 2024, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''Person Authentication Service (PAS)'' (18–11–12).

If you wish to gain access to the information in the Federal Loan Servicers' IT systems that is about you and accessible in this system, please refer to the RECORD ACCESS PROCEDURES section in the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16).

CONTESTING RECORD PROCEDURES:

If you wish to contest or change the content of a record about you in the system of records, provide the respective system manager with your name, DOB, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals with the same name. Identify the specific items to be changed and provide a written justification for the change.

To contest information submitted or included on a FAFSA application for the current award year, send your request to the FOIA Service Center listed in the Notification Procedures section.

Financial aid history from NSLDS is accessible in this system. To contest name and address records about you, provide the respective system manager with your name, DOB, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals with the same name. All other financial aid history records from NSLDS must be contested by following the CONTESTING RECORD PROCEDURES identified in the system of records notice entitled ''National Student Loan Data System (NSLDS)'' (18–11–06).

For title IV, HEA program applicants and recipients of Federal grants or loans, if you wish to contest such information about you, please refer to the CONTESTING RECORD PROCEDURES section in the system of records notice entitled ''Common Origination and Disbursement (COD) System'' (18–11–02).

To contest information about you in a Federal Loan Servicer IT system, such as the payment and loan information that is accessible in this system, please refer to the CONTESTING RECORD PROCEDURES section in the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16).

To contest the EDMAPS system information that is accessible in this system, please refer to the CONTESTING RECORD PROCEDURES section in the system of records notice entitled ''Enterprise Data Management and Analytics Platform Services (EDMAPS) System'' (18–11–22).

To contest the PAS system information about you that is maintained in this system until CPS is decommissioned after September 30, 2024, please refer to the CONTESTING RECORD PROCEDURES section in the system of records notice entitled ''Person Authentication Service (PAS)'' (18–11–12).

Requests to amend a record must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.7.

NOTIFICATION PROCEDURES:

If you wish to determine whether a record exists about you in the system of records, contact the respective system manager at the address listed above. You must provide necessary particulars such as your name, SSN, and any other identifying information requested by the Department while processing the request to distinguish between individuals with the same name.

Alternatively, you may make a Privacy Act request through the U.S. Department of Education, FOIA Service Center at *https://www2.ed.gov/policy/gen/leg/foia/request_privacy.html* by completing the applicable request forms.

If you wish to submit a request for notification to determine whether a record exists about you in the COD System as a title IV, HEA program applicant or recipient of a Federal grant or loan, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''Common Origination and Disbursement (COD) System'' (18–11–02).

Borrowers are able to access their financial aid history from NSLDS in this system. If you wish to submit a request for notification to determine whether a record exists about you in the NSLDS system of records, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''National Student Loan Data System (NSLDS)'' (18–11–06).

If you wish to submit a request for notification to determine whether a record exists about you in a Federal Loan Servicer IT system, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''Common Services for Borrowers (CSB)'' (18–11–16).

If you wish to submit a request for notification to determine whether a record exists about you in EDMAPS system, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''Enterprise Data Management and Analytics Platform Services (EDMAPS) System'' (18–11–22).

If you wish to submit a request for notification to determine whether a record exists about you in the PAS system, please refer to the NOTIFICATION PROCEDURES section in the system of records notice entitled ''Person Authentication Service (PAS)'' (18–11–12).

Requests for notification about whether the system of records contains information about an individual must meet the requirements of the Department's Privacy Act regulations at 34 CFR 5b.5, including proof of identity.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The system of records entitled ''Aid Awareness and Application Processing'' (18–11–21) was last modified and

published in full in the **Federal Register** on February 2, 2024 (89 FR 7381).

[FR Doc. 2024–11852 Filed 5–29–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2326–054]

Great Lakes Hydro America, LLC; Notice of Availability of Draft Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for license for the Cross Power Hydroelectric Project, located on the Androscoggin River in Coos County, New Hampshire and has prepared a Draft Environmental Assessment (DEA) for the project. No federal land is occupied by project works or located within the project boundary.

The DEA contains staff's analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the DEA 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. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/eSubscription.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *https://ferconline.ferc.gov/QuickComment.aspx.* For assistance, please contact FERC Online Support. 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, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–2326–054.

Any questions regarding this notice may be directed to Ryan Hansen at (202) 502–8074 or *ryan.hansen@ferc.gov.*

Dated: May 23, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–11886 Filed 5–29–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 10253–042; 10254–039]

Pelzer Hydro Company, LLC; Consolidated Hydro Southeast, LLC; Notice of Application of Transfer of Licenses and Soliciting Comments, Motions To Intervene, and Protests

On April 23, 2024, Pelzer Hydro Company, LLC (Pelzer Hydro) and Consolidated Hydro Southeast, LLC (Consolidated Hydro) filed an application for partial transfer of licenses of their 3,300-kilowatt Lower Pelzer Hydroelectric Project No. 10253 and the 1,950-kilowatt Upper Pelzer Hydroelectric Project No. 10254. The projects are located on the Saluda River in Anderson and Greenville counties, South Carolina and do not occupy federal land.

Pursuant to 16 U.S.C. 801, the applicants, co-licensees for the projects, seek Commission approval to transfer the licensee interest of Consolidated Hydro to Pelzer Hydro, which would become sole licensee for both projects.

Applicants Contacts:

For Pelzer Hydro: Kevin Webb, Hydro Licensing Manager, Patriot Hydro, LLC, 670 N. Commercial Street, Suite 204, Manchester, NH 03101, *kwebb@patriothydro.com.*

For Consolidated Hydro: Consolidated Hydro Southeast, LLC, Attn: General Counsel, 100 Brickstone Sq., Suite 300, Andover, MA 01810, *generalcounsel@enel.com.*

FERC Contact: Steven Sachs, Phone: (202) 502–8666, Email: *Steven.Sachs@ferc.gov.*

Deadline for filing comments, motions to intervene, and protests: 30 days from the date that the Commission issues this notice. The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

In lieu of electronic filing, you may submit a paper copy. Submissions sent via 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. The first page of any filing should include docket numbers P–10253–042 and P–10254–039. Comments emailed to Commission staff are not considered part of the Commission record.

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: May 23, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–11883 Filed 5–29–24; 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 in Existing Proceedings

Docket Numbers: PR24–62–001.

Applicants: Delaware Link Ventures, LLC.

Description: 284.123(g) Rate Filing: Amendment to 1 to be effective 4/1/2024.

Filed Date: 5/23/24.

Accession Number: 20240523–5079.

Comment Date: 5 p.m. ET 5/31/24.

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: May 23, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–11888 Filed 5–29–24; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2015–0453; FRL—12008–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Notification of Chemical Exports Under TSCA Section 12(b) (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Notification of Chemical Exports under TSCA Section 12(b) (EPA ICR Number 0795.17, and OMB Control Number 2070–0030) 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 May 31, 2024. Public comments were previously requested via the **Federal Register** on September 22, 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 July 1, 2024.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OPPT–2015–0453, 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: Katherine Sleasman, Office of Program Support (7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–1206; email address: *sleasman.katherine@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through May 31, 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 September 22, 2023 during a 60-day comment period (88 FR 65390). 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: This ICR covers the information collection activities associated with the reporting and recordkeeping requirements under section 12(b) of the Toxic Substances Control Act (TSCA) which requires any person who exports or intends to export to a foreign country a chemical substance or mixture for which submission of information is required under TSCA sections 4 or 5(b), or for which a rule, action or order has been proposed or promulgated under TSCA sections 5, 6, or 7, shall notify EPA of such export or intent to export. The Agency must, in turn, notify the government of the importing country of the notice and of EPA's regulatory action with respect to the substance.

In implementing TSCA section 12(b), EPA described the notification requirements applicable to persons exporting chemicals, including frequency of notification, covered chemicals, and content of the notification. See 40 CFR part 707, subpart D. In summary, the export notice must include five easily ascertainable items: (1) The name and address of the exporter; (2) The name of the chemical; (3) The country of import, (4) The date of export or intended export; and (5) The section of TSCA under which EPA has taken action (*i.e.,* TSCA sections 4, 5, 6 or 7). There are currently over 1,000 substances or categories of substances that have been regulated or proposed to be regulated

under the applicable sections of TSCA. For additional information about export requirements under TSCA, visit our website at *https://www.epa.gov/tsca-import-export-requirements.*

Form Numbers: 9600–031.

Respondents/affected entities: Entities potentially affected by this ICR include exporters of chemical substances regulated under TSCA which are mostly chemical companies classified under the North American Industrial Classification System (NAICS) codes 325 and 324.

Respondent's obligation to respond: Mandatory under TSCA section 12(b), as implemented by 40 CFR part 707, subpart D.

Estimated number of respondents: 226 (total).

Frequency of response: On occasion.

Total estimated burden: 2,694 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $184,690 (per year), which includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is a decrease of 238 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease reflects the net result from a decrease in burden caused by assuming 100 percent electronic submissions despite a small increase in burden due to a larger number of respondents compared to the previous ICR. This change is an adjustment to the estimates.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–11802 Filed 5–29–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2011–0742; FRL–12009–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Air Pollution Regulations for Outer Continental Shelf (OCS) Activities (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Air Pollution Regulations for Outer Continental Shelf (OCS) Activities (EPA ICR Number 1601.11, OMB Control Number 2060–0249) 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 May 31, 2024. Public comments were previously requested via the **Federal Register** on February 8, 2024, during a 60-day comment period. This notice allows for 30 days for public comments.

DATES: Comments may be submitted on or before July 1, 2024.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2011–0742, online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Avenue 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 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: Ben Garwood, Air Quality Policy Division, Office of Air Quality Planning and Standards, C504–03, U.S. Environmental Protection Agency, Post Office Box 12055, Research Triangle Park, NC 27711; telephone number: (919) 541–1358; fax number: (919) 541–4028; email address: *garwood.ben@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through May 31, 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 February 8, 2024, during a 60-day comment period (89 FR 8677). 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 *https://www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Avenue NW, Washington, DC. The telephone number for the Docket Center is (202) 566–1744. For additional information about EPA's public docket, visit *https://www.epa.gov/dockets.*

Abstract: Section 328 of the Clean Air Act (CAA) gives the EPA responsibility for regulating air pollution from OCS sources located offshore of the States along the Atlantic and Pacific Coasts (except the North Slope Borough of Alaska), and along the Gulf Coast off the State of Florida eastward of longitude 87 degrees and 30 minutes (*i.e.,* off the coast of Florida). In general, these OCS sources must obtain OCS permits that comply with the New Source Review preconstruction permit program and title V operating permit program among other requirements, and then maintain ongoing compliance with their permit conditions. Industry respondents must prepare permit applications and, after receiving their permits, conduct testing, monitoring, recordkeeping and reporting as required by their permits. The EPA has delegated the authority to implement and enforce the OCS regulations to four local air pollution control agencies in California and three State air pollutions control agencies (Delaware Maryland, and Virginia). These agency respondents must review sources' permit applications and reports, issue permits, observe performance tests and conduct inspections to ensure that the sources off their coasts are meeting all the requirements that apply to them. The type and quantity of information required will depend on the circumstances surrounding the action but may include that required in applicability determinations, Notices of Intent (NOI), New Source Review (NSR) preconstruction permitting requirements, Part 70 Title V (Title V) operating permit requirements, New Source Performance Standards (NSPS) and some National Emission Standards for Hazardous Air Pollutants (NESHAP) promulgated under section 112 of the CAA. In addition, inner OCS sources could be subject to other requirements as those that would be applicable if the source were located in the corresponding onshore area (COA). Sources locating beyond 25 nautical miles from the State seaward boundary (outer OCS) are subject to Federal air quality requirements which could

include the EPA's PSD preconstruction permit program, Part 71 Title V operating permit program, NSPS and NESHAP promulgated under section 112 of the CAA. State and local air pollution control agencies are usually requested to provide information concerning regulation of offshore sources and are provided opportunities to comment on the proposed determinations. The public is also provided an opportunity to comment on the proposed determinations.

Form numbers: None.

Respondents/affected entities: Entities potentially affected by this action are those that must apply for and obtain an OCS permit pursuant the OCS permit program. In addition, State and local agencies that have been delegated authority to implement and enforce the OCS permit program, which must review permit applications and issue permits, are affected entities.

Respondent's obligation to respond: Mandatory (CFR part 55).

Estimated number of respondents: 74 industrial facilities and 7 State and local permitting agencies.

Frequency of response: On occasion, as necessary.

Total estimated burden: 36,001 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $3,755,783.00 (per year), includes $380,372 annualized capital or operation & maintenance costs.

Changes in estimates: There is a projected increase of 15,778 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is primarily due to the projected number of OCS sources subject to the program mainly related to alternative energy sources including new wind power farms along the eastern seaboard of the United States.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–11806 Filed 5–29–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OMS–2023–0605; FRL—12011–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (EPA ICR Number 2434.204, OMB Control Number 2030–0051) 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 May 31, 2024. Public comments were previously requested via the **Federal Register** on January 26, 2024 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 July 1, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number: EPA–HQ–OMS–2023–0605, 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: Aaron Jackson, Information Engagement Division (IED), Office of Information Management (OIM), 282T, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 566–0348; email address: *jackson.aaron@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through May 31, 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 January 26, 2024 during a 60-day comment period (89 FR 5228). 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: The information collection activity provides EPA with an opportunity to efficiently engage its customers and stakeholders by gathering qualitative information about their current or potential future interaction with Agency. Getting such feedback in a timely manner is critical if the Agency is to know how and where it should focus while seeking to improve, or expand upon, its products and services. Following the pathway established by OMB for fast-track generic ICRs, the Agency will submit individual requests for specific information collections on an as-needed basis. Those requests will describe the collection and the public burden created. The Agency will submit a collection request for approval under this generic clearance only if the collections are: voluntary; low burden and low-cost for both the respondents and the federal government; noncontroversial; targeted to respondents who have experience with the program or may have experience with the program in the near future; and abstain from collecting personally identifiable information (PII) to the greatest extent possible. Information gathered will be used internally for general service improvement and program management purposes and released publicly only in an anonymized or aggregated fashion. Information gathered will not be used in

statistical analysis intended to yield results that can be generalized to the population of study, nor will it be used to substantially inform influential policy decisions.

Form Numbers: To be provided in individual collection requests.

Respondents/affected entities: Individuals, businesses, organizations, and state, local, and Tribal representatives that are stakeholders in, consumers of, or partners in providing, EPA or EPA-supported current or potential services and programs.

Respondent's obligation to respond: Voluntary.

Estimated number of respondents: 180,000 (total).

Frequency of response: Varies.

Total estimated burden: 45,000 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: There are no expected capital or operation & maintenance costs.

Changes in the Estimates: There are no changes or adjustments reported in the burden or capital/O&M cost estimates.

Courtney Kerwin,

Director, Information Engagement Division.

[FR Doc. 2024–11805 Filed 5–29–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than July 1, 2024.

A. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri, 64198–0001. Comments can also be sent electronically to *KCApplicationComments@kc.frb.org:*

1. *West 4 Bancshares, Inc., Healy, Kansas;* to become a bank holding company by acquiring First State Bank, Healy, Kansas.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2024–11903 Filed 5–29–24; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Peripheral Nerve Blocks for Postoperative Pain Management in Cardiothoracic Surgery

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submission.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Peripheral Nerve Blocks for Postoperative Pain Management in Cardiothoracic Surgery,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before July 1, 2024.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301–427–1656 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Peripheral Nerve Blocks for Postoperative Pain Management in Cardiothoracic Surgery.* AHRQ is conducting this review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Peripheral Nerve Blocks for Postoperative Pain Management in Cardiothoracic Surgery.*

The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/peripheral-nerve-blocks/protocol.*

This is to notify the public that the EPC Program would find the following information on *Peripheral Nerve Blocks for Postoperative Pain Management in Cardiothoracic Surgery* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements, if relevant: study number, study period, design, methodology,

indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

▪ *A list of ongoing studies that your organization has sponsored for this topic.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

▪ Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *https://effectivehealthcare.ahrq.gov/email-updates.*

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

- KQ 1. In adult intrathoracic surgical patients, what are the effectiveness, comparative effectiveness, and harms of peripheral nerve blocks for managing postoperative pain and its sequelae—including opioid use?
  - KQ 1a. How do findings vary by baseline patient clinical characteristics (*e.g.,* ASA status, chronic opioids (>90 days), pre-existing psychiatric diagnoses)?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

KQ1	Inclusion	Exclusion
Population	Adult patients (18 years and older) undergoing the following open or minimally invasive (laparoscopic/thoracoscopic), elective, or urgent intrathoracic surgeries*: • Cardiac • Lung • Other intrathoracic KQ 1a Subgroups: Patients taking opioid medications for chronic pain, those with preexisting psychiatric diagnoses, and ASA status.	—Pediatric patients under the age of 18 years. —Patients undergoing spine, head/neck, orthopedic, breast, abdominal, pelvic, peritoneal, retroperitoneal, or obstetric surgery. —Pregnant patients. —Other surgery not listed. —Emergency surgery.
Intervention	Peripheral nerve block (PNB) either alone or as part of multimodal analgesia for postoperative pain management.	—Other pain management strategies not considered peripheral nerve blocks. —Cryoanesthesia/cryoanalgesia. —PNBs used for limb or excluded surgery. —Neuraxial blockade (epidural, spinal, caudal, and paravertebral nerve blocks).
Comparators	Placebo, sham, usual care, multimodal analgesia without peripheral nerve block, other peripheral nerve block administration (*e.g.,* differing location, continuous vs. single shot), local anesthesia infiltration at surgical incision, neuraxial blockade (epidural, spinal, caudal, and paravertebral nerve blocks).	Same peripheral nerve block but with different dose/additives or different local anesthetic (bupivacaine vs. ropivacaine or vs. liposomal/long-acting local anesthetic).
Outcomes	*Early//intermediate (72 hours or time of discharge to ≤3 months postoperative):* • Pain intensity • Opioid use • Pain trajectory • Pain interference • Quality of recovery • Health-related quality of life (HRQoL) • Patient satisfaction • Hospital length of stay • Cost to patient *Long-term (>3 months postoperative):* • Physical functional status • Opioid use • Chronic postsurgical pain • Intensity of chronic postsurgical pain • HRQoL • Patient satisfaction *Harms:* • Complications/adverse events of treatment (nerve damage, bleeding, all-cause return to ED/hospital within 30 days, etc.) • Rebound pain—increased pain relative to controls when the block subsides.	Outcomes not listed. Studies excluded if postoperative pain intensity is not reported.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

KQ1	Inclusion	Exclusion
Outcome Timing	Post-operative period ≤3 months subdivided into 72 hours or less; >72 hours or discharge up to <30 days; 30 days up to ≤3 months. Post-operative period 3–12 months.	Other timing.
Setting	Perioperative (inpatient or outpatient) setting for intervention. Perioperative and all follow-up settingsfor outcomes.	Nerve blocks performed in the outpatient clinic. Nerve blocks performed outside of the preoperative day-of-surgery to the 24-hours postoperative.
Study design	Randomized controlled trials (RCTs). Minimum sample size per arm of ≥30 participants. If a particular intervention/comparator is not represented in the studies of 30/arm or greater, we will include studies of smaller size for that unique intervention/comparator.	Non-randomized, observational, non-controlled study designs, cross-sectional, prevalence, qualitative, case reports, opinions/letters, pilot studies, feasibility studies. Studies with a sample size <30 participants analyzed in any arm.
Publications	English-only peer-reviewed publications from 2013. (Consistent with other current ASA systematic reviews on regional anesthesia.)	Comments, editorials, and letters.

* EMERGENCY—A surgical, therapeutic, or diagnostic procedure that cannot be delayed without causing a significant risk of death or permanent impairment. *Note:* The American Society of Anesthesiologists (ASA) Physical Status should include ''E''. The designation of a procedure as an emergency is determined by a surgeon and/or an anesthesiologist.

URGENT—A surgical, therapeutic, or diagnostic procedure that must be performed to prevent death or permanent impairment but that can be delayed. *Note:* The procedure may be delayed to allow for medical optimization of the patient or to permit better availability of resources (*e.g.,* personnel or equipment).

ELECTIVE—A surgical, therapeutic, or diagnostic procedure that can be performed at any time or date with an agreement between the surgeon and the patient.

Dated: May 22, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–11834 Filed 5–29–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Advisory Committee to the Director, Centers for Disease Control and Prevention; Notice of Extension

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations for membership on the Advisory Committee to the Director, Centers for Disease Control and Prevention (ACD, CDC). The ACD, CDC consists of up to 15 experts knowledgeable in areas pertinent to the CDC mission, such as public health, global health, health disparities, biomedical research, and other fields, as applicable.

DATES: The deadline for submission of nominations for membership on the ACD, CDC published May 8, 2024, at 89 FR 38900, is extended. Nominations for membership on the ACD, CDC must be received no later than July 8, 2024. Late nominations will not be considered for membership.

ADDRESSES: All nominations (cover letters, reference letters, and curriculum vitae/resumes) should be emailed to *ACDirector@cdc.gov* with the subject line: ''Nomination for CDC ACD.''

FOR FURTHER INFORMATION CONTACT: Tiffany Brown, J.D., M.P.H., Office of the Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–10, Atlanta, Georgia 30329–4027. Telephone: (404) 498–6655; Email: *ACDirector@cdc.gov.*

SUPPLEMENTARY INFORMATION: The deadline for nominations for appointment to the Advisory Committee to the Director, Centers for Disease Control and Prevention has been extended from June 7, 2024, to July 8, 2024. The original solicitation of nominations notice was published in the **Federal Register** on May 8, 2024, Volume 89, Number 90, page 38900.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–11871 Filed 5–29–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Family Violence Prevention and Services Grants to States; Native American Tribes and Alaskan Native Villages; and State Domestic Violence Coalitions (Office of Management and Budget #0970–0280)

AGENCY: Office of Family Violence Prevention and Services; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Family Violence Prevention and Services Act (FVPSA) program within the Office of Family Violence Prevention and Services (OFVPS) plans revised program announcements and minor changes to the previously approved Performance Progress Report for States and Tribes (Office of Management and Budget (OMB) #0970–0280; Expiration Date: May 31, 2024). Minor changes are

proposed to the existing information collection.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Under the FVPSA, OFVPS has a legislative requirement for grantees to report on activities carried out throughout their grant period and provide an evaluation on the effectiveness of the activities in achieving the purposes of the grant. Grantees must collect unduplicated data and only share non-personally identifying information, in the aggregate, regarding services to their clients in order to comply with federal, state, or tribal reporting, evaluation, or data collection requirements, (42 U.S.C. 10406(c)(5)(D)). Client-level data shall not be shared with a third party, regardless of encryption, hashing, or other data security measures, without a written, time-limited release as described in 42 U.S.C. 10406(c)(5).

Respondents: FVPSA-funded grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
FVPSA State Grants Notice of Funding Opportunity	52	1	10	520	173
FVPSA Tribes/Tribal Organizations Grants Notice of Funding Opportunity	143	1	10	1,430	477
FVPSA State Domestic Violence Coalitions Grants Notice of Funding Opportunity	56	1	10	560	187
State FVPSA Grant Performance Progress Report	52	3	10	1,560	520
Tribal FVPSA Grant Performance Progress Report	143	3	10	4,290	1,430
State Domestic Violence Coalition Performance Progress Report	56	3	10	1,680	560
Estimated Total Annual Burden Hours:					3,347

Authority: The Family Violence Prevention and Services Act, 42 U.S.C. 10401.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–11830 Filed 5–29–24; 8:45 am]

BILLING CODE 4184–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Stakeholder Listening Session for the G7 Health Track

AGENCY: Office of Global Affairs, Department of Health and Human Services.

ACTION: Notice of public listening session; request for comments.

DATES: The listening session will be held on Wednesday, July 24, 2024, from 10 a.m. to 12 p.m. Eastern Daylight Time. This meeting is open to the public but requires RSVP to *oga.rsvp@hhs.gov* by Friday, July 19, 2024. *See RSVP section in* **SUPPLEMENTARY INFORMATION** *for details.*

ADDRESSES: The session will be held virtually, with online and dial-in information shared with registered participants.

SUPPLEMENTARY INFORMATION:

Purpose: The U.S. Department of Health and Human Services (HHS), with support from relevant health-related U.S. Government offices, is charged with leading U.S. engagement in the Group of 7 (G7) Health Track and will convene an informal Stakeholder Listening Session.

The Stakeholder Listening Session is designed to seek input from stakeholders and subject matter experts to help inform and prepare for U.S. government engagement with G7 health ministries.

The Group of Seven (G7) is an informal grouping of advanced democracies that meets annually to coordinate global economic policy and address other transnational issues. The Group was established as a platform for economic and financial cooperation in response to the 1973 energy crisis. Over the years G7 has progressively expanded its focus. From an ad-hoc gathering to discuss financial challenges, it has become a more formal, prominent venue to address major global issues.

The G7 is comprised of 7 countries: Canada, France, Germany, Italy, Japan, the United Kingdom, and the U.S. The European Union also participates in the Group as a ''nonenumerated'' member.

Each year, a different member country holds the presidency of the group and hosts the meetings. The presidency proposes the group's priorities for the year and hosts discussions to work towards consensus positions and actions on those priorities. This year's G7 presidency is Italy, which will be hosting Health Working Group meetings throughout the year, culminating in a Health Ministers' Meeting on in mid-October in Ancona, Italy.

Matters to be Discussed: The Stakeholder Listening Session will cover global health issues under the general themes of global health security and health systems strengthening, prevention and healthy aging, and addressing urgent challenges to health, which could benefit from G7 engagement.

Participation is welcome from stakeholder communities, including:

- Public health and advocacy groups
- State, local, and Tribal groups
- Private industry
- Minority health organizations
- Academic and scientific organizations

RSVP: Persons seeking to attend or speak at the listening session *must register by Friday, July 19, 2024.*

Registrants must include their full name and organization, if any, and

indicate whether they are registering as a *listen-only attendee* or as a *speaker participant* to *oga.rsvp@hhs.gov.*

Requests to participate as a speaker *must include:*

1. The name and email address of the person desiring to participate
2. The organization(s) that person represents, if any
3. Identification of the primary topic(s) of interest

Other Information: Written comments should be emailed to *oga.rsvp@hhs.gov with the subject line ''Written Comment Re: Stakeholder Listening Session in preparation for the G7 Health Track''* by Friday, July 26, 2024.

We look forward to your comments on U.S. engagement in the G7 Health Track.

Dated: May 23, 2024.

Susan Kim,

Principal Deputy Assistant Secretary, Office of Global Affairs.

[FR Doc. 2024–11787 Filed 5–29–24; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Darrion Nguyen (Respondent), who was formerly a Laboratory Technician, Division of Pediatric Neurology and Developmental Neuroscience, Baylor College of Medicine (BCM). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically Office of the Director (OD), National Institutes of Health (NIH), grant DP5 OD026428–01 and National Institute of Neurological Disorders and Stroke (NINDS), NIH, grant K12 NS098482–01. The questioned research was included in a PHS-funded research project progress report (RPPR), specifically DP5 OD026428–04 submitted to OD, NIH. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on May 14, 2024, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, JD, MPH, MBA, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Darrion Nguyen, Baylor College of Medicine (BCM): Based on the report of an investigation conducted by BCM and additional analysis conducted by ORI in its oversight review, ORI found that Mr. Darrion Nguyen (Respondent), former Laboratory Technician, Division of Pediatric Neurology and Developmental Neuroscience, BCM, engaged in research misconduct in research supported by PHS funds, specifically OD, NIH, grant DP5 OD026428–01 and NINDS, NIH, grant K12 NS098482–01. The questioned research was included in a PHS-funded RPPR, specifically DP5 OD026428–04 submitted to OD, NIH.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating experimental data and results that were included in the following one (1) RPPR, one (1) presentation, one (1) poster, six (6) research records, and two (2) figures of a prospective manuscript:

- DP5 OD026428–04, ''Illuminating GABAergic Signaling in Neurodevelopmental Disorders,'' submitted to OD, NIH, on July 12, 2021 (hereafter referred to as ''DP5 OD026428–04'').
- Elucidating the role of EBF3 haploinsufficiency in HADD syndrome pathogenesis. Jan and Dan Duncan Neurological Research Institute Seminar (NRI) Series, January 6, 2020 (hereafter referred to as ''NRI Seminar 2020'').
- Elucidating the role of EBF3 haploinsufficiency in 10q26 deletion and HADD syndrome pathogenesis. Poster presentation, Baylor College of Medicine—Texas Children's Hospital Pediatric Research Symposium, March 24, 2020 (hereafter referred to as ''Poster 2020'').
- Research Record ''2019–5–1_Cerebellar PC Dens_P0.xlsx'' (hereafter referred to as ''RR1 2019'').
- Research Record ''2019–6–27_Cerebellar PC Dens_P0.xlsx'' (hereafter referred to as ''RR2 2019'').
- Research Record ''2019–5–1_P0 Cerebellum Quants.pzfx'' (hereafter referred to as ''RR3 2019'').
- Research Record ''2019–5–21_DN-Cohort5 (Analyzed).xlsx'' (hereafter referred to as ''RR4 2019'').
- Research Record ''2019–8–28_Partition-Cohorts 1, 2, 3, 4, 5, 6.pzfx'' (hereafter referred to as ''RR5 2019'').
- Research Record ''2019–12–11_Dystonia.xlsx'' (hereafter referred to as ''RR6 2019'').
- ''Fig1—GeneratingNullLines.v5.tif'' (hereafter referred to as ''PM Figure 1'') and ''Fig3—Behavior.v6.png'' (hereafter referred to as ''PM Figure 3'') in a prospective manuscript with working title ''Ebf3 haploinsufficiency perturbs cerebellar development and complex behaviors'' (hereafter referred to as the ''manuscript'').

Specifically, ORI found that Respondent intentionally, knowingly, or recklessly falsified and/or fabricated:

- the Purkinje Cell (PC) density measurements in the cerebellum lobes of newborn (P0) wild-type (WT) and Early B Cell Factor 3 heterozygous ($Ebf3^{+/-}$) mice in RR1 2019, RR2 2019, RR3 2019, and Slide 24 of NRI Seminar 2020 by copying and pasting measurement values collected from the histology sections of the brain from a single mouse to falsely represent the data measurements as from the brains of three (3) mice;
- the measurements of the distance between the anchor points in the cerebellum lobes of P0 WT and $Ebf3^{+/-}$ mice in RR1 2019, RR2 2019, and RR3 2019 by copying and pasting measurement values collected from the histology sections of the brain from a single mouse to falsely represent the data measurements as from the brains of three (3) mice;
- the measurements of phosphorylated Histone 3 (PH3) positive neurons in the cerebellum lobes of P0 WT and $Ebf3^{+/-}$ mice in RR1 2019, RR2 2019, RR3 2019, and Slide 28 of NRI Seminar 2020 by copying and pasting measurement values collected from the histology sections of the brain from a single mouse to falsely represent the data measurements as from the brains of three (3) mice;
- the external granule layer (EGL) thickness measurements in the cerebellum lobes of P0 WT and $Ebf3^{+/-}$ mice in RR1 2019, RR2 2019, and RR3 2019 by copying and pasting measurement values collected from the histology sections of the brain from a single mouse to falsely represent the data measurements as from the brains of three (3) mice;
- the manual scoring of the social interaction behavior of Cohort 5 mice in a three-chamber assay in RR4 2019 by copying and pasting the manually scored social interaction behavior values from Cohort 4 mice;
- the interaction data of male mice by inserting fabricated and/or falsified values for two (2) mice that had not been collected as part of the experiment in RR5 2019, Slide 44 of NRI Seminar 2020, Figure F in the ''Motor Incoordination and Altered Social Behavior'' section of Poster 2020, PM Figure 3 of the manuscript, and Figure 6E of DP5 OD026428–04;
- the number of mice used in the Western blot analysis for the expression of Ebf3 protein in $Ebf3^{-/-}$ mice in PM Figure 1B(iv) of the manuscript, Figure

4A(iii) of DP5 OD026428–04, Slide 16 of NRI Seminar 2020, and Figure C(i) of the ''Generation and Characterization of Ebf3Null Alleles'' section of Poster 2020; specifically, Western blot data from three (3) mice were falsely represented as data from five (5) mice;

• the hindlimb splay measurements of *Ebf3*$^{+/+}$ and *Ebf3*$^{+/-}$ mice in RR6 2019 and Figure 4D(ii) of DP5 OD026428–04 by changing the severity score of the splay measurements in male and female mice to falsely show enhanced severity of the dystonia symptoms in *Ebf3*$^{+/-}$ mice;

Respondent entered into a Voluntary Settlement Agreement (Agreement). Respondent neither admits nor denies ORI's findings of research misconduct. This settlement is not an admission of liability on the part of Respondent. Respondent voluntarily agreed to the following:

(1) Respondent will have his research supervised for a period of three (3) years beginning on May 14, 2024 (the ''Supervision Period''). Prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI. Respondent will comply with the agreed-upon supervision plan.

(2) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2–3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for a period of three (3) years from the effective date of the Agreement. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates and Respondent's compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

(3) During the Supervision Period, Respondent will ensure that any institution employing him submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported and not plagiarized in the application, report, manuscript, or abstract.

(4) If no supervision plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the Supervision Period that his participation was not proposed on a research project for which an application for PHS support was submitted and that he has not participated in any capacity in PHS-supported research.

(5) During the Supervision Period, Respondent will exclude himself voluntarily from serving in any advisory or consultant capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee.

Dated: May 23, 2024.

Sheila Garrity,

Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2024–11829 Filed 5–29–24; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Stimulating Access to Research in Residency (StARR) (R38 Independent Clinical Trial Not Allowed).

Date: July 15, 2024.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: Richard G. Kostriken, Ph.D., A.B., B.A., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20852, 240–669–2075, *richard.kostriken@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 24, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11857 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Exploratory Clinical Trials of Mind and Body Interventions (MB).

Date: June 27–28, 2024.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Complementary and Integrative, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mei Qin, MD, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH/NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, *mei.qin@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: May 23, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11854 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Development of Medical Countermeasures for Biodefense and Emerging Infectious Diseases, Research Area 003—In Vitro Diagnostics (N01).

Date: June 25–July 2, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52A, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: Shilpakala Ketha, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52A, Rockville, MD 20852, (301) 761–6821, *shilpa.ketha@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 24, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11858 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the Interagency Autism Coordinating Committee.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other accommodations should notify the Contact Person listed below at least seven (7) business days prior to the meeting. The meeting can be accessed from the NIH Videocast website (*http://videocast.nih.gov/*).

Name of Committee: Interagency Autism Coordinating Committee.

Date: July 10, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To discuss committee business, updates, and issues related to autism research and services activities.

Place: National Institute of Mental Health (NIMH), Neuroscience Center (NSC), 6001 Executive Boulevard, First Floor Conference Room, Rockville, MD 20852 (In Person and Virtual).

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (*www.iacc.hhs.gov*) prior to the meeting. Pre-registration is recommended.

Deadlines: Public Comment Due Date: Monday, June 24, by 5:00 p.m. ET, Public Comment Guidelines, For public comment instructions, see below.

Contact Person: Ms. Rebecca Martin, Office of National Autism Coordination, National Institute of Mental Health, NIH, Phone: 301–435–0886, *Email: IACCPublicInquiries@mail.nih.gov.*

Public Comments: The IACC welcomes written and oral/virtual public comments from members of the autism community and asks the community to review and adhere to its Public Comment Guidelines. In the *2021–2023 IACC Strategic Plan,* the IACC lists the ''Spirit of Collaboration'' as one of its core values, stating that, ''We will treat others with respect, listen with open minds to the diverse lived experiences of people on the autism spectrum and their families, consider multiple solutions, and foster discussions where participants can comfortably share different opinions.'' In keeping with this core value, the IACC and the NIMH Office of National Autism Coordination (ONAC) ask that members of the public who provide public comments or participate in meetings of the IACC also adhere to this core value.

A limited number of slots are available for individuals to provide a ~3-minute summary or excerpt of their written comment to the Committee during the meeting either in person or via videoconference. For those interested in that opportunity, please indicate ''Interested in providing oral/virtual comment'' in your written submission, along with your name, address, email, phone number, and professional/organizational affiliation so that ONAC staff can contact you if a slot is available.

For any given meeting, priority for comment slots will be given to individuals and organizations that have not previously provided comments in the current calendar year. This will help ensure that as many individuals and organizations as possible have an opportunity to share comments. Commenters going over their allotted 3-minute slot may be asked to conclude immediately in order to allow other comments and the rest of the meeting to proceed on schedule.

Public comment submissions received by 5:00 p.m. ET on Monday, June 24, 2024, will be provided to the Committee prior to the meeting for their consideration. Any written comments received after 5:00 p.m. ET, Monday, June 24, 2024, may be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. The Committee is not able to respond individually to comments. All public comments become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided. For public comment guidelines, see: *https://iacc.hhs.gov/meetings/public-comments/guidelines/.*

Technical issues: If you experience any technical problems with the webcast, please email *IACCPublicInquiries@mail.nih.gov.*

Disability Accommodations: All IACC Full Committee Meetings provide Closed Captioning through the NIH videocast website. Individuals whose full participation in the meeting will require special accommodations (*e.g.,* sign language or interpreting services, etc.) must submit a request to the Contact Person listed on the notice at least seven (7) business days prior to the meeting. Such requests should include a detailed description of the accommodation needed and a way for the IACC to contact the requester if more information is needed to fill the request. Special requests should be made at least seven (7) business days prior to the meeting; last-minute requests may be made but may not be possible to accommodate.

Security: During the check-in process, attendees will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Pre-registration is recommended. Seats will be on a first come, first served basis, with expedited check-in for those who are pre-registered. Meeting schedule subject to change.

More Information: Information about the IACC is available on the website: *http://www.iacc.hhs.gov.*

Dated: May 23, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11848 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Sickle Cell Disease Advisory Committee.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: July 23, 2024.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: NHLBI Sickle Cell Disease Program Updates.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

The event is free and open to the public, however, registration is required. Please use this link to register: *https://nih.zoomgov.com/webinar/register/WN_RZK8GeENQWO9DmGH3bBFnQ.*

Contact Person: Julie A. Panepinto, MD, MSPH, DFO/Executive Secretary SCDAC, Director, Division of Blood Diseases and Resources, 6701 Rockledge Drive, Suite 9166, Bethesda, MD 20892, (301) 435–0080, *NHLBIDBDRGrantResource@nhlbi.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nhlbi.nih.gov/advisory-and-peer-review-committees/nhlbi-sickle-cell-disease-advisory-committee,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 23, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11856 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Stakeholder Measures and Advocate Forms at the National Cancer Institute (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health, National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Amy Williams, Director of the Office of Advocacy Relations (OAR), NCI, NIH, 31 Center Drive, Bldg. 31, Room 10A28, MSC 2580, Bethesda, MD 20892, call non-toll-free number 240–781–3406, or email your request, including your address, to *amy.williams@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Stakeholder Measures and Advocate Forms at the National Cancer Institute (NCI), 0925–0774, Expiration Date10/31/2024, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for OMB to approve the revision of the collection titled, ''Stakeholder Measures and

Advocate Forms at the National Cancer Institute (NCI)'' for an additional three years of data collection. The Office of Advocacy Relations (OAR) disseminates cancer-related information to a variety of stakeholders, seeks input and feedback, and facilitates collaboration to advance NCI's authorized programs. It is beneficial for NCI, through the OAR, to pretest strategies, concepts, activities and materials while they are under development. Additionally, administrative forms are a necessary part of collecting demographic information and areas of interest for advocates. Since OAR is responsible for matching advocates to NCI programs and initiatives across the cancer continuum, it is necessary to measure the satisfaction of both internal and external stakeholders with this collaboration. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many initiatives and products that OAR and NCI produce. Past research has enabled OAR to monitor stakeholder trends, design and develop materials based on user feedback, assess the impact of activities, and improve service delivery. Primary users are internal with some advocates providing contact information, demographics and prior advocacy experience via a link provided to them to input their data.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 17.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Individuals	Advocates Survey	6	1	5/60	1
Individuals	Requestor Survey	6	1	5/60	1
Individuals	Profile Completion	30	1	30/60	15
Total			42		17

Dated: May 24, 2024

Diane Kreinbrink,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2024–11897 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; Clinical and Data Coordinating Center Applications for NCCIH Multi-Site Clinical Trials of Mind and Body Interventions.

Date: June 27, 2024.

Time: 9:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Complementary and Integrative, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892.

Contact Person: Mei Qin, MD, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH/NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, *mei.qin@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: May 23, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11851 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the licensing contact Michael Shmilovich, Esq, MS, CLP; 301–435–5019; *michael.shmilovich@nih.gov* at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A25, MSC2479, Bethesda, MD 20892–2479. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: This notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404. Technology description follows.

Next generation MRI platform Signal Amplification by Reversible Exchange (SABRE) hyperpolarization:

Hyperpolarized magnetic resonance imaging (MRI) is an emerging molecular imaging method for metabolic imaging for detecting cancer, cardiovascular disease, stroke, and traumatic brain injury and monitoring therapy with no Gadolinium or Iron. Available for licensing and commercial development is a patent estate covering a perfluorinated single amplification by reversible exchange (SABRE) catalyst for generating MRI agents that includes a d-block element and a perfluorinated ligand hyperpolarized substrate comprising a ½ spin nucleus or nuclei using the perfluorinated SABRE catalysts, and isolating the resulting hyperpolarized substrate for administration. The invention also provides methods for separating a hyperpolarized substrate from the SABRE catalyst and/or hyperpolarized SABRE catalyst complex containing a

heavy metal. These changes can be observed in patients in real time with a specialized MRI approach called hyperpolarization. By transiently changing the nuclear spin of naturally occurring intermediates in cellular energy production, the metabolic fate can be observed with greater than 10,000-fold sensitivity. Current methods of hyperpolarization require expensive machines with limited throughput.

Potential Commercial Applications:

- MRI imaging
- Hyperpolarization
- Infusion Device for imaging reagents
- Cancer diagnostics
- Cardiovascular disease diagnostics

Development Stage:

- Early stage

Inventors: Rolf E. Swenson (NHLBI), Jessica H. Ettedgui-Benjamini (NHLBI), Carolyn Woodroofe Hitko (NCI), Murali K. Cherukuri (NCI), and Natarajan Raju (NHLBI).

Intellectual Properties:

- HHS Reference No. E–035–2022–0 ''Preparation Of Isotopically Labeled Ketoglutarates And Methods Of Hyperpolarization Through Signal Amplification By Reversible Exchange (SABRE)''; U.S. Provisional Patent Application No. 63/303,190 filed January 26, 2022; Patent Cooperation Treaty Application PCT/US2023/011640 filed January 26, 2023.
- HHS Reference No. E–036–2022 ''Sabre Catalysts Containing Fluorinated Carbon Chains For Delivery Of Metal-Free MRI Contrast Agents''; U.S. Provisional Patent Application 63/328,545 filed April 7, 2022; Patent Cooperation Treaty Application PCT/US2023/017885 filed April 7, 2023, U.S. Patent Application 18/410,773 filed January 11, 2024, Applications also pending in Japan, Canada, Israel, China, and Europe.
- HHS Reference No. E–052–2022 ''Infusion device for the preparation and delivery of MRI probes,'' U.S. Provisional Patent Application 63/328,556 filed April 7, 2022, Patent Cooperation Treaty Application PCT/US2023/017895 filed April 7, 2023.
- HHS Reference No. E–069–2020 ''Real-time Monitoring Of In Vivo Free Radical Scavengers Through Hyperpolarized [1-^{13}C] N-acetyl Cysteine,'' U.S. Provisional Patent Application 62/961,855 filed January 16, 2020, Patent Cooperation Treaty Application PCT/US2021/013634 filed January 15, 2021, European Patent Application 21741034.9 filed January 15, 2021, Israeli Patent Application 294365 filed January 15, 2021, European Patent Application 17/793,083 filed January 15, 2021.
- HHS Reference No. E–070–2020 ''Isotopes Of Alpha Ketoglutarate And Related Compounds For Hyperpolarized MRI Imaging,'' U.S. Provisional Patent Application 62/962,473 filed January 17, 2020, Patent Cooperation Treaty Application PCT/US2021/013658 filed January 15, 2021, European Patent Application 21741941.5 filed January 15, 2021, Israeli Patent Application 294464 filed January 15, 2021, U.S. Patent Application 17/793,089 filed January 15, 2021.
- HHS Reference No. E–039–2022 ''Temperature Cycling Method for Hyperpolarization of Target Molecules and Contrast Agents using Parahydrogen,'' US Provisional Patent Application 63/203591 filed July 27, 2021. Patent Cooperation Treaty Application PCT/US2022/074122 filed July 26, 2022, U.S. Application 18/291,681.

Publications:

- Perfluorinated Iridium catalyst for signal amplification by reversible exchange provides metal-free aqueous hyperpolarized [1-^{13}C]-Pyruvate. J. Ettedgui, B. Blackman, N. Raju, S. Kotler, E. Chekmenev, B. Goodson, H. Merkle, C. Woodroofe, C. LeClair, K. Murali, R. Swenson J. Am. Chem. Soc. 2024, 146, 946–953.
- Monitoring response to a clinically relevant IDH inhibitor in glioma—Hyperpolarized ^{13}C magnetic resonance spectroscopy approaches. D. Hong, Y. Kim, C. Mushti, N. Minami, J. Wu, M. K. Cherukuri, R. E. Swenson, D. B. Vigneron, S. M. Ronen. Neuro-Oncology Advances 2023, DOI: *https://academic.oup.com/noa/article/5/1/vdad143/7337326.*
- Catalyst-Free Aqueous Hyperpolarized ^{13}C-Pyruvate Obtained by Re-Dissolution Signal Amplification by Reversible Exchange A. B. Schmidt; H. de Maissin; I. Adelabu; S. Nantogma; J. Ettedgui; P. TomHon; B. M Goodson.; T. Theis; E. Y. Chekmenev. *ACS Sensors* 2022, *7* (11), 3430–3439.
- Rapid ^{13}C Hyperpolarization of the TCA-Cycle Intermediate α-Ketoglutarate via SABRE–SHEATH. I. Adelabu, Isaiah; Ettedgui, Jessica; Joshi, Sameer; Nantogma, Shiraz; Chowdhury, Md Raduanul; McBride, Stephen; Theis, Thomas; Sabbasani, Venkata; Chandrasekhar, Mushti; Sail, Deepak; Yamamoto, Kazutoshi; Swenson, Rolf; Krishna, Murali; Goodson, Boyd; Chekmenev, Eduard. Anal. Chem. 2022, 94, 13422–13431.
- Order-Unity ^{13}C Nuclear Polarization of [1-^{13}C]Pyruvate in Seconds and the Interplay of Water and SABRE Enhancement. I. Adelabu, P. TomHon, M. S. H. Kabir, S Nantogma, M. Abdulmojeed, I. Mandzhieva, J. Ettedgui, R. E. Swenson, M. C. Krishna, T. Theis, B. M. Goodson, and E. Y. Chekmenev. ChemPhysChem. 2022, 23, 131–136.
- Simple esterification of [1-^{13}C]-alpha-ketoglutarate enhances membrane permeability and allows for non-invasive tracing of glutamate and glutamine production. J. AbuSalim, K. Yamamoto, N. Miura, B. Blackman, J. Brender, C. Mushti, T. Seki, K. Camphausen, R. Swenson, M. Krishna, A. Kesarwala. ACS Chem. Biol. 2021, 16, 2144–2150. DOI: 10.1021/acschembio.1c00561
- Synthesis of [1-^{13} C–5–12 C]-alpha-ketoglutarate enables non-invasive detection of 2-hydroxyglutarate. N. Miura, C. Mushti, D. Sail, J. E. Bingham, K. Yamamoto, J. R. Brender, T. Seki, D. I. AbuSalim, S. Matsumoto, K. A. Camphausen, M. C. Krishna, R. E. Swenson, A. H. Kesarwala. NMR in Biomedicine 2021, 34, e4588. *https://doi.org/10.1002/nbm.4588.*
- Low-cost High-Pressure Clinical-Scale 50% Parahydrogen Generator Using Liquid Nitrogen at 77 K. B. Chapman, B. Joalland, C. Meersman, J. Ettedgui, R. E. Swenson, M. C. Krishna, P. Nikolaou, K.V. Kovtunov, O. G. Salnikov, I. V. Koptyug, M. E. Gemeinhardt, B. M. Goodson, R. V. Shchepin, and E. Y. Chekmenev. Anal. Chem. 2021, 93, 8476–8483.
- Real Time Insight into In Vivo Redox Status utilizing Hyperpolarized [1-^{13}C] N-Acetyl Cysteine. K. Yamamoto, A. Opina, D. Sail, B. Blackman, K. Saeito, J. R. Brender, R. M. Malinowski, T. Seki, N. Oshima, D. R. Crooks, S. Kishimoto, Y. Saida, Y. Otowa, P. L. Choyke, J. H. Ardenkjaer-Larsen, J. B. Mitchell, W. M. Linehan, R. E. Swenson, M. C. Krishna. Sci. Reports 2021, 11, 12155.

Dated: May 23, 2024.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2024–11796 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Aging and Neurodegeneration Integrated Review Group; Cellular and Molecular Biology of Neurodegeneration Study Section.
Date: June 24–25, 2024.
Time: 8:30 a.m. to 8:30 p.m.
Agenda: To review and evaluate grant applications.
Place: The Darcy, 1515 Rhode Island Ave. NW, Washington, DC 20005.
Meeting Format: In Person.
Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7850, Bethesda, MD 20892, 301–435–1203, *laurent.taupenot@nih.gov*.

Name of Committee: Infectious Diseases and Immunology B Integrated Review Group; Bacterial-Host Interactions Study Section.
Date: June 25–26, 2024.
Time: 9:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Uma Basavanna, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–1398, *uma.basavanna@nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurodifferentiation, Plasticity, Regeneration and Rhythmicity Study Section.
Date: June 25–26, 2024.
Time: 9:00 a.m. to 8:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Jacek Topczewski, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1002A1, Bethesda, MD 20892, (301) 594–7574, *topczewskij2@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biobehavioral Processes.
Date: June 25–26, 2024.
Time: 9:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Jeanne M. McCaffery, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3854, *jeanne.mccaffery@nih.gov*.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Science of Implementation in Health and Healthcare Study Section.
Date: June 25–26, 2024.
Time: 9:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Wenjuan Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, Bethesda, MD 20892, (301) 480–8667, *wangw22@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Health Services Research: Health Information Technology and Clinical Informatics.
Date: June 25–26, 2024.
Time: 9:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.

Contact Person: Debasmita Patra, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1006E, Bethesda, MD 20892, (301) 827–5187, *debasmita.patra@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Advancing Therapeutics.
Date: June 25–26, 2024.
Time: 9:30 a.m. to 6:30 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Lystranne Alysia Maynard Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–4809, *lystranne.maynard-smith@nih.gov*.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Population based Research in Infectious Disease Study Section.
Date: June 25–26, 2024.
Time: 9:30 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: In Person and Virtual Meeting.
Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 257–2638, *steeleln@csr.nih.gov*.

Name of Committee: Infectious Diseases and Immunology A Integrated Review Group; Bacterial Virulence Study Section.
Date: June 25–26, 2024.
Time: 10:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.
Meeting Format: Virtual Meeting.
Contact Person: Susan Daum, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, Bethesda, MD 20892, 301–827–7233, *susan.boyle-vavra@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 23, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11853 Filed 5–29–24; 8:45 am].

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; NCCIH Training and Education Review Panel (CT).
Date: June 24, 2024
Time: 9:30 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Center for Complementary and Integrative, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892.

Contact Person: Michael E Authement, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, 6707 Democracy Boulevard, Bethesda, MD 20817, *michael.authement@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: May 23, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11855 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; National Center for Advancing Translational Sciences R13 Conference Grants Special Emphasis Panel.

Date: June 24, 2024.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences. National Institutes of Health, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Scientific Review Branch, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, MSC 4874, Bethesda, MD 20892, (301) 827–9549. *mooremar@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: May 23, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11850 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative Marmoset Colonies and Coordination Centers.

Date: June 26, 2024.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Bethesda, MD 20892–9606, 301–443–2742, *nick.gaiano@nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Pathway to Independence Awards (K99/R00).

Date: June 27, 2024.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: David W. Miller, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Bethesda, MD 20892–9608, 301–443–9734, *millerda@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 23, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11849 Filed 5–29–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0010]

Agency Information Collection Activities; Extension; Certificate of Registration (CBP Form 4455 & Form 4457)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection (CBP) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than July 29, 2024) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice must include the OMB Control Number 1651–0010 in the subject line and the agency name. Please submit written comments and/or suggestions in English. Please use the following method to submit comments:

Email. Submit comments to: *CBP_PRA@cbp.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at

877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Certificate of Registration.

OMB Number: 1651–0010.

Form Number: 4455 & 4457.

Current Actions: This submission will extend the expiration date of this information collection, with no change to the burden or information collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Abstract: CBP Form 4455, *Certificate of Registration,* is used primarily for the registration, examination, and supervised lading of commercial shipments of articles exported for repair, alteration, or processing, which will subsequently be returned to the United States either duty free or at a reduced duty rate. CBP Form 4455 is accessible at: *http://www.cbp.gov/newsroom/publications/forms?title=4455&=Apply.*

Travelers who do not have proof of prior possession in the United States of foreign made articles and who do not want to be assessed duty on these items can register them prior to departing on travel. To register these articles, the traveler completes CBP Form 4457, *Certificate of Registration for Personal Effects Taken Abroad,* and presents it at the port at the time of export. This form must be signed in the presence of a CBP official after verification of the description of the articles is completed. CBP Form 4457 is accessible at: *http://www.cbp.gov/newsroom/publications/forms?title=4457&=Apply.*

CBP Forms 4455 and 4457 are used to provide a convenient means of showing proof of prior possession of a foreign made item taken on a trip abroad and later returned to the United States. This registration is restricted to articles with serial numbers or unique markings. These forms are provided for by 19 CFR 148.1.

Type of Information Collection: CBP Form 4455.

Estimated Number of Respondents: 60,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 60,000.

Estimated Time per Response: 10 minutes (0.166 hours).

Estimated Total Annual Burden Hours: 9,960.

Type of Information Collection: CBP Form 4457.

Estimated Number of Respondents: 140,000.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 140,000.

Estimated Time per Response: 3 minutes (0.05 hours).

Estimated Total Annual Burden Hours: 7,000.

Dated: May 24, 2024.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2024–11863 Filed 5–29–24; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7086–N–13]

60-Day Notice of Proposed Information Collection: Requirements for Single Family Mortgage Instruments, OMB Control No.: 2502–0404

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* July 29, 2024.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; telephone (202) 402–3577 (this is not a toll-free number) or email: *PaperworkReductionActOffice@hud.gov* for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT: Colette Pollard Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410, Room 8210; telephone (202) 402–3577, (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.*

Copies of available documents submitted to OMB may be obtained from [Ms. Pollard].

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Requirements for Single Family Mortgage Instruments.

OMB Approval Number: 2502–0404.

Type of Request: Extension.

Form Number: None.

Description of the need for the information and proposed use: The Department of Housing and Urban Development (HUD) collects

information about customers who contact the agency with questions/comments. P323J, HUD Central Customer Relationship Management (CRM) solution is leveraged by HUD staff and HUD Customer Services Representative contractors when the public calls a 1–800 number, or physically comes to a HUD office, or emails HUD with a question/comment. The HUD staff enters the information into the system to support answering the public question/comment. If the inquiry can be answered immediately, then HUD addresses the request. If the inquiry requires follow-up, then the customer's information is collected for a future response. Minimum data is collected to create an interaction history between the individual and HUD, name, home address, email address, or phone number.

Estimated Number of Respondents: 2,064.

Frequency of Response: One per mortgage.

Estimated Number of Responses: 737,276.

Average Hours per Response: 0.0833 (5 minutes).

Total Estimated Burdens: 61,415.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Single Family	2,064	1	737,276	0.0833	61,415	$40.46	$2,484,855

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary for Housing.

[FR Doc. 2024–11832 Filed 5–29–24; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6465–N–01]

Appointments to the Housing Counseling Federal Advisory Committee; Solicitation of Nominations

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: The Department of Housing and Urban Development (HUD) established the Housing Counseling Federal Advisory Committee (HCFAC) on April 14, 2015. This notice invites nominations for appointments to fill vacancies on the HCFAC.

DATES: All nominations must be received no later than July 15, 2024.

ADDRESSES: Nominations must be in writing using form HUD 95000 (Application for Membership on the HCFAC, OMB Approval Number: 2502–0606) and submitted via email to *HCFAC.application@hud.gov.* Individuals who do not have internet access may submit nominations to the Office of the Deputy Assistant Secretary for Housing Counseling, HUD, Attn: Toneisha Basil, 451 7th Street SW, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Virginia F. Holman, Housing Program Specialist, U.S. Department of Housing and Urban Development, Office of Housing Counseling, Office of Outreach and Capacity Building, *Virginia.F.Holman@hud.gov,* telephone number 540–894–7790 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Individuals with questions may also email *HCFAC.application@hud.gov* with ''HCFAC application question'' in the subject line.

SUPPLEMENTARY INFORMATION:

I. Background and Authority

The HCFAC is congressionally mandated to provide advice to the Office of Housing Counseling (OHC) (42 U.S.C. 3533(g)(4)). The HCFAC provides the OHC valuable advice regarding its mission to provide individuals and families with the knowledge they need to obtain, sustain, and improve their housing through a strong national network of HUD-approved housing counseling agencies and HUD-certified counselors. The HCFAC, however, does not have any role in reviewing or awarding OHC housing counseling grants and procurement contracts. The HCFAC is subject to the requirements of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. 1001 *et seq.*).

By statute, the HCFAC shall consist of not more than 12 individuals appointed by the Secretary (42 U.S.C. 3533(g)(4)(B)). The membership will equally represent the mortgage industry, the real estate industry, consumers, and HUD-approved housing counseling agencies. Each member shall be appointed in his or her individual capacity for a term of up to 3 years.

II. Nominations for the Housing Counseling Federal Advisory Committee

HUD is seeking nominations for membership on the HCFAC. Nominees shall equally represent the mortgage and real estate industries, including consumers and HUD-approved housing counseling agencies. Nominations may be made by agency officials, members of Congress, the general public, or professional organizations, as well as self-nominations. Nominees must be U.S. citizens and cannot be U.S. Government employees.

All appointed nominees will be serving on the HCFAC in their individual capacity, and not in a representative capacity, therefore, no Federally-registered lobbyists may serve on the HCFAC.[1] Individual capacity, as

[1] See 79 FR 47482 (''Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards, and Commissions'') (clarifying

clarified by OMB, refers to individuals who are appointed to committees to exercise their own individual best judgment on behalf of the Government, such as when they are designated as Special Government Employees as defined in 18 U.S.C. 202.

Nominations to the HCFAC must be submitted using a HUD–90005 which is available on the Office of Housing Counseling's Federal Advisory Committee web page at: *https://www.hud.gov/program_offices/housing/sfh/hcc.* It is also available at HUD's Client Information Policy Systems (HUDClips) at: *https://www.hud.gov/guidance.* Each nominee will be required to provide all the information on HUD–90005. The submission of a resume with work experience is optional.

Nominations should be submitted via email to *HCFAC.application@hud.gov.* Individuals that do not have internet access may submit nominations to the Office of the Deputy Assistant Secretary for Housing Counseling, HUD, Attn: Toneisha Basil, 451 7th Street SW, Washington, DC 20410. Those who submitted applications previously, and those who have been appointed previously, must reapply if they wish to be considered for an appointment. Nominations submitted under this **Federal Register** Notice shall remain valid for two (2) years after the close of this nomination period. HUD reserves the right to solicit new nominations, at any time, to fill HCFAC vacancies.

All Nominations must be received no later than July 15, 2024.

HCFAC members will be required to adhere to the conflict-of-interest rules applicable to Special Government Employees as such employees are defined in 18 U.S.C. 202(a). The rules include relevant provisions in 18 U.S.C. related to criminal activity, Standards of Ethical Conduct for Employees of the Executive Branch (5 CFR part 2635) and Executive Order 12674 (as modified by E.O. 12731). Therefore, applicants will be required to submit to pre-appointment screenings relating to identity of interest and financial interests that HUD might require. If selected, HCFAC members will also be asked to complete OGE Form 450 (Confidential Financial Disclosure Report).

Members of the HCFAC shall serve without pay but shall receive travel expenses including per diem in lieu of subsistence as authorized by 5 U.S.C. 5703. Regular attendance is essential to the effective operation of the HCFAC.

Please note this notice is not intended to be the exclusive method by which HUD will solicit nominations and expressions of interest to identify qualified candidates; however, all nominees for membership on the HCFAC will be subject to the same application process and evaluation criteria.

III. Selection and Meetings

Member selections will be made by the Secretary and will be based on the Nominee's qualifications to contribute to the accomplishment of the HCFAC's objectives. Membership on the HCFAC is personal to the appointee and committee members serve at the discretion of the Secretary.

The estimated number of meetings (in-person or virtual) anticipated within a fiscal year is four (4). Additional meetings may be held as needed to render advice to the Deputy Assistant Secretary for the Office of Housing Counseling. The meetings may use electronic communication technologies for attendance.

All meetings will be announced by notice in the **Federal Register** and at Housing Counseling Federal Advisory Committee website at: *https://www.hud.gov/program_offices/housing/sfh/hcc/housing_counseling_federal_advisory_committee.* Announcements of the meetings will be made using other outreach methods as well.

Julia R. Gordon,

Assistant Secretary for Housing Federal Housing Commission.

[FR Doc. 2024–11799 Filed 5–29–24; 8:45 am]

BILLING CODE 4210–67–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint *Certain Storage Containers and Toolboxes, Organizers, Component Boxes, Coolers, and Accessories Used Therewith,* DN 3749*;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov* . The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Milwaukee Electric Tool Corporation and Keter Home and Garden Products Ltd. on May 23, 2024. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain storage containers and toolboxes, organizers, component boxes, coolers, and accessories used therewith. The complaint names as a respondent: Klein Tools, Inc. of Lincolnshire, IL. The complainant requests that the Commission issue a general exclusion order, limited exclusion order, cease and desist orders, and impose a bond upon respondent alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

that federally registered lobbyists may not serve on advisory committee, board, or Commission in an ''individual capacity.'')

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3749'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures.) [1]

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: May 23, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–11845 Filed 5–29–24; 8:45 am]

BILLING CODE 7020–02–P

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

INTERNATIONAL TRADE COMMISSION

[USITC SE–23–023]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: June 6, 2024 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Agendas for future meetings:* None.
2. Minutes.
3. Ratification List.
4. Commission vote on Inv. Nos. 701–TA–721 and 731–TA–1689 (Preliminary) (Alkyl Phosphate Esters from China). The Commission currently is scheduled to complete and file its determinations on June 7, 2024; views of the Commission currently are scheduled to be completed and filed on June 14, 2024.
5. *Outstanding action jackets:* None.

CONTACT PERSON FOR MORE INFORMATION: Sharon Bellamy, Supervisory Hearings and Information Officer, 202–205–2000.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.

Issued: May 28, 2024.

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–11971 Filed 5–28–24; 11:15 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–23–024]

Sunshine Act Meetings

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: June 7, 2024 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. *Agendas for future meetings:* None.
2. Minutes.
3. Ratification List.
4. Commission vote on Inv. Nos. 701–TA–722–725 and 731–TA–1690–1693 (Preliminary) (Crystalline Silicon Photovoltaic Products (Solar Panels) from Cambodia, Malaysia, Thailand, and Vietnam). The Commission currently is scheduled to complete and file its determinations on June 10, 2024; views of the Commission currently are scheduled to be completed and filed on June 17, 2024.

5. Commission vote on Inv. Nos. 701–TA–726 and 731–TA–1694 (Preliminary) (High Chrome Cast Iron Grinding Media from India). The Commission currently is scheduled to complete and file its determinations on June 10, 2024; views of the Commission currently are scheduled to be completed and filed on June 17, 2024.

6. *Outstanding action jackets:* None.

CONTACT PERSON FOR MORE INFORMATION: Sharon Bellamy, Supervisory Hearings and Information Officer, 202–205–2000.

The Commission is holding the meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b). In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

By order of the Commission.
Issued: May 28, 2024

Sharon Bellamy,

Supervisory Hearings and Information Officer.

[FR Doc. 2024–12007 Filed 5–28–24; 4:15 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1378]

Importer of Controlled Substances Application: Revvity, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Revvity, Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 1, 2024. Such persons may also file a written request for a hearing on the application on or before July 1, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 29, 2024, Revvity, Inc., 120 East Dedham Street, Boston, Massachusetts 02118–2852, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Lysergic Acid Diethylamide.	7315	I
Thebaine	9333	II

The company plans to import the listed controlled substances for bulk manufacturing into radioactive formulations for sale to its customers for research purposes. Drug code 9333 (Thebaine) will be used to import the Thebaine derivative Diprenorphine. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11822 Filed 5–29–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1377]

Importer of Controlled Substances Application: Almac Clinical Services Incorporate

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Almac Clinical Services Incorp (ACSI) has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 1, 2024. Such persons may also file a written request for a hearing on the application on or before July 1, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on May 6, 2024, Almac Clinical Services Incorp (ACSI), 25 Fretz Road, Souderton, Pennsylvania 18964, applied to be registered as an importer

of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Psilocybin	7437	I
Oxycodone	9143	II
Hydromorphone	9150	II
Morphine	9300	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to import the listed controlled substances as finished dosage form units for clinical trials purposes only. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11817 Filed 5–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1376]

Importer of Controlled Substances Application: Vici Health Sciences, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Vici Health Sciences, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 1, 2024. Such persons may also file a written request for a hearing on the application on or before July 1, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 16, 2024, Vici Health Sciences, LLC, 6655 Amberton Drive, Suite O, Elkridge, Maryland 21075–6202, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Ibogaine	7260	I

The company plans to import the listed controlled substance for use in clinical trials, research and analytical testing as well as dosage formulation development. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11818 Filed 5–29–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1374]

Importer of Controlled Substances Application: VA Cooperative Studies Program

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: VA Cooperative Studies Program has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 1, 2024. Such persons may also file a written request for a hearing on the application on or before July 1, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 12, 2024, VA Cooperative Studies Program, 2401 Centre Avenue South East, Albuquerque, New Mexico 87106, applied to be registered as an importer

of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Tetrahydrocannabinols	7370	I

The company plans to import finished dosage unit products containing the above listed controlled substances for research and clinical trial studies only. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11795 Filed 5–29–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1368]

Bulk Manufacturer of Controlled Substances Application: Royal Emerald Pharmaceuticals

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Royal Emerald Pharmaceuticals has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 29, 2024. Such persons may also file a written request for a hearing on the application on or before July 29, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on April 10, 2024, Royal Emerald Pharmaceuticals, 14011 Palm Drive, Building B, Desert Hot Springs, California 92240–6845, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to bulk manufacture the listed controlled substances to provide Marihuana (Cannabis) as botanical raw material and/or active pharmaceutical ingredients (API) to Drug Enforcement Administration-registered researchers and manufacturers. No other activities for these drug codes are authorized for this registration.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11786 Filed 5–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1381]

Importer of Controlled Substances Application: Quagen Pharmaceuticals LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Quagen Pharmaceuticals LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 1, 2024. Such persons may also file a written request for a hearing on the application on or before July 1, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 16, 2024, Quagen Pharmaceuticals LLC, 37 Fairfield Place, West Caldwell, New Jersey 07006, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Diphenoxylate	9170	II

The company plans to import the listed controlled substance for distribution to its customer. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Matthew J. Strait,

Deputy Assistant Administrator.

[FR Doc. 2024–11892 Filed 5–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1369]

Importer of Controlled Substances Application: Veranova, L.P.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Veranova, L.P. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 1, 2024. Such persons may also file a written request for a hearing on the application on or before July 1, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 8, 2024, Veranova, L.P., 2003 Nolte Drive, West Deptford, New Jersey 08066–1727, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Coca Leaves	9040	II
Thebaine	9333	II
Opium, raw	9600	II
Noroxymorphone	9668	II
Poppy Straw Concentrate	9670	II
Fentanyl	9801	II

The company plans to import Coca Leaves (9040), Opium, raw (9600), and Poppy Straw Concentrate (9670) in order to bulk manufacture Active Pharmaceutical Ingredients (API) for distribution to its customers. The company plans to also import Thebaine (9333), Noroxymorphone (9668), and Fentanyl (9801) to use as analytical reference standards, both internally and to be sold to their customers to support testing of Veranova, L.P. APIs only. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11821 Filed 5–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1373]

Importer of Controlled Substances Application: ANI Pharmaceuticals Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: ANI Pharmaceuticals Inc., applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 1, 2024. Such persons may also file a written request for a hearing on the application on or before July 1, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on April 9, 2024, ANI Pharmaceuticals Inc., 70 Lake Drive, East Windsor, New Jersey 08520–5321, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Psilocybin	7437	I
Levorphanol	9220	II
Tapentadol	9780	II

Psilocybin (7437) will be imported for use in dosage form development leading to use in clinical trials. Levorphanol (9220) will be imported for distribution to customers. Tapentadol (9780) will be used to import small quantities for internal research and reference standards purposes. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-

approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11794 Filed 5–29–24; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1375]

Bulk Manufacturer of Controlled Substances Application: Chemtos, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Chemtos, LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 29, 2024. Such persons may also file a written request for a hearing on the application on or before July 29, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on April 10, 2024, Chemtos, LLC, 16713 Picadilly Court, Round Rock, Texas 78664–8544, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
3-methylmethcathinone (2-(methylamino)-1-(3- methylphenyl)propan-1-one)	1259	I
Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine	2780	I
Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine)	2785	I
Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepin	2786	I
Flubromazolam (8-bromo-6-(2-fluorophenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine	2788	I
Diclazepam (7-chloro-5-(2-chloro-5-(2-chlorophenyl)-1- methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one	2789	I
ADB-BUTINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1H-indazole-3-carboxamide)	7027	I
MDMB-4en-PINACA (methyl 3,3-dimethyl-2-(1-(pent-4- en-1-yl)-1H-indazole-3-carboxamido)butanoate)	7090	I
4F-MDMB-BUTICA (methyl 2-[[1-(4-fluorobutyl)indole-3- carbonyl]amino]-3,3-dimethyl-butanoate	7091	I
ADB-4en-PINACA (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3- carboxamide)	7092	I
CUMYL-PEGACLONE (5-pentyl-2-(2-phenylpropan-2- yl)pyrido[4,3-b]indol-1-one)	7093	I
5F-EDMB-PICA (ethyl 2-[[1-(5-fluorophentyl)indole-3- carbonyl]amino]-3,3-dimethyl-butanoate	7094	I
MMB-FUBICA (methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate	7095	I
α-PiHP (4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one)	7551	I

The company plans to bulk manufacture the listed controlled substances for sale as reference standards to their customers. No other activities for these drug codes are authorized for this registration.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11816 Filed 5–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1371]

Bulk Manufacturer of Controlled Substances Application: AMPAC Fine Chemicals Virginia LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: AMPAC Fine Chemicals Virginia LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 29, 2024. Such persons may also file a written request for a hearing on the application on or before July 29, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on December 22, 2023, AMPAC Fine Chemicals Virginia LLC, 2820 Normandy Drive, Petersburg, Virginia 23805–2380, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Lisdexamfetamine	1205	II

The company plans to bulk manufacture the above listed controlled substances for the internal use as intermediates or for distribution to its customers. No other activities for these

drug codes are authorized for this registration.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11790 Filed 5–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1370]

Importer of Controlled Substances Application: Skalar Pharma, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Skalar Pharma, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before July 1, 2024. Such persons may also file a written request for a hearing on the application on or before July 1, 2024.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on March 1, 2024, Skalar Pharma, LLC, SR 53 KM 82 Guayama, Guayama, Puerto Rico 00784, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Phenylacetone	8501	II

The company plans to import the listed controlled substance to be used in the manufacturing process for other controlled substances. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Marsha L. Ikner,

Acting Deputy Assistant Administrator.

[FR Doc. 2024–11793 Filed 5–29–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act and the Clean Water Act

On May 23, 2024, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Northern District of Ohio in the lawsuit entitled *The State of Ohio and The United States of America* v. *Norfolk Southern Railway Company, et al.,* Case No. 4:23–cv–00517.

The proposed Consent Decree settles claims brought by the United States under sections 309 and 311 of the Clean Water Act (''CWA''), 42 U.S.C. 1311 and 1321 and sections 107 and 113 of the Comprehensive Environmental Response, Compensation, and Liability Act (''CERCLA''), 42 U.S.C. 9607 and 9613, against Norfolk Southern Railway Company and Norfolk Southern Corporation (''Defendants'') related to the February 3, 2023 train derailment in East Palestine, Ohio. The proposed Consent Decree would require Norfolk Southern: (i) to reimburse all CERCLA and CWA section 311 response costs incurred by the United States; (ii) pay a civil penalty of $15 million for violating CWA sections 301 and 311; (iii) establish a $25 million community health program for qualifying members of the public impacted by the derailment; (iv) implement an array of specified rail safety procedures; (v) develop and adopt programs for coordination of rail track restoration and vent and burn procedures; (vi) implement a $6 million local waterways remediation plan; (vii) pay $175,000 for natural resource damages; and (viii) implement compliance and future monitoring requirements in the various work plans approved under EPA's Unilateral Administrative Orders and CWA Order.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *The State of Ohio and The United States of America* v. *Norfolk Southern Railway Company, et al.,* D.J. Ref. No. 90–11–3–12792. All comments must be submitted no later than 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 proposed 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.

Laura Thoms,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2024–11862 Filed 5–29–24; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1103–0118]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; Tribal Access Program Application

AGENCY: Office of the Chief Information Officer, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Office of the Chief Information Officer, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register** on March 15, 2024, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until July 1, 2024.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Allison Spratlin, Program Manager, 145 N Street NW, Washington, DC 20530; (202)532–5047; *Allison.spratlin@usdoj.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number [OMB Number 1103–0118]. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *Title of the Form/Collection:* Tribal Access Program Application.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* There is no agency form number for this collection. The applicable component within the Department of Justice is Office of the Chief Information Officer.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Affected Public: Federally recognized Tribes. The obligation to respond is voluntary.

Abstract: The U.S. Department of Justice (DOJ) launched the Tribal Access Program for National Crime Information (TAP) provide Tribes access to national crime information systems for both criminal justice and non-criminal justice purposes. DOJ has developed an application for use by federally recognized Tribes interested in participating in TAP.

5. *Obligation to Respond:* Voluntary to obtain a benefit.

6. *Total Estimated Number of Respondents:* The estimated number of respondents for this collection is 50.

7. *Estimated Time per Respondent:* The total annual burden hours for this collection is 50 hours.

8. *Frequency:* Annually.

9. *Total Estimated Annual Time Burden:* The total annual burden hours for this collection is 50 hours.

10. *Total Estimated Annual Other Costs Burden:* $0.

Activity	Number of respondents	Frequency (annually)	Total annual responses	Time per response (hours)	Total annual burden (hours)
TAPS Application	50	1	50	1	50
Totals	50		50		50

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: May 23, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–11831 Filed 5–29–24; 8:45 am]

BILLING CODE 4410–ML–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Claim for Medical Reimbursement

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Office of Workers' Compensation Programs (OWCP)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 1, 2024.

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: Michelle Neary by telephone at 202–693–6312, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Form OWCP–915 is used to claim reimbursement for out-of-pocket covered medical expenses paid by a beneficiary, and must be accompanied by required billing data elements (prepared by the medical provider) and by proof of payment by the beneficiary. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 12, 2024 (89 FR 9869).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OWCP.

Title of Collection: Claim for Medical Reimbursement.

OMB Control Number: 1240–0007.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 54,067.

Total Estimated Number of Responses: 54,067.

Total Estimated Annual Time Burden: 9,029 hours.

Total Estimated Annual Other Costs Burden: $1,184.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michelle Neary,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–11810 Filed 5–29–24; 8:45 am]

BILLING CODE 4510–CR–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Authorization Request Form/Certification/Letter of Medical Necessity

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Office of Workers' Compensation Programs (OWCP)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 1, 2024.

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: Michelle Neary by telephone at 202–693–6312, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The form, Authorization Request Form and Certification/Letter of Medical Necessity Certification/Letter of Medical Necessity for Opioid Medications (CA–27), requires an injured worker's treating physician to answer a number of questions about the prescribed opioids and certify that they are medically necessary to treat the work-related injury. The responses to the questions on the form is intended to ensure that treating physicians have considered non-opioid drug alternatives, and are only prescribing the most cost effective and medically necessary drugs. The form will also permit OWCP to more easily track the volume, type, and characteristics of opioids authorized by the FECA program. The form will serve as a means for injured workers to continue receiving opioids drugs only where medically necessary and simultaneously give OWCP greater oversight in monitoring their appropriate use and gather additional data about their use. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 26, 2024 (89 FR 5263).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OWCP.

Title of Collection: Authorization Request Form/Certification/Letter of Medical Necessity.

OMB Control Number: 1240–0055.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 78.

Total Estimated Number of Responses: 490.

Total Estimated Annual Time Burden: 245 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michelle Neary,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–11813 Filed 5–29–24; 8:45 am]

BILLING CODE 4510–CH–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Occupational Exposure to Beryllium Standard in the Construction Industry

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety & Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 1, 2024.

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: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Occupational Exposure to Beryllium Standard in the Construction Industry requires covered employers to establish written exposure control plan, to conduct medical surveillance, and to establish and maintain accurate records of employee exposure to beryllium and beryllium compounds and medical records. These records will be used by employers, workers, physicians and the Government to ensure that construction workers are not being harmed by exposure to beryllium and beryllium compounds. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 19, 2024 (89 FR 19602).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Occupational Exposure to Beryllium Standard in the Construction Industry.

OMB Control Number: 1218–0275.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 2,100.

Total Estimated Number of Responses: 12,642.

Total Estimated Annual Time Burden: 7,047 hours.

Total Estimated Annual Other Costs Burden: $2,249,246.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Certifying Official.

[FR Doc. 2024–11875 Filed 5–29–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Occupational Exposure to Beryllium and Beryllium Compounds Standard in the Shipyard Sector

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety & Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 1, 2024.

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: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Occupational Exposure to Beryllium and Beryllium Compounds Standard in the Shipyard Sector requires covered employers to establish written exposure control plan, to conduct medical surveillance, and to establish and maintain accurate records of employee exposure to beryllium and beryllium compounds and medical records. These records will be used by employers, workers, physicians and the Government to ensure that shipyard workers are not being harmed by

exposure to beryllium and beryllium compounds. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on March 12, 2024 (89 FR 17880).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Occupational Exposure to Beryllium and Beryllium Compounds Standard in the Shipyard Sector.

OMB Control Number: 1218–0272.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 696.

Total Estimated Number of Responses: 4,661.

Total Estimated Annual Time Burden: 2,565 hours.

Total Estimated Annual Other Costs Burden: $824,741.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Certifying Official.

[FR Doc. 2024–11874 Filed 5–29–24; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Mine Safety and Health Administration Grant Performance Reports

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 1, 2024.

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: Michael Howell by telephone at 202–693–6782, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: MSHA grantees are required by DOL regulations to submit project and final reports. Grantees are also required to submit final reports no later than 90 days after the end of the grant period.

Technical Project Reports: A grantee submits a technical project report to MSHA no later than 30 days after quarterly deadlines. Technical project reports provide both quantitative and qualitative information and a narrative assessment of performance for the preceding three-month period. This includes the current grant progress against the overall grant goals. Between reporting dates, the grantee informs MSHA of significant developments or problems affecting the organization's ability to accomplish the work Final Reports: At the end of the grant period, each grantee provides a project summary of its technical project reports, an evaluation report, and a close-out financial report. These final reports are due no later than 90 days after the end of the 12-month performance period. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 24, 2024 (89 FR 4626).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Agency: DOL–MSHA.

Title of Collection: Mine Safety and Health Administration Grant Performance Reports.

OMB Control Number: 1219–0154.

Affected Public: Businesses or other for-profits.

Number of Respondents: 76.

Frequency: Quarterly and annually.

Number of Responses: 380.

Annual Burden Hours: 850 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–11812 Filed 5–29–24; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Authorization Request Forms

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Office of Workers' Compensation Programs (OWCP)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with

the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before July 1, 2024.

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: Michelle Neary by telephone at 202–693–6312, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Office of Workers' Compensation Programs (OWCP) is the primary agency responsible for administration of the Energy Employees Occupational Illness Compensation Program Act of 2000, as amended (EEOICPA), 42 U.S.C. 7384 *et seq.* EEOICPA provides for the payment of compensation to covered employees and, where applicable, survivors of deceased employees, who sustained either an ''occupational illness'' or a ''covered illness'' in the performance of duty for the Department of Energy and certain of its contractors and subcontractors. One element of the compensation provided to covered employees is medical benefits for the treatment of their occupational or covered illnesses that are accepted as compensable. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 12, 2024 (89 FR 9868).

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OWCP.

Title of Collection: Authorization Request Forms.

OMB Control Number: 1240–0060.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 41,728.

Total Estimated Number of Responses: 98,020.

Total Estimated Annual Time Burden: 16,337 hours.

Total Estimated Annual Other Costs Burden: $0.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michelle Neary,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2024–11809 Filed 5–29–24; 8:45 am]

BILLING CODE 4510–CR–P

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

Acquisition Data Management

AGENCY: Office of Federal Procurement Policy, Office of Management and Budget.

ACTION: Notice of final Office of Management and Budget Circular No. A–137, ''Strategic Management of Acquisition Data and Information''.

SUMMARY: The Office of Federal Procurement Policy (OFPP) in the Office of Management and Budget (OMB) is issuing a Circular entitled ''Strategic Management of Acquisition Data and Information.'' This Circular will improve agency access to reliable data and information at the point of need throughout the acquisition lifecycle to ensure successful contracting outcomes without duplicating data, tools, or effort. The Circular establishes a centralized data management strategy to allow for the creation of more comprehensive knowledge and data banks, the development of standard data sharing processes, and improved access to tools and resources for acquisition-related decision-making in a Hi-Definition Intelligent Acquisition Data Environment.

FOR FURTHER INFORMATION CONTACT: *Kristen.H.Wilson@omb.eop.gov,* Office of Federal Procurement Policy, 725 17th Street NW, Washington, DC 20006, at 202–881–9246.

SUPPLEMENTARY INFORMATION:

A. Overview

Across the Federal enterprise, there are tens of billions of acquisition data points residing in over 170 contract writing systems (including legacy systems) and over 15 payment processing platforms. Historically, much of this data has been collected and managed at the agency level. Agencies have used their resources to build tools within their agency, harnessing internal data and databases, but this has often led to duplicative tools and efforts and a lack of coordination across agencies. This approach has limited central capacity for analytics, insights, and efficiency gains outside of the System for Award Management and the Federal Procurement Data System, which generally provide aggregate data but very little pricing and best practices information.

To address these challenges, OMB's new Circular establishes a centralized data management policy framework for the creation of a High-Definition Environment (HDE). Through the HDE, which is the technical architecture for the data, users will have access to the right data at the point of need through a single, central access point, better enabling them to buy as an organized entity. Creating the HDE is a critical component of the acquisition community's work to make purchases as an organized enterprise. The HDE will provide agencies with access to the breadth and depth of information needed to support the acquisition needs of the Federal Government—the largest and most sophisticated buyer in the world.

Achieving the HDE will require greater transparency and collaboration in agency data systems planning and investment decisions. This is particularly true with respect to activities that would affect the Government's ability to achieve data interoperability for information that is critical or can otherwise significantly improve acquisition decision-making at

both the Government-wide and agency-wide level.

To this end, the Circular: (1) establishes the principle that agencies should no longer view acquisition data as a singular agency asset, but rather an asset critical to supporting the missions of the Government at large, and should be prepared to collect and share the data accordingly; (2) defines agency roles and responsibilities; and (3) supports the design and development of solutions to drive data interoperability, allowing systems to connect and share acquisition data wherever they reside within the Federal Government without duplication.

B. Summary

The Circular

Establishes a centralized data management policy framework, including a comprehensive data governance process. Outcome oriented data policy and governance serves as both a safeguard and an accelerator for data initiatives. OMB will facilitate the development of policies and practices to support the collection, sharing, and use of the data and a governance process to ensure appropriate representation and accountability for how datasets and data products are prioritized, managed, consumed, and secured in the HDE.

Directs the establishment of the HDE. Agency data will be shared and accessed by Federal users through a coordinated, Government-wide solution for accessing and using acquisition data and developing and deploying innovative tools that better support the acquisition lifecycle. The HDE leverages a scalable technical architecture to store, access, utilize, share, and archive acquisition data without duplicating data, tools, or effort. The HDE will use existing agency investments in systems and data infrastructure to the maximum extent practicable.

Requires agencies to prepare annual strategic plans. In accordance with guidance issued by OMB, agencies will report on steps to address general data management stewardship, government-wide priority initiatives and individualized acquisition data hurdles or responsibilities that may affect other agencies.

Builds appropriate centralization. The Circular will support centralized standards, knowledge banks, and data-sharing tools using established and strengthened governance. Existing standards and processes will be updated, modernized, and enforced through greater transparency and interoperability. Data sharing tools will allow agencies to maintain existing systems but create the ability to pull data from the source where it resides for improved analytics and insights. Shared solutions will increase efficiency across all agencies, rather than within a single agency, when internal tools are developed.

Promotes data-sharing technologies. The Circular prepares agencies for an interoperable future where all acquisition data can be accessed on-demand. Current data sharing efforts are being conducted through pilots on a voluntary basis to address challenges in interoperability. This Circular anticipates that agencies will begin exploring, planning for, and building application programming interfaces, Extract-Transfer-Load processes, and other access points while working within the HDE governance structure to develop appropriate standards. It provides a mechanism to enable agencies to ask for further direction and resources in these endeavors from OMB and through the budget process. Increased collaboration among agencies will facilitate sharing knowledge and best practices.

Requires data-sharing. Contract cost efficiencies increase, and wasteful cost variances between agencies decrease, when buyers are able to improve their negotiating posture with access to standardized transactional data that can give them insight into prices paid and favorable contract terms and conditions. Accordingly, with limited exceptions, agencies will be required to share their acquisition data—such as prices paid and terms and conditions—on a phased basis as directed by OMB. This is to ensure an enterprise approach to the Federal acquisition function. Part of the challenge to increasing interoperability is the protection of data within each agency. Agencies must use appropriate protocols to prevent the unauthorized disclosure of data. Accordingly, templates for data-sharing agreements and memoranda of understanding (MOUs) will be developed to help facilitate acquisition data sharing. Standardized processes for data-sharing that explicitly emphasize data protection and security will decrease barriers to interoperability and greatly increase the speed of transfer, all while maintaining critical data protections.

Facilitates other collaborative actions and workforce development with data management. Agencies will be expected to actively contribute to existing knowledge portals on innovative techniques and emerging technology and support expansion, implementation, and promotion of acquisition data management training and certification efforts for the acquisition workforce.

C. Public Comments

In response to its November 17, 2023 notice inviting public comment on the proposed Circular, 88 FR 80339, OFPP received public comments from seven respondents, including from several coalitions representing industry interests. Copies of the public comments received are available for review at *https://www.regulations.gov/document/OFPP-2023-0001-0001.* A summary of the comments and OFPP's responses and changes adopted in the final Circular are described below.

Data Protection

Respondents representing industry interests commented on the potential misuse of pre- and post-award pricing data about the scope of the user base. Specifically, concerns were raised about the potential accessibility of proprietary information by the public or by competitors, as well as the management of the data chain of command and the management of Freedom of Information Act (FOIA) requests.

To address these concerns, OFPP added language to section 2 of the Circular to clarify agency responsibilities for securing data shared within the Government and to make clear that any requests for release of information, such as through FOIA, will be handled in accordance with statutes, regulations, and protocols that address the release of contractor information to non-governmental sources. The Circular makes no changes to policies or practices governing the release of contractor data to the public.

Furthermore, OFPP added additional language to define roles and responsibilities that address data security and data sharing. Specifically, OMB will work with the Hi-Def Managing Agency, which is identified as the General Services Administration (GSA), to support the creation of standard data sharing MOU templates that can be tailored on an agency-by-agency basis to document comprehensive data management and security protocols.

The Circular now clearly defines that the role of the Hi-Def Managing Agency (GSA) includes comprehensive data security. GSA is tasked with coordinating with agencies to define an acceptable set of data security standards for the transfer, storage, and use of Hi-Def data through data sharing agreements and properly securing all agency data, based on established data security standards, once transmitted into the HDE.

Finally, the Circular establishes that any Government-wide data products ''powered by'' data originating from the HDE are subject to an interagency governance process to ensure that the use of the data is aligned with law and policy.

Data Context

OFPP received comments highlighting the complexity of pricing data, expressing concerns that if prices paid data are used without the relevant context to adjust for contract terms and conditions, supply chain fluctuations, and other time-bound factors, the usefulness of the data is jeopardized for forward decision making and market research.

OFPP agrees. While the final Circular reflects the importance of context surrounding data, it is important to recognize that key elements of the contextualizing data, such as contract terms and conditions, are often stored separately in an unstructured, decentralized manner across the enterprise. The collection of this data is on the Hi-Def roadmap but full implementation will take time and coordination with the agencies.

Through the annual planning process, agency stakeholders will have the opportunity to assess agency data sharing readiness and identify critical acquisition data needs. Agency responses will enable prioritized and orderly data collection efforts to fulfill these needs through small, scalable pilot efforts complete with assessments of the required data context. Data quality issues within existing datasets (for example, low quality data in the Unit of Measure field) will be addressed through both the governance and training processes.

Training and Workforce Development

OFPP received a comment asserting that training of the acquisition workforce must be part of the implementation of the Circular and is critical to its success. A second, related comment noted that successfully implementing these initiatives will require significant ''human-focused'' cultural and process changes within the Government's acquisition and related workforces.

OFPP agrees. The final Circular establishes that OMB, in coordination with the Federal Acquisition Institute, agency working groups, and data experts, will launch a role-based Federal Acquisition Data Training Curriculum that addresses best practices and policies related to data sharing, data use, and the current landscape of Government-wide acquisition tools and resources. The Circular also notes that through the new curriculum and other applicable training paths, agencies are responsible for building data analysis and related skills as a core acquisition workforce capability.

Scope of the Circular

OFPP received comments requesting that the Circular express a position on the impacts to procurement administrative lead time, challenges associated with sub-tier contractor and vendor data, the role of GSA in negotiating prices for GSA Schedules, and the data differences that will arise between best value and lowest price, technically acceptable contracts.

The intention of the Circular is to establish the framework for data sharing to improve enterprise-wide contracting outcomes. Specific use cases may be defined and addressed through the Hi-Def planning process for government-wide, agency-wide, or targeted use, as needed.

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Circular No. A–137

To the Heads of Executive Departments and Establishments

Subject: Strategic Management of Acquisition Data and Information

1. Introduction

The United States Government is the largest buyer of goods and services in the world. However, due to the decentralized nature of Federal acquisition processes and systems, the acquisition workforce is not able to fully utilize the volume of data collected across the Federal enterprise for more informed procurements, resulting in time and cost burdens on both the workforce and industry.

To address this issue, the Office of Management and Budget (OMB) seeks to promote Hi-Definition (Hi-Def) acquisitions where agencies are able to acquire supplies or services using relevant acquisition data that is easily accessed and available when it is needed. Government-wide acquisition initiatives such as Category Management have established that there is significant commonality in the goods and services procured across the enterprise. It follows that the strategy to collect, share, and use procurement data should also extend beyond agency-specific strategies and systems.

Agencies should no longer view acquisition data as a singular agency asset, but rather as an asset that is critical to support the mission of the Government. As such, agencies should be prepared to collect and share the data accordingly.[1]

Important work is already underway in this area through key data modernization efforts resulting from OMB Circular A–130,[2] The Foundations for Evidence-Based Policymaking Act of 2018,[3] and the Open, Public, Electronic and Necessary Government Data Act.[4] However, these efforts address agency-specific data requirements and do not speak to making data available centrally across the entire Government. This Circular aims to address that gap by establishing a centralized data management policy framework to promote acquisition data interoperability, data sharing between agencies, and enterprise-wide data analytics; and a Hi-Def Environment (HDE) for Federal users to enable access to critical data, tools, and resources for acquisition-related decision-making.

2. Purpose

Using relevant acquisition data as a strategic asset throughout the acquisition lifecycle facilitates successful contracting outcomes. The Federal Government has taken significant steps to improve the collection and use of data related to contracting transactions, including amounts obligated, information about how contracts are awarded, and the identity of the awardees.

However, other important acquisition-related data and information are not being shared Government-wide. For example, contract line item (CLIN) pricing information[5] may be kept in agency-specific contract writing systems, in one or more payment platforms, or in internal or external databases that are not easily accessible. All stakeholders from across the Federal Government may not have access to key information for contract planning, negotiations, and other critical contract management functions. Most commonly, the information resides in

[1] For purposes of this Circular, ''agency'' is defined as in 41 U.S.C. 133.

[2] Office of Mgmt. & Budget, Executive Office of the President, Circular No. A–130, *Managing Information as a Strategic Resource* (July 28, 2016), *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/OMB/circulars/a130/a130revised.pdf.*

[3] Public Law 115–435, *https://www.congress.gov/bill/115th-congress/house-bill/4174/text.*

[4] Public Law 115–435, title II, *https://www.congress.gov/bill/115th-congress/house-bill/4174/text.*

[5] The term ''line item pricing'' as used in this Circular broadly covers the price the Government pays for a commodity or service. Under the current systems landscape, pricing at this level can be complex (*e.g.,* pricing conditions that roll up to a line item price, line item discounts, and premiums).

disparate agency systems or includes non-standardized data elements and definitions that impedes interoperability across agencies. In many cases, agencies have agreed to terms and conditions with their contractors or shared service providers that prohibit the sharing of their acquisition data with other Government agencies, even though the data or information is not classified or proprietary and sharing would not otherwise be prohibited by law.

To address these issues and the broader landscape of acquisition data management, OMB is creating a Hi-Def centralized data management policy framework to promote data interoperability, the sharing of acquisition data between agencies, and enterprise-wide data analysis. This framework will be supported and enabled by the HDE, the technical architecture used to consume and make acquisition data collected across the Federal enterprise accessible in a secure and scalable solution. The HDE will:

- serve as a centralized access point and aggregator of acquisition data;
- provide Federal users with a secure entry point to access acquisition data collected by disparate systems and processes across the enterprise; and
- leverage existing architectures, agency offerings, and established governance bodies and processes to the greatest extent possible to avoid duplicative efforts.

Data ingested into the HDE will be phased based on agency data sharing readiness, Hi-Def targeted outcomes, and Government-wide data use cases prioritized through the data governance process.[6]

The data collected and used through the HDE will allow stakeholders [7] to understand acquisition community needs, opportunities for data and process improvement, and future program and policy requirements through interagency governance structures including existing committees, such as the Procurement Committee for E-Government and other working groups. The data collected through the HDE is intended for internal Federal use only and will be secured and used in accordance with law. Any requests for release of information to non-governmental sources will be managed in accordance with applicable laws and regulations.

3. Policy

Agencies should regard acquisition data as a Government asset, and should utilize acquisition data management practices that promote collection, interoperability, scalability, sharing, and usability across the Government.[8] These practices should make acquisition data easily accessible when it is needed to inform decision-making throughout the acquisition lifecycle. Agencies should begin to establish the infrastructure and relevant policies needed to collect and share data into the HDE, and identify appropriate security and privacy controls to ensure agency data is protected from misuse in a common environment.

a. Data Collection—agencies shall identify opportunities to improve the collection and sharing of both structured and unstructured acquisition data, including but not limited to prices paid data, contract files, CLIN data, terms and conditions, sub-contracting plans, survey data, purchase card data, and other relevant data sources as identified by OMB.[9]

b. Data Sharing—agencies shall:

i. Continually facilitate adoption of new and emerging technologies to support the ability for cross-agency data sharing, including but not limited to the use of Application Programming Interfaces (APIs), data exchange platforms, and Extract-Transfer-Load tools;

ii. Identify and take steps to update agency-specific policies or operational practices, as necessary, to remove any prohibitions or limitations on the collection and sharing of acquisition data within and among agencies in the Federal Government, consistent with applicable law;

iii. Include clauses, as appropriate and consistent with applicable law, in new contracts to inform contractors that acquisition data included or generated in connection with the contract by either the Government or the contractor may be shared within and among agencies of the Federal Government;

iv. Review and maintain protocols to protect against the unauthorized release of data; and

v. Identify and mitigate data sharing risks as outlined in § 3.c.

c. Data Risk Management—agencies shall:

i. Consistent with OMB Circular A–130,[10] identify and mitigate, either internally or in coordination with OMB, information security, privacy, records management, and supply chain security issues for data sharing activities throughout the acquisition data lifecycles so that risks are appropriately identified and mitigated;

ii. To the maximum extent possible, align acquisition data sets with data security standards, which shall be determined by the Hi-Def Managing Agency [11] and the Hi-Def Governance Plan; [12]

iii. Regularly review and address risk regarding acquisition processes, people, and technology; and

iv. Practice and share data management best practices relevant to acquisition data.

d. Leadership and Workforce—agencies shall:

i. Ensure that the acquisition workforce has appropriate knowledge and skills to facilitate the data lifecycle, including best practices for acquisition data entry and maintenance;

ii. As aligned with OMB Circular A–130,[13] implement innovative approaches and track workforce development training, including cross-functional training, rotational development and assignments, and other Federal and private sector training opportunities to maintain and enhance data literacy and data skills; and

iii. Promote the use of the HDE and associated tools to meet agency data requirements, as they become operational.

4. *Responsibilities:* This policy will be implemented in accordance with the following responsibilities.

a. *OMB:* With the support of the Government-wide governance structures identified in Appendix B, OMB will:

i. *Provide direction to agencies for an annual strategic plan to prioritize acquisition data management activities.* OMB will provide direction to agencies for the creation of an Annual Acquisition Data Strategic Hi-Def Plan (Hi-Def Plan) that addresses the agency's acquisition data resources and infrastructure and the status of the agency's activities to implement Government-wide and agency-specific priorities.

ii. *Facilitate the development of a comprehensive Hi-Def data governance*

[6] The Comprehensive Hi-Def Data Governance Plan will be established within one year of this Circular and is further detailed in § 7.b.

[7] Hi-Def Stakeholders are further described in Appendix G.

[8] Acquisition Data Management best practices will be posted and updated on the Hi-Def website at *The Hi-Def Initiative, https://acquisitiongateway.gov/Hi-Def.*

[9] Further guidance on targeted datasets and the required context will be issued by OMB on a phased basis, based on responses to the Agency Baseline Assessment outlined in § 7.a and the Hi-Def annual planning process outlined in § 4a.i and § 4.b.i.

[10] Office of Mgmt. & Budget, Executive Office of the President, Circular No. A–130, *Managing Information as a Strategic Resource,* Appendix I §§ 3, 4.

[11] As defined in § 4.c.

[12] As defined in § 7.b.

[13] Office of Mgmt. & Budget, Executive Office of the President, OMB Circular A–130, *Managing Information as a Strategic Resource* § 5(c)(3).

plan. OMB will work with agency stakeholders to develop a governance process to ensure appropriate representation and accountability for how datasets and data products are prioritized, managed, consumed, and secured in the HDE.

iii. *Facilitate the development of standards, in coordination with appropriate data governance structures, to support transactional pricing data or any other acquisition activity requiring standardization.* OMB will identify minimum transactional pricing data elements (*e.g.,* CLIN standards) for collection and transmission that would minimize agency burden while providing insight at a Government-wide level. OMB will consider the commonalities identified from the initial data assessment, outlined in Section 7, performed by agencies as a basis for standardization.

iv. *Require appropriate information sharing and collaboration.* OMB will collaborate with the Federal Acquisition Regulatory Council on any appropriate regulatory amendments to support sharing of acquisition data within and among agencies with proper data security. OMB will also work with individual governance groups identified in Appendix B and agencies to prioritize information sharing needs and capabilities and to develop appropriate templates, and guidance to support scalability.

v. *Prioritize data collection efforts and targeted data sets based on targeted outcomes.* Given the wide range of data required to support the acquisition process, OMB will leverage the Hi-Def data governance process to collaborate with agency stakeholders, Hi-Def data domain stewards, the Hi-Def Managing Agency, and the government-wide Category Managers to establish prioritized outcomes and the agency datasets required to support outcome implementation.

vi. *Establish a Federal acquisition data training curriculum.* OMB, in coordination with the Federal Acquisition Institute (FAI), agency working groups and data experts, will establish a role-based Federal acquisition data training curriculum that addresses best practices and policies related to data sharing, data use, and the current landscape of Government-wide acquisition tools and resources.

vii. *Support the development of standard data-sharing agreements for Hi-Def purposes.* OMB will facilitate the development of memorandum-of-understanding (MOU) templates that agencies can use to expedite data sharing into the HDE in coordination with the Hi-Def Managing Agency, the Hi-Def Executive Steering Committee and, on an as needed basis, the Senior Agency Officials for Privacy,[14] and agency general counsels. MOUs can be customized on an as-needed basis; standard data elements can be found in Appendix F.

b. *Agencies:* Agencies are responsible for taking the following actions in furtherance of the acquisition data management policies established by this Circular:

i. *Develop an annual strategic Hi-Def plan to prioritize and resource their acquisition data management activities, consistent with direction from OMB.* Starting one year after the initial baseline assessment [15] agencies shall annually evaluate and document results of assessments along with any new agency policies, processes, and tools in an annual Hi-Def Plan, as outlined in Appendix E, using the template provided [16] to support agency budget planning and investment discussions.

ii. *Integrate best business practices into agency data strategy for the generation, collection, use, sharing, and improvement of data.* Agencies should utilize the Federal Integrated Business Framework [17] in developing their annual Hi-Def Plan and share best business practices with the General Services Administration (GSA), which will make the information publicly available and easily accessible.

iii. *Collect data centrally and be prepared, upon OMB's request, to share their acquisition data into the HDE, including the relevant context and security protocols required, on an agreed upon cadence.*[18] Centralized data collection within the agency is critical to the agency's ability to readily share their acquisition data Government-wide, as well as the terms and conditions that provide critical context to making use of data. Agencies that are responsible for collecting agency data must use appropriate protocols to prevent the unauthorized disclosure of data. Agencies shall not agree to terms and conditions with their contractors or shared service providers that prohibit the sharing of their acquisition data with other Federal agencies, except where sharing is prohibited by law, where the contract identifies the data or information is classified, or where the agency makes a determination approved by the agency senior procurement executive (without delegation) after consultation with the Administrator for Federal Procurement Policy of a compelling business interest to restrict sharing.

iv. *Actively contribute to existing knowledge portals on innovative techniques and emerging technology.* Agencies shall actively collect and share information and data about their innovative activities through organized means, including but not limited to the Inventory of Emerging Technologies, the Periodic Table of Acquisition Innovations, and future knowledge management tools in the HDE, that contribute to the collective advancement of a more effective acquisition system.

v. *Appoint an accountable official responsible for Hi-Def activities.* This individual will be the primary point of contact for coordinating with OMB and the Hi-Def Managing Agency on functions that include (but are not limited to): use case identification, dataset prioritization, submission of the baseline assessment and annual Hi-Def plans, and sharing Hi-Def updates with agency stakeholders.

vi. *Support expansion, implementation, and promotion of acquisition data management training and certification efforts for the acquisition workforce.* Agencies shall work with OMB and FAI to build data analysis and related skills as a core acquisition workforce capability. Agencies shall promote and monitor workforce participation in the OMB Federal Acquisition Data Literacy training curriculum, once available. Agencies shall take steps to ensure members of the workforce with responsibilities for managing common spending are trained in using relevant Government-wide data and tools, as they become available through the Hi-Def initiative.

vii. *Generate quality data consistent with procurement policy, standards for business processes, data, and interoperability.* This includes using independent verification and validation (V&V) processes and acquisition data dictionaries maintained through the Integrated Award Environment (IAE), as well as the other agency responsibilities outlined in Appendix D.

c. *Hi-Def Environment Managing Agency:* As aligned with GSA's mission

[14] As defined in Office of Mgmt. & Budget, Executive Office of the President, Circular No. A–130, *Managing Information as a Strategic Resource* § 5(f).

[15] As defined in § 7.a.

[16] A template will be provided on a yearly basis and found on the Hi-Def website at *The Hi-Def Initiative, https://acquisitiongateway.gov/Hi-Def.*

[17] *Mission Support Business Standards, https://ussm.gsa.gov/fibf/.*

[18] Office of Mgmt. & Budget, Executive Office of the President, Memorandum M–19–13, *Category Management: Making Smarter Use of Common Contract Solutions and Practices* (Mar. 20, 2019), *https://www.whitehouse.gov/wp-content/uploads/2019/03/M-19-13.pdf.*

to deliver comprehensive products and services to the Government at the best value possible, GSA will serve as the Managing Agency for the HDE. With oversight from the multi-agency HDE Executive Steering Committee and other governing bodies as identified in Appendix B, GSA is responsible for:

i. Managing the technical architecture and planned capabilities for the HDE;

ii. Maintaining a sustainable support function to address the program management elements described in this Circular;

iii. Coordinating with agencies to define an acceptable set of data security standards for the transfer, storage, and use of Hi-Def data through data sharing agreements;

iv. Properly securing all agency data, based on established data security standards, once transmitted into the HDE; and

v. Monitoring use and adoption for the HDE.

d. *Electronic Invoicing Providers:* Electronic Invoicing Providers are responsible for providing electronic interfaces. Agencies shall ensure compliance with OMB Memorandum M–15–19 [19] and successor policies, directing all Federal Shared Service Providers and other electronic invoice solution providers to integrate with the Integrated Award Environment and develop electronic interfaces.

5. *Authorities:* OMB issues this Circular pursuant to the Office of Federal Procurement Policy Act (as amended, codified at 41 U.S.C. 101–4714); the Clinger-Cohen Act, also known as ''Information Technology Management Reform Act of 1996'' (as amended, codified at 40 U.S.C. 11101–11704); and 31 U.S.C. ch. 5.

6. *Effective Date, Applicability, and Scope:* The Circular is effective upon publication. The policies in this Circular apply to all Federal agencies and shall only be used for unclassified data.

7. *Transition:* The following phase-in actions shall be taken to help agencies prepare for the responsibilities enumerated in Section 3.

a. *Within one year of the effective date of this Circular, agencies shall perform an initial one-time baseline assessment of their acquisition data management capabilities based on a template provided by OMB.* The assessment shall focus, at a minimum, on acquisition data principles, reduction of duplicative efforts, data sharing capabilities, and actions to exchange innovative practices and solutions. Agencies shall complete and submit an assessment of and a roadmap for acquisition data systems, structures, and elements involving invoicing, contract writing systems, and transactional pricing data. The results of this initial assessment may be used to inform future Hi-Def plans and will cover:

i. Identification of the agency's accountable official responsible for Hi-Def activities;

ii. Analysis of the current collection of transactional pricing data (*i.e.,* contract line-item data) including existing systems, analytical capabilities, reporting requirements, and, if not currently being collected by a vendor, agency level of effort and required resources if changes are needed to collect that data;

iii. Acquisition data domains that are defined and managed within the agency enterprise;

iv. Adherence to the existing Federal G-Invoicing Standards; [20]

v. The extent of unstructured acquisition data in contract writing systems that are not in a machine-readable format and would be unable to be transmitted via API (*e.g.,* ''flat'' file PDFs, contract clauses, or additional scanned items that are not machine readable), with a focus on data that cannot easily be transformed to be machine readable. For example, line item pricing information may be kept in agency-specific contract writing systems, in one or more payment platforms, or in internal or external databases that are not easily accessible; and

vi. Existing and planned capabilities to share data centrally within the agency and to share data with other agencies.

b. *Within one year of this Circular, OMB shall establish a comprehensive, outcome-driven Hi-Def Data Governance Plan to ensure that data stored and shared through the HDE is responsibly and securely managed and consumed.* The Hi-Def Data Governance Plan shall be updated at regular intervals and posted to the Hi-Def website.[21]

c. Within two years of the effective date of this Circular, the Department of Defense and FAI, in coordination with OMB and GSA, will create an outline for the Federal Acquisition Data Literacy training curriculum.

8. Attachments

a. Appendix A—Definitions
b. Appendix B—Governance
c. Appendix C—Examples of Hi-Def Applications
d. Appendix D—Assuring Uniform Implementation and Data Integrity
e. Appendix E—Agency Planning
f. Appendix F—Sample Elements for Data Sharing Agreements
g. Appendix G—Hi-Def Stakeholders

Appendix A. Definitions

Acquisition—as defined in FAR 2.101,[22] acquisition is the acquiring by contract with appropriated funds of supplies or services (including construction) by and for the use of the Federal Government through purchase or lease, whether the supplies or services are already in existence or must be created, developed, demonstrated, and evaluated. Acquisition begins at the point when agency needs are established and includes the description of requirements to satisfy agency needs, solicitation and selection of sources, award of contracts, contract financing, contract performance, contract administration, and those technical and management functions directly related to the process of fulfilling agency needs by contract. For the purposes of this Circular, acquisition and procurement are used interchangeably.

Acquisition data—data or information that a contracting official, program official, or other member of the integrated product team would use during the acquisition lifecycle as part of their stewardship responsibility to obtain the best value for the Federal Government, such as, but not limited to, market research, contract documents such as statements of work, performance work statements, and statements of objective, terms, conditions, rates, and prices paid for commodities or services.

Acquisition data sharing agreement—a document that creates an understanding between two or more agencies on how acquisition data will be accessed, used, and shared, including an understanding of the overall requirements, permissions, procedures, and limitations on sharing to ensure compliance with applicable law.

Acquisition lifecycle—end-to-end management and execution of programs/contracts and projects. The lifecycle begins with the identification of a business need and ends with program or contract closeout.

Data integrity—the accuracy, completeness, and reliability of data both in its physical location and during transmission and throughout the stages of generation, collection, use, sharing, and improvement, which summarize the Federal Data Lifecycle.

Hi-Definition Environment (HDE)—a technical environment that uses a scalable architecture to store, access, utilize, share, and archive acquisition data without having to duplicate data, tools, or effort. The HDE is supported by a centralized data management policy framework (see definition of Hi-Definition framework). The HDE and the Hi-Def framework will provide a coordinated,

[19] Office of Mgmt. & Budget, Executive Office of the President, Memorandum M–15–19, *Improving Government Efficiency and Saving Taxpayer Dollars Through Electronic Invoicing* (July 17, 2015), *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2015/m-15-19.pdf.*

[20] *Bureau of the Fiscal Service, G-Invoicing, Resources, https://fiscal.treasury.gov/g-invoice/resources.html#standards.*

[21] *The Hi-Def Initiative, https://acquisitiongateway.gov/Hi-Def.*

[22] 48 CFR 2.101.

Government-wide solution for accessing and utilizing acquisition data and for developing and deploying innovative tools that use this data to better support the acquisition lifecycle. As the functional arm of the Hi-Def framework, the HDE will improve the accessibility and usability of Government-wide data through the following four general capabilities:

1. *Data Management Layer:* Aggregating siloed Government-wide acquisition data from agencies and other sources so that it is accessible centrally through a single data management layer.

2. *Data Product Development and Publication*: Developing and publishing interoperable data products to power various analysis capabilities within the HDE and across customer agencies, including scalable and secure transmission across agency security boundaries.

3. *Customer Agency Access to Data Management Functionality:* Hosting a workspace through which agency data analysts can access the HDE data management layer, allowing them to leverage HDE data sources to perform advanced analyses and develop custom data products for their agency, as aligned with data governance processes and procedures.

Dashboard and Report Management: Hosting a data visualization application, usable by both agency stakeholders and the Hi-Def Team, to develop custom Federal user-facing dashboards and reports that provide immediate value to Hi-Def stakeholders.

Hi-Definition Framework—policies, data standards, and governance addressing the acquisition of supplies or services using relevant acquisition data that is easily accessed and consumed at the time of need. The framework promotes data interoperability, secure sharing of acquisition data between agencies, and enterprise-wide data analysis to inform Government-wide and individual agency procurements.

Integrated Award Environment (IAE)—a Government-wide initiative administered by the General Services Administration that consists of a suite of systems and processes supporting parts of the Federal acquisition and financial assistance awards lifecycle. The IAE facilitates the awards processes in multiple online systems, including the System for Award Management (SAM), that each play a role in the awards lifecycle. Those systems are used for registering to do business with the Federal Government, listing contract opportunities, reporting performance, analyzing contract data, and more.

Appendix B. Governance

The acquisition ecosystem requires a strong governance structure covering Hi-Def data and the HDE, as well as Government-wide acquisition systems and processes.

Governing bodies and structures may periodically be updated and are subject to change; current charters and other updates will be posted to the Governance and Policies page on the Acquisition Gateway.[23]

1. *Hi-Def Governance:* The Hi-Def framework will be supported and operationalized by the HDE. The HDE uses a scalable technical architecture to store, access, utilize, share, and archive acquisition data without having to duplicate data, tools, or effort. Together, the Hi-Def framework and HDE will provide a coordinated, Government-wide solution for accessing and utilizing acquisition data and for developing and deploying innovative tools that use this data to better support the acquisition lifecycle.

a. Hi-Def Data Governance Plan, as referenced in Section 7.b: This plan will be established within one year of this Circular and updated on a regular basis. The plan will, at a minimum, cover the following:

i. Accountability and decision rights;
ii. Transparency and ethics considerations;
iii. Data risk management;
iv. Data security;
v. Business outcomes prioritization;
vi. Product development and dissemination; and
vii. Data domain definition and management.

b. Hi-Def Environment Executive Steering Committee: Technical oversight of the HDE will reside initially with the HDE Executive Steering Committee. This interagency committee will be responsible for establishing the strategic, technical, and change management approaches for building and maintaining the HDE. Oversight of the HDE is subject to change once the comprehensive Hi-Def Data Governance Plan is established.

c. Hi-Def Implementation Groups: On an as-needed basis, OMB may convene working groups composed of agency policy, workforce, or acquisition system experts who are knowledgeable on key topics to support Hi-Def outcomes, including but not limited to: improving machine-readable data; interoperability and system integration (*i.e.,* exposing data through application programming interfaces); the agency contract writing system(s) and associated interfaces; agency electronic invoicing solutions; and information technology infrastructure. Agency participation in these working groups is highly encouraged as outcomes may inform future guidance.

2. *Acquisition Systems Governance:* Acquisition systems governance will be carried out using the established Integrated Award Environment governance structures including the Procurement Committee for E-Government (PCE) which serves as the primary interagency body advising OMB on acquisition data with a particular focus on the procurement process. In its role, and in consultation with additional governing groups, as needed, the PCE will provide recommendations, priorities, and implementation decisions that consider the policy, operational, and technological improvements necessary to effect positive change in the efficiency and effectiveness of the use of technology and data in the Federal acquisition and procurement processes.

In addition, agencies will ensure that their current representatives selected for each governance structure or established in support of the goals of the Circular adhere to their respective charters, and possess the necessary skills and abilities to make recommendations and decisions that affect the generation, collection, use, sharing, and improvement of agency data.

Appendix C. Examples of Hi-Def Applications

This appendix provides illustrative examples of how a future HDE will benefit the acquisition lifecycle, agency planning, and budgeting. Based on agency feedback, the Office of Federal Procurement Policy has identified five initial targeted outcomes:

1. Improved Market Research
2. Supply Chain & Demand Management Insights
3. Vendor Management & Engagement Support
4. Streamlined Requirement Definition & Solicitation Development
5. Enhanced Contract Evaluation

The table below demonstrates how the impacts of the HDE will map to each stakeholder group, summarizing the impact and noting to which Hi-Def Targeted Outcomes the impact primarily relates.

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[23] *The Hi-Def Initiative, https://acquisitiongateway.gov/Hi-Def.*

Stakeholders		Anticipated Impacts*	Relevant Targeted Outcomes				
			1	2	3	4	5
USERS	Data Analysts	• Maximize access to Government-wide acquisition data • Gain a suite of tooling to generate Acquisition Workforce (AWF)-facing applications, dashboards, and reports	✓	✓	✓	✓	✓
	AWF	• Minimize the time and effort needed to conduct effective market research • Use previous solicitation packages as templates for future acquisitions	✓			✓	
	Acquisition Executives	• Better assess the supplier base and Government-wide purchasing trends to identify acquisition risks • Assess contract vehicle utilization to better make strategic decisions on which vehicles to invest in		✓	✓		✓
Customer Agencies		• Gain access to Government-wide data and a suite of tools that enable broad opportunities for improved acquisition processes and outcomes • Obtain opportunities for cost savings through more informed vendor negotiations and efficiencies	✓	✓	✓	✓	✓
Data Providers		• Increase their own (and all agencies') ability to gain value from the data available via the HDE, driving better overall outcomes for the Federal Government	✓	✓	✓	✓	✓

Industry	• Reduced burden of repeated negotiations as the Federal Government shares best practices • Simplified contracts as a result of Government standardization of buying practices (e.g., terms and conditions) • Better vendor recognition due to ease of data access	✓		✓	

**Note, anticipated impacts have been simplified and extrapolated from the Hi-Def Targeted Outcomes. While the impacts above are representative of the key impacts stakeholder groups can expect, they are not comprehensive.*

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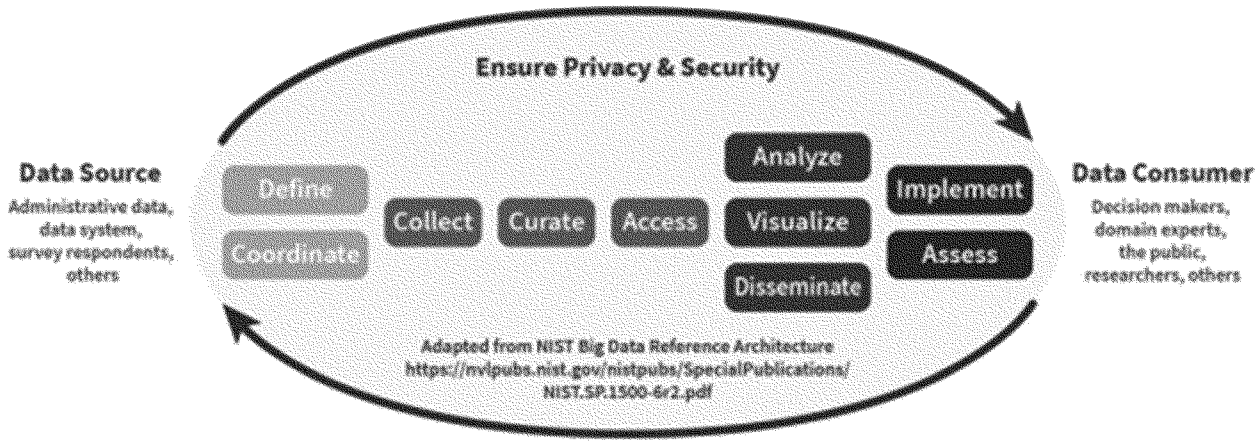
Appendix D. Ensuring Uniform Implementation and Data Integrity

Data integrity refers to the accuracy, completeness, and reliability of data in its physical location, during transmission, and throughout the stages of generation, collection, use, sharing, and improvement, which support the Federal Data Lifecycle (see Figure 1). Data integrity is maintained through compliance with laws, policies, and standards established by governance. The integrity of the Federal acquisition process, including budgeting for, planning, managing, and closing out contracts that support programs, depends on the quality and availability of data. Innovation leads to ongoing business process improvements, requiring regular assessments of processes and data against established standards. The standardized processes and data will drive strong foundations across the Federal acquisition enterprise, while encouraging and enabling agency innovation and agility in acquisition planning, management, and operations.

Figure 1: Federal Data Lifecycle



Data Roles

This policy builds on the Federal Data Lifecycle by organizing its data roles into the five phases of the acquisition data lifecycle: Generate, Collect, Share, Use, and Improve. In addition, privacy and security are roles that affect every aspect of acquisition data, and agencies should ensure that the most current data protection methodologies are used and that all applicable statutes and regulations are followed.

- *Generate*—
  - Define: Identify agency and stakeholder needs for acquisition data of sufficient quality for intended uses
  - Coordinate: Assess the ability of acquisition data resources and infrastructure to meet agency and stakeholder needs
- *Collect*—
  - Collect: Organize, plan, and execute acquisition data collections and acquisitions to meet agency and stakeholder needs
  - Curate: Organize, refine, and maintain agency acquisition data resources with sufficient quality to meet agency and stakeholder needs
- *Share*—Access: Identify and develop multiple acquisition data access methods for agency staff and stakeholders
- *Use*—
  - Analyze: Optimize the ability of staff and stakeholders to use agency acquisition data to generate insights
  - Visualize: Present acquisition data insights for consumption by all users, stakeholders, and leaders for their intended needs
  - Disseminate: Provide multiple avenues for release of acquisition data and insights
- *Improve*—Implement & Assess: Maximize the use of acquisition data for decision-making, accountability, and the public good by continuously improving the acquisition data process

Vision for Data Integrity

The governance model identified in Appendix B will support efforts to identify, develop, and implement common business processes, data, and standards. This includes assessing existing standards instituted at an agency level for their potential application to the broader Federal acquisition community. The future HDE will make possible a seamless flow of data from authoritative sources to the point of need. Data will only need to be entered once and will be available for use at any point in the acquisition lifecycle consistent with applicable regulations and policies through implemented machine-readable data, in an open format, and available to computer applications to promote interoperability and system integration such as APIs.

As new regulations or policies are developed, new data may be required. Ongoing processes to review how best to collect this data from new or existing sources should be put into place, including for the review of the quality, security, and integrity of that data. Business process re-engineering may be required to avoid manual or redundant processes, improve quality, and make data available at the time of need. Reporting requirements may need to be adjusted or integrated as a result of increased data availability. Agencies must strategically plan how various Federal-wide and agency specific efforts can be harmonized and used to avoid duplication of effort, costs, and diminished data quality resulting from multiple instances of similar data across an agency.

Quality Technology and Data

In collaboration with the Integrated Award Environment governance structures and the Federal Acquisition Regulatory Council, and in consultation with Managing Partners for common technology tools, the PCE will ensure that applicable regulations and policy are reflected in any technologies, processes, systems, and data to reduce agency burden and ensure quality data are available for downstream use.

In addition, the PCE, in coordination with OMB and Integrated Award Environment governance structures, will review, and as needed, update the existing parameters and methods for annual V&V [24] reporting every 5 years to align with policy, regulatory and agency needs as aligned with policy.

Agency Responsibilities

In the distributed procurement information technology environment, agencies have responsibilities to generate data consistent with procurement policy, as well as standards for business processes, data, and interoperability. Federal agencies must manage data consistent with statutes, regulations, and OMB policies. Agency Chief Acquisition Officers, Senior Procurement Executives, Chief Data Officers, Chief Financial Officers, Chief Information Officers, and Budget Officers must collaborate to:

- Ensure independent V&V processes for data quality in accordance with relevant guidance;
- Assess the feasibility of building and maintaining appropriate and secure APIs to permit sharing and interoperability of procurement data and are developed through the appropriate working group(s) and after the initial data assessment period;
- Promote best business practices of appropriate data hygiene, principles, and standards as developed by the PCE;
- Further innovation and efficiency in the Federal acquisition system by leading or actively participating in the development and implementation of emerging technology tools that align with policy;
- Actively develop professionals with skills in Federal Acquisition Regulation (FAR)-based data analytics for decision-making;
- Assume responsibility for making data-driven decisions and for providing their acquisition workforce with critical information needed to negotiate contracts in the best interest of taxpayers;
- Build security and fraud protection into the management of procurement data to ensure data availability and usability; and
- Practice and share data management best practices through interagency working groups, such as the Chief Data Officers Council.

Appendix E. Annual Agency Planning Requirements

Strategic and operational planning by agencies, including budget planning, is essential to an interoperable environment where data are shared and available at the point of need. These activities provide opportunities for addressing gaps identified through assessments and innovation in business processes and technology, including lessons learned from pilots or shared activities. As such, agencies must include appropriate analyses of these considerations in agency annual strategic plans, as required by OMB Circular A–11 and any supplementary direction from OMB during the budget process. These plans will be reviewed by OMB to inform and shape actions necessary to support Hi-Def implementation and maintenance.

The Office of Federal Procurement Policy will provide a template with questions and structure for compiling agency Hi-Def strategic plans. The template will include sections for responding to questions related to acquisition data resources and infrastructure, Government-wide priorities established by OMB and governance groups, and agency-specific priorities. The yearly priority areas will be posted with an updated template on the Hi-Def website.[25] The acquisition data resources and infrastructure questions will generally address the following areas and may include other areas of interest as appropriate:

a. Appropriate resource management activities necessary to support innovative practices and alignment of data with statutes, regulations, policies, and standards to support interoperability. The identification of activities should be accomplished in coordination with the appropriate agency leaders directing the acquisition, information, security, data, finance, and human capital functions.

b. Solutions (active, in development, or planned for future development) identified by the agency workforce as the greatest opportunity for improving processes and leveraging technology to support innovation and reduce burden. Such ideas support agency operations and mission success by addressing issues, challenges, and best practices identified by those most impacted on a daily basis by access (or lack thereof) to data and information.

c. Details on how agencies are assuring any new technologies at the agency level are aligned with policy and regulations, and how agency technology supports the interoperability of data in the federated model established through this Circular.

d. Recommendations on any business processes that should be re-engineered to support innovation or just-in-time access to quality information or data. Re-imagining the process before applying emerging technologies or shared tools can lead to a more impactful change. This can be done by seeking workforce input, taking maximum advantage of FAR flexibilities, leveraging data and information technology as strategic assets, consulting with governance on how data is supposed to be used and displayed, and driving changes to agency-specific requirements.

Appendix F. Sample Elements for Data Sharing Agreements

Based on input collected through agency plans and stakeholder use cases, OMB will identify and prioritize datasets to be shared into the HDE.

Once identified, an MOU may be required to share data between the Hi-Def Managing Agency and the originating agency to ensure that data is properly stored, secured, and accessed. OMB is responsible for developing standard MOU templates to cover probable data scenarios, including but not limited to:

1. Exchange of discoverable, non-classified data;
2. Exchange of unstructured, document-based data such as contract terms and conditions; and
3. Exchange of classified or otherwise sensitive data that requires additional security considerations.

Sample elements for a data sharing MOU may include, but are not limited to:

1. Scope of data: Specify the types of data involved and any restrictions on use.

[24] Office of Mgmt. & Budget, Executive Office of the President, OFPP Memorandum, *Improving Acquisition Data Quality for Fiscal Years 2009 and 2010* (Oct. 7, 2009), *https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/procurement_memo/data_quality_guidance_100709.pdf;* Office of Mgmt. & Budget, Executive Office of the President, OFPP Memorandum, *Improving Federal Procurement Data Quality—Guidance for Annual Verification and Validation* (May 31, 2011), *https://obamawhitehouse.archives.gov/sites/default/files/omb/procurement/memo/improving-data-quality-guidance-for-annual-verification-and-validation-may-2011.pdf.*

[25] *The Hi-Def Initiative, https://acquisitiongateway.gov/Hi-Def.*

2. Data Ownership: Clarify who owns the data and any rights or responsibilities associated with it.

3. Confidentiality: Outline privacy considerations and measures to protect sensitive information.

4. Security: Detail security protocols required for transmitting, storing, and accessing data

5. Permitted Uses: Specify the authorized uses of the shared data and any limitations (for example, vendor names must be anonymized).

6. Duration of Agreement: Define the start and end dates or conditions for termination.

7. Responsibilities of the Parties: Clearly outline the obligations and responsibilities of each party involved.

8. Data Accuracy and Quality: Address the accuracy and quality standards expected for the shared data.

9. Data Access and Sharing Procedures: Specify how data will be accessed and shared.

10. Dispute Resolution: Establish procedures for resolving disputes or breaches of the agreement.

11. Governing Authorities: Specify the governing authorities that provide for the sharing of this data.

12. Amendments: Outline procedures for making changes to the agreement, as necessary.

Appendix G. HDE Stakeholders

HDE Stakeholders fall into four categories: Users, Customer Agencies, Data Providers, and Industry. This list is subject to further refinement, with updates posted to the Hi-Def website.[26]

1. Data Providers will enable and provide access to their acquisition data to improve the capabilities, scope, and value of the HDE.

a. All Federal agencies are expected to ultimately be data providers. However, in the initial phase of the HDE, individual agencies will be consulted by OMB and the Hi-Def Executive Steering Committee about pilot opportunities on a case-by-case basis.

b. Other data providers may include non-Federal Government data sources and commercial data providers, where such data sources significantly enhance Hi-Def capabilities (*e.g.,* market, business, sales, supply chain, and/or product intelligence information).

2. *Customer Agencies* will be composed of HDE users (outlined below) and will have access to select HDE capabilities. They can leverage the HDE to help equip their agency users with Hi-Def insights and functionality.

a. Customers will be Federal agencies who access select capabilities such as data products, applications, and support services.

b. The customer base and services available are expected to grow and evolve as HDE functionality matures.

3. *Users* will engage directly with the HDE or leverage HDE data.

a. The Acquisition Workforce (AWF) will primarily engage with various AWF-facing applications, dashboards, and reports that leverage HDE data products, initially those focused on commodity and service prices-paid analysis for market research, monitoring buying patterns, and solicitation development. The AWF can also use their understanding of the data in the HDE to identify more complex acquisition questions that they would like their data analysts to address. AWF users will primarily be agency Contracting Officers, Contract Specialists, and Agency Buyers and Program Managers.

b. Data Analysts from customer agencies will have access to usable agency acquisition data through various HDE components and features. This includes: (1) direct access to the HDE data management layer to perform custom analyses and develop new data products; (2) use of the dashboard and report management application to provide streamlined insights to their AWF in the HDE; and (3) ability to use HDE data products to power functionality developed and hosted by their home agency (*e.g.,* an advanced web-application).

c. Acquisition Executives will primarily engage with various end-user applications that use HDE data products to quickly identify key insights (*e.g.,* demand trends, contractor performance, etc.) that support overall program direction and high-level decision making. Similar to the AWF, Acquisition Executives can also identify additional acquisition questions they would like data analysts to address. Acquisition Executives will include a range of program, category, and schedule managers.

4. *Industry* will benefit from enhanced acquisition efficiencies from the HDE, but will not be given access to the HDE, unless in a manner explicitly specified by the agencies and approved by OMB based on need, and in accordance with statutes, regulations, and protocols that address the release of contractor information to non-governmental sources.

[26] *The Hi-Def Initiative, https://acquisitiongateway.gov/Hi-Def.*

[FR Doc. 2024–11864 Filed 5–29–24; 8:45 am]

BILLING CODE 3110–01–P

NATIONAL FOUNDATION OF THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

49th Meeting of the National Museum and Library Services Board

AGENCY: Institute of Museum and Library Services (IMLS), National Foundation of the Arts and the Humanities (NFAH).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the National Museum and Library Services Board will meet to advise the Director of the Institute of Museum and Library Services (IMLS) with respect to duties, powers, and authority of IMLS relating to museum, library, and information services, as well as coordination of activities for the improvement of these services.

DATES: *Dates and Time:* The meeting will be held on June 24, 2024, from 1 p.m. ET until 4:30 p.m. ET.

Place: The meeting will convene in a virtual format. Virtual meeting and audio conference technology will be used. Instructions for joining will be sent to all registrants.

FOR FURTHER INFORMATION CONTACT: Katherine Maas, Chief of Staff and Alternate Designated Federal Officer, Institute of Museum and Library Services, Suite 4000, 955 L'Enfant Plaza North SW, Washington, DC 20024; (202) 653–4798; *kmaas@imls.gov.*

SUPPLEMENTARY INFORMATION: The National Museum and Library Services Board is meeting pursuant to the National Museum and Library Service Act, 20 U.S.C. 9105a, and the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App.

The 49th Meeting of the National Museum and Library Services Board, which is open to the public, will convene at 1 p.m. Eastern Time on June 24, 2024.

The agenda for the 49th Meeting of the National Museum and Library Services Board will be as follows:

I. Call to Order
II. Approval of Minutes of the 48th Meeting
III. Director's Welcome and Update
IV. PCAH Update
V. FY25 Budget Update
VI. Equity Action Plan: Framing Breakouts
VII. Breakout Groups
VIII. Report Outs
IX. Discussion

If you wish to attend the meeting, please inform IMLS as soon as possible, but no later than close of business on June 17, 2024, by contacting Katherine Maas at *kmaas@imls.gov.* Virtual meeting information will be sent to all public registrants. Please provide notice of any special needs or accommodations by June 5th, 2024.

Dated: May 22, 2024.

Brianna Ingram,

Paralegal Specialist.

[FR Doc. 2024–11808 Filed 5–29–24; 8:45 am]

BILLING CODE 7036–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024–312 and CP2024–320; MC2024–313 and CP2024–321; MC2024–314 and CP2024–322; MC2024–315 and CP2024–323; MC2024–316 and CP2024–324]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the

Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 3, 2024.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2024–312 and CP2024–320; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 73 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 23, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Almaroof Agoro; *Comments Due:* June 3, 2024.

2. *Docket No(s).:* MC2024–313 and CP2024–321; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 266 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 23, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Almaroof Agoro; *Comments Due:* June 3, 2024.

3. *Docket No(s).:* MC2024–314 and CP2024–322; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 74 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 23, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Almaroof Agoro; *Comments Due:* June 3, 2024.

4. *Docket No(s).:* MC2024–315 and CP2024–323; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 75 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 23, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* June 3, 2024.

5. *Docket No(s).:* MC2024–316 and CP2024–324; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 76 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 23, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* June 3, 2024.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2024–11873 Filed 5–29–24; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Notice of Availability and Request for Information; Federal Evidence Agenda on Disability Equity

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Request for information (RFI).

SUMMARY: Through this Request for information (RFI), the White House Office of Science and Technology Policy (OSTP) seeks input from the public to help inform the development of the Federal Evidence Agenda on Disability Equity. Executive Order 14091 on Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (February 16, 2023) directed the OSTP National Science and Technology Council Subcommittee on Equitable Data (SED) to coordinate implementation of recommendations of the Equitable Data Working Group. To address the recommendations relevant to disability, the SED established the Disability Data Interagency Working Group (DDIWG). The DDIWG is tasked with the development and release of a Federal Evidence Agenda on Disability Equity, in order to improve the Federal government's ability to make data-informed policy decisions that advance equity for the disability community.

DATES: Interested persons and organizations are invited to submit comments on or before July 15, 2024.

ADDRESSES: Interested individuals and organizations should submit comments electronically via the Federal eRulemaking Portal at *https://www.regulations.gov/.* Information on how to use regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''FAQ'' (*https://www.regulations.gov/faq*).

Instructions for Submission: OSTP has provided some key questions on which public insights would be most valuable (see **SUPPLEMENTARY INFORMATION**, Part II). You may respond

to some or all of these questions, and additional feedback beyond these questions is also welcome. Any links you provide to online materials or presentations must be publicly accessible. Please feel free to share this RFI with colleagues or others for feedback.

Privacy Act Statement: Response to this RFI is voluntary. Please note that all submissions received in response to this notice may be posted on *https://www.regulations.gov/* or otherwise released in their entirety.

Do not include in your submissions any copyrighted material; information of a confidential nature, such as personal or proprietary information; or any information you would not like to be made publicly available. Individuals and organizations who respond to this RFI may be contacted for additional clarification.

OSTP will not respond to individual submissions. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed. This RFI is not accepting applications for financial assistance or financial incentives.

Responses containing references, studies, research, and other empirical data that are not widely published should include copies of or electronic links to the referenced materials. Responses from minors, or responses containing profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

Comments submitted in response to this notice are subject to the Freedom of Information Act (FOIA). Please note that the United States Government will not pay for response preparation, or for the use of any information contained in a response.

FOR FURTHER INFORMATION CONTACT: Please email *disabilitydata@ostp.eop.gov* with ''Federal Evidence Agenda on Disability Equity RFI'' in the subject line, or contact Adam Politis, Senior Policy for Disability and Equity, at 202–881–8448. Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Executive Order (E.O.) 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021) established the Equitable Data Working Group (EDWG) to study existing Federal data collection policies, programs, and capabilities and provide recommendations for increasing data available for measuring equity and representing the diversity of the American people. Subsequently, E.O. 14091 on Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (February 16, 2023) directed the White House Office of Science and Technology Policy (OSTP) National Science and Technology Council Subcommittee on Equitable Data (SED) to coordinate implementation of the recommendations of the EDWG.

To address the recommendations relevant to disability, the SED established the Disability Data Interagency Working Group (DDIWG). The DDIWG is tasked with the development and release of a Federal Evidence Agenda on Disability Equity, in order to improve the Federal Government's ability to make data-informed policy decisions that advance equity for the disability community.

The Federal Evidence Agenda on Disability Equity will:

i. Describe disparities faced by individuals with disabilities that could be better understood through Federal statistics and data collection, such as disparities in health, employment, educational, and other outcomes, or in Federal program participation.

ii. Identify, in coordination with agency staff, Federal data collections where improved disability data collection may be important for advancing the Federal Government's ability to measure disparities facing individuals with disabilities; and

iii. Identify practices for all Federal agencies engaging in disability data collection to follow in order to safeguard privacy, security, and civil rights, including with regard to appropriate and robust practices of consent for the collection of this data and restrictions on its use or transfer.

We invite members of the public to share perspectives on how the DDIWG should address these requirements in the Federal Evidence Agenda on Disability Equity. OSTP seeks responses to one, some, or all of the questions that follow.

II. Topics and Key Questions

Describing Disparities

In its March 2023 progress report, the Subcommittee on Equitable Data states, ''At its core, the principle of equitable data is about disaggregating and analyzing data to identify disparities in federal policies and programs, using levers of the federal government to address those disparities, and then enabling members of the public to hold government accountable.'' With this in mind, OSTP seeks response to the following questions:

1. What disparities faced by individuals with disabilities are not well-understood through existing Federal statistics and data collection?

2. What types of community-based or non-Federal statistics or data collections could help inform the creation of the Federal Evidence Agenda on Disability Equity?

3. Community-based research has indicated that individuals with disabilities experience disparities in a broad range of areas. What factors or criteria should the DDIWG consider when considering policy research priorities?

Informing Data Collections and Public Access

Ultimately, individual agencies decide what data to collect and publish through their surveys and forms, taking into account considerations like informed consent, privacy risk, statistical rigor, intended use of the data, budget, burden to respondents, and more. With that in mind, OSTP seeks response to the following questions:

1. Disability can be defined and measured in multiple ways. Federal surveys and administrative data collections use different definitions of disability and measure it in different ways depending upon the goal(s) of data collection. What frameworks for defining and measuring disability or specific considerations should the DDIWG be aware of?

2. In some instances, there are multiple surveys or data collection tools that could be used to collect data about a particular disparity faced by the disability community. In addition to factors like sample size, timeliness of the data, and geographic specificity of related data products, what other factors should be considered when determining which survey or data collection tool would best generate the relevant data? Which surveys or data collection tools would be uniquely valuable in improving the Federal Government's ability to make data-informed decisions that advance equity for the disability community, and why?

3. Are there any Federal surveys or administrative data collection tools for which you would recommend the Federal Government *should not* explore collecting disability data due to privacy risk, the creation of barriers to participation in Federal programs, or other reasons? Which collections or type

of collections are they, and why would you make this recommendation?

4. How can Federal agencies increase public response rates to questions about disability in order to improve sample sizes and population coverage?

5. What barriers may individuals with disabilities face when participating in surveys or filling out administrative forms?

6. Disaggregated data—data about groups separated out by disability, race/ethnicity, gender identity, sexual orientation, geography, income level, veteran status, rural/urban location, and other factors—are essential for identifying and remediating disparities in how the government serves American communities. Which data disaggregated by disability that are currently collected by Federal agencies are useful? Which data disaggregated by disability are not currently collected by Federal agencies and would be useful, and why?

7. How can Federal agencies best raise public awareness about the existence of sources of disability data? How can Federal agencies best communicate with the public about methodological constraints to collecting data or publishing disability statistics?

8. How do individuals and organizations external to the Federal Government utilize data from Federal surveys and administrative data collections? Which practices employed by Federal agencies facilitate access to and use of these data? Are there additional practices that would be beneficial?

Privacy, Security, and Civil Rights

The EDWG recommended that ''. . . as the federal government expands its use of disaggregated demographic data, it must be intentional about when data are collected and shared, as well as how data are protected so as not to exacerbate the vulnerability of members of underserved communities, many of whom face the heightened risk of harm if their privacy is not protected.'' Though previous work by the SED has identified how privacy, confidentiality, and civil rights practices apply to other marginalized groups, OSTP seeks input on privacy, confidentiality, and civil rights considerations that are unique to the disability community and/or are experienced differently by individuals with disabilities. Accordingly, OSTP seeks response to the following questions:

1. What specific privacy and confidentiality considerations should the DDIWG keep in mind when determining promising practices for the Federal collection of data for administrative purposes, such as applications for programs or benefits, compliance forms, and human resources and restrictions on their use or transfer?

2. Unique risks may exist when collecting disability data in the context of both surveys and administrative forms. Please tell us about specific risks Federal agencies should think about when considering whether to collect these data in surveys or administrative contexts.

3. Once disability data have been collected for administrative or statistical purposes, what considerations should Federal agencies be aware of concerning retention of these data? Please tell us how privacy or confidentiality protections could mitigate or change these concerns.

4. Where administrative data are used to enforce civil rights protections, such as in employment, credit applications, healthcare settings, or education settings, what considerations should the DDIWG keep in mind when determining promising practices for the collection of these data and restrictions on its use or transfer?

Dated: May 24, 2024.

Stacy Murphy,

Deputy Chief Operations Officer/Security Officer.

[FR Doc. 2024–11838 Filed 5–29–24; 8:45 am]

BILLING CODE 3270–F1–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100223; File No. SR–ISE–2024–21]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing of Proposed Rule Change To Permit the Listing of Two Monday Expirations for Options on GLD, SLV, TLT, USO, and UNG

May 23, 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 May 16, 2024, Nasdaq ISE, LLC (''ISE'' 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Short Term Option Series Program in Supplementary Material .03 of Options 4, Section 5.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/ise/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Short Term Option Series Program in Supplementary Material .03 of Options 4, Section 5. Specifically, the Exchange proposes to expand the Short Term Option Series Program to permit the listing of two Monday expirations for options on United States Oil Fund, LP (''USO''), United States Natural Gas Fund, LP (''UNG''), SPDR Gold Shares (''GLD''), iShares Silver Trust (''SLV''), and iShares 20+ Year Treasury Bond ETF (''TLT'') (collectively ''Exchange Traded Products'' or ''ETPs'').[3]

Currently, as set forth in Supplementary Material .03 to Options 4, Section 5, after an option class has been approved for listing and trading on the Exchange as a Short Term Option Series pursuant to Options 1, Section 1(a)(49),[4] the Exchange may open for

[3] Today, the Exchange permits the listing of two Wednesday expirations for options on USO, UNG, GLD, SLV, and TLT. *See* Securities Exchange Act Release No. 98905 (November 13, 2023), 88 FR 80348 (November 17, 2023) (SR–ISE–2023–11) (''Wednesday Approval Order''). The Exchange began listing Wednesday expirations on these five symbols on November 21, 2023. *See* Options Trader Alert #2023–55.

[4] Options 1, Section 1(a)(49) provides that a Short Term Option Series means a series in an option class that is approved for listing and trading on the

trading on any Thursday or Friday that is a business day (''Short Term Option Opening Date'') 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 expire (''Friday Short Term Option Expiration Dates''). The Exchange may have no more than a total of five Short Term Option Expiration Dates. Further, if the Exchange is not open for business on the respective Thursday or Friday, the Short Term Option Opening Date for Short Term Option Weekly Expirations will be the first business day immediately prior to that respective Thursday or Friday. Similarly, if the Exchange is not open for business on a Friday, the Short Term Option Expiration Date for Short Term Option Weekly Expirations will be the first business day immediately prior to that Friday.

Additionally, the Exchange may open for trading series of options on the symbols provided in Table 1 of Supplementary Material .03 to Options 4, Section 5 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'').[5] For those symbols listed in Table 1, the Exchange may have no more than a total of two Short Term Option Daily Expirations beyond the current week for each of Monday, Tuesday, Wednesday, and Thursday expirations, as applicable, at one time.

Proposal

At this time, the Exchange proposes to expand the Short Term Option Daily Expirations to permit the listing and trading of options on USO, UNG, GLD, SLV, and TLT expiring on Mondays. The Exchange proposes to permit two Short Term Option Expiration Dates beyond the current week for each Monday expiration at one time, and would update Table 1 in Supplementary Material .03 to Options 4, Section 5 for each of those symbols accordingly.

The proposed Monday USO, UNG, GLD, SLV, and TLT expirations will be similar to the current Monday SPY, QQQ, and IWM Short Term Option Daily Expirations set forth in Supplementary Material .03 to Options 4, Section 5, such that the Exchange may open for trading on any Friday or Monday that is a business day (beyond the current week) series of options on USO, UNG, GLD, SLV, and TLT to expire on any Monday of the month that is a business day and is not a Monday in which standard expiration options series, Monthly Options Series, or Quarterly Options Series expire, provided that Monday expirations that are listed on a Friday must be listed at least one business week and one business day prior to the expiration (''Monday USO Expirations,'' ''Monday UNG Expirations,'' ''Monday GLD Expirations,'' ''Monday SLV Expirations,'' and ''Monday TLT Expirations'') (collectively, ''Monday ETP Expirations'').[6] In the event Short Term Option Daily Expirations expire on a Monday and that Monday is the same day that a standard expiration options series, Monthly Options Series, or Quarterly Options Series expires, the Exchange would skip that week's listing and instead list the following week; the two weeks would therefore not be consecutive. Today, Monday expirations in SPY, QQQ, and IWM similarly skip the weekly listing in the event the weekly listing expires on the same day in the same class as a standard expiration options series, Monthly Options Series, or Quarterly Options Series.

The interval between strike prices for the proposed Monday ETP Expirations will be the same as those currently applicable for SPY, QQQ, and IWM Monday expirations in the Short Term Option Series Program.[7] Specifically, the Monday ETP Expirations will have a strike interval of (i) $0.50 or greater for strike prices below $100, and $1 or greater for strike prices between $100 and $150 for all option classes that participate in the Short Term Option Series Program, (ii) $0.50 for option classes that trade in one dollar increments and are in the Short Term Option Series Program, or (iii) $2.50 or greater for strike prices above $150.[8] As is the case with other equity options series listed pursuant to the Short Term Option Series Program, the Monday ETP Expirations series will be P.M.-settled.

Pursuant to Options 1, Section 1(a)(49), with respect to the Short Term Option Series Program, if a Monday is not a business day, the series shall expire on the first business day immediately following that Monday.

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.[9] 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.[10] With the proposed changes, this thirty (30) series restriction would apply to Monday USO, UNG, GLD, SLV, and TLT Short Term Option Daily Expirations as well. In addition, the Exchange will be able to list series that are listed by other exchanges, assuming they file similar rules with the Commission to list Monday ETP Expirations.

With this proposal, Monday ETP Expirations would be treated similarly to existing Monday SPY, QQQ, and IWM Expirations. With respect to standard expiration option series, Short Term Option Daily Expirations will be permitted to expire in the same week in which standard expiration option series on the same class expire.[11] Not listing Short Term Option Daily Expirations for one week every month because there was a standard options series on that same class on the Friday of that week would create investor confusion.

Further, as with Monday SPY, QQQ, and IWM Expirations, the Exchange would not permit Monday ETP Expirations to expire on a business day in which standard expiration option series, Monthly Options Series, or Quarterly Options Series expire.[12] Therefore, all Short Term Option Daily Expirations would expire at the close of business on each of the next two Mondays, Tuesdays, Wednesdays, and

Exchange in which the series is opened for trading on any Monday, Tuesday, Wednesday, Thursday or Friday that is a business day and that expires on the Monday, Wednesday or Friday of the following business week that is a business day, 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. 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.

[5] As set forth in Table 1, the Exchange currently only permits Wednesday expirations for USO, UNG, GLD, SLV, and TLT.

[6] Today, USO, UNG, GLD, SLV, and TLT may trade on Wednesdays. *See supra* note 3. They may also trade on Fridays, as is the case for all options series in the Short Term Option Series Program.

[7] *See* Supplementary Material .03(e) to Options 4, Section 5.

[8] *Id.*

[9] *See* Supplementary Material .03(a) to Options 4, Section 5.

[10] *Id.*

[11] *See* Supplementary Material .03(b) to Options 4, Section 5.

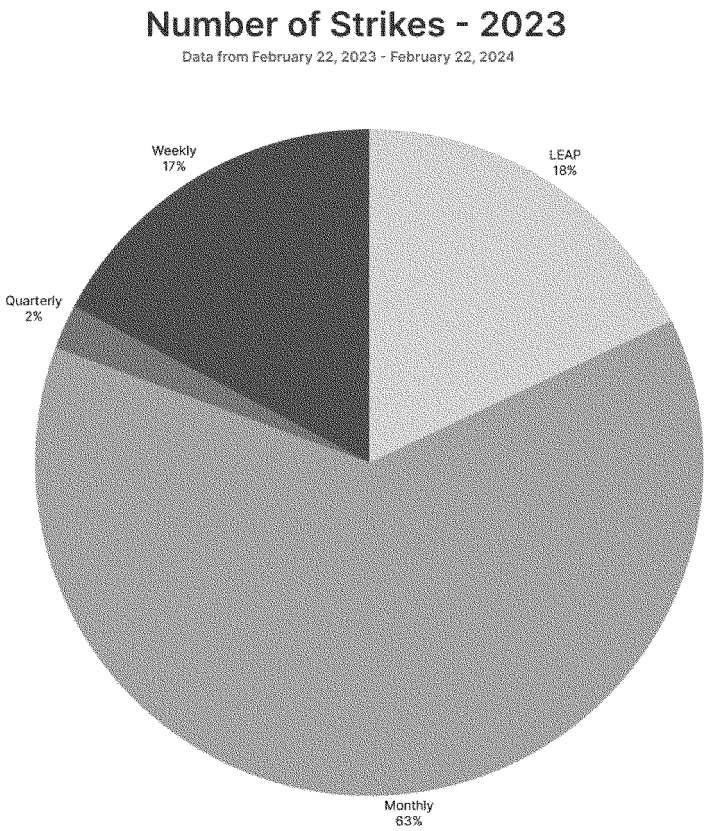
[12] *See* Supplementary Material .03 to Options 4, Section 5.

Thursdays, respectively, that are business days and are not business days in which standard expiration option series, Monthly Options Series, or Quarterly Options Series expire. The Exchange believes that it is reasonable to not permit two expirations on the same day in which a standard expiration option series, Monthly Options Series, a Quarterly Options Series would expire because those options would be duplicative of each other.

The Exchange does not believe that any market disruptions will be encountered with the introduction of Monday ETP Expirations. The Exchange currently trades P.M.-settled Short Term Option Series that expire Monday for SPY, QQQ and IWM and has not experienced any market disruptions nor issues with capacity. In addition, the Exchange has not experienced any market disruptions or issues with capacity in expanding the five ETPs to the Wednesday expirations.[13] Today, the Exchange has surveillance programs in place to support and properly monitor trading in Short Term Option Series that expire Monday for SPY, QQQ and IWM. Further, the Exchange has the necessary capacity and surveillance programs in place to support and properly monitor trading in the proposed Monday ETP Expirations.

Impact of Proposal

The Exchange notes that listings in the Short Term Option Series Program comprise a significant part of the standard listings in options markets. The below diagram demonstrates the percentage of weekly listings in the options industry compared to monthly, quarterly, and Long-Term Option Series for a twelve-month period ending on February 22, 2024.[14]



While the Exchange is expanding the Short Term Option Series Program to permit USO, UNG, GLD, SLV, and TLT Monday Expirations, the Exchange anticipates that it would overall add a small number of weekly expiration dates because the Exchange will limit the number of Short Term Option Daily Expirations for these ETPs to two Monday expirations. Expanding the Short Term Option Series Program in the foregoing manner will account for the addition of 4% (GLD), 8% (SLV), and 4% (TLT), 16% (UNG), and 9% (USO) of strikes for the respective symbol.[15] With respect to the impact on the Short Term Option Series Program for each symbol overall, the impact would be a 13% (GLD), 20% (SLV), and 18% (TLT), 26% (UNG), and 18% (USO) increase in strikes for the respective symbol.[16] With respect to the impact on the Short Term Option Series Program overall, the impact would be a 0.05% (GLD), 0.03% (SLV), and 0.04% (TLT), 0.04% (UNG), and 0.04% (USO) increase in strikes for the respective symbol.[17]

Further, as shown below, weeklies comprise 48% of the total volume of

[13] *See supra* note 3.

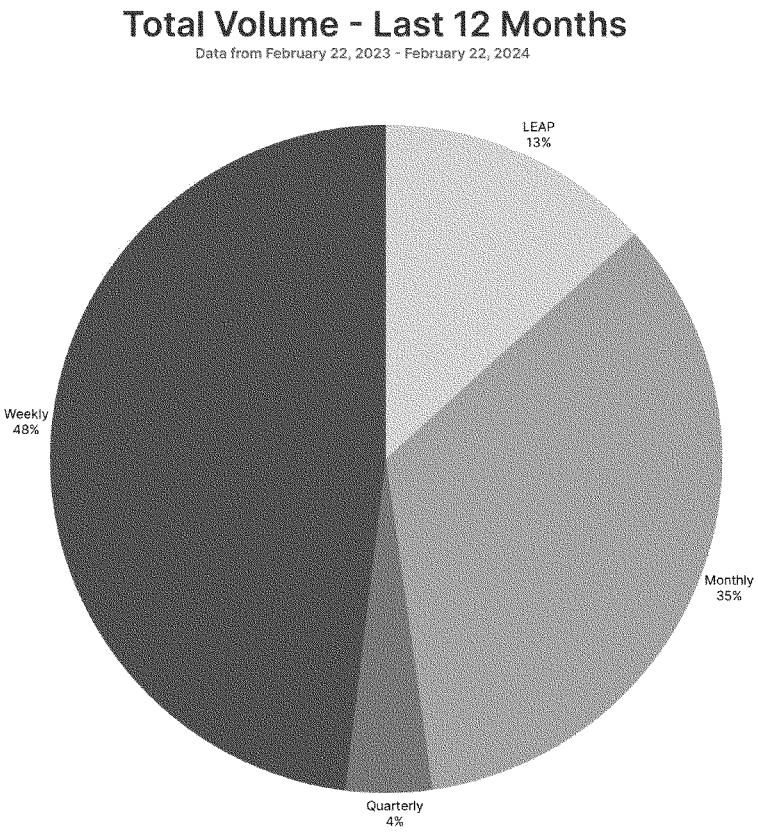
[14] The Exchange sourced this information from The Options Clearing Corporation (''OCC''). The information includes time averaged data (the number of strikes by maturity date divided from the number of trading days) for all 17 options markets through February 22, 2024.

[15] The Exchange sourced this information, which are estimates, from OCC. The information includes data for all 17 options markets as of February 22, 2024.

[16] The Exchange sourced this information, which are estimates, from OCC. The information includes data for all 17 options markets as of February 22, 2024.

[17] The Exchange sourced this information, which are estimates, from OCC. The information includes data for all 17 options markets as of February 22, 2024.

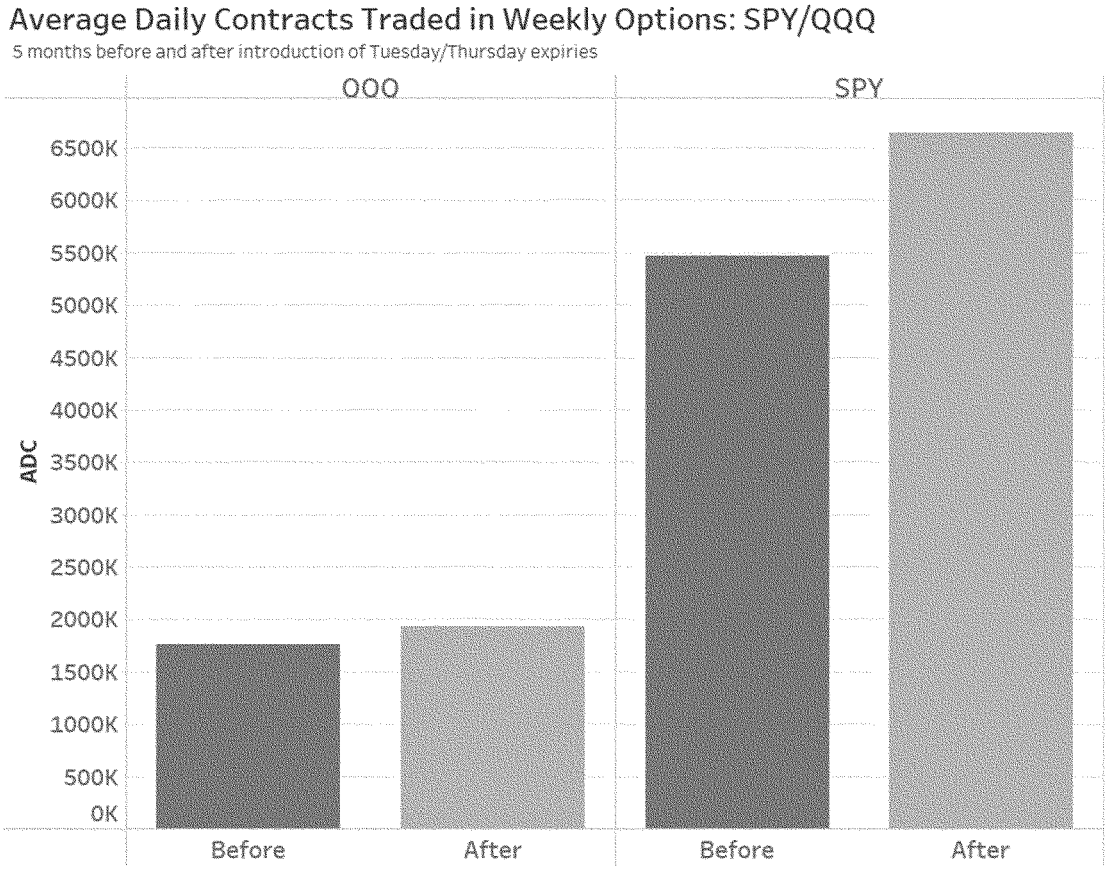
options contracts.[18] The Exchange believes that inner weeklies (first two weeks) represent high volume as compared to outer weeklies (the last three weeks) and would be more attractive to market participants.



In addition, the Exchange looked at the average daily contracts traded in SPY and QQQ five months before and five months after the introduction of Tuesday and Thursday expirations on those two symbols to assess whether there was new interest from adding alternative expirations (as opposed to existing interest being cannibalized).[19] The below chart shows a volume increase in terms of average daily contracts traded in SPY and QQQ in the five-month period following the introduction of Tuesday and Thursday expirations, which the Exchange believes indicate the existence of genuine new interest in alternative expirations for SPY and QQQ.

[18] The chart represents industry volume in terms of overall contracts. Weeklies comprise 48% of volume while only being 17% of the strikes, each as shown above. The Exchange sourced this information from OCC. The information includes data for all 17 options markets through February 22, 2024.

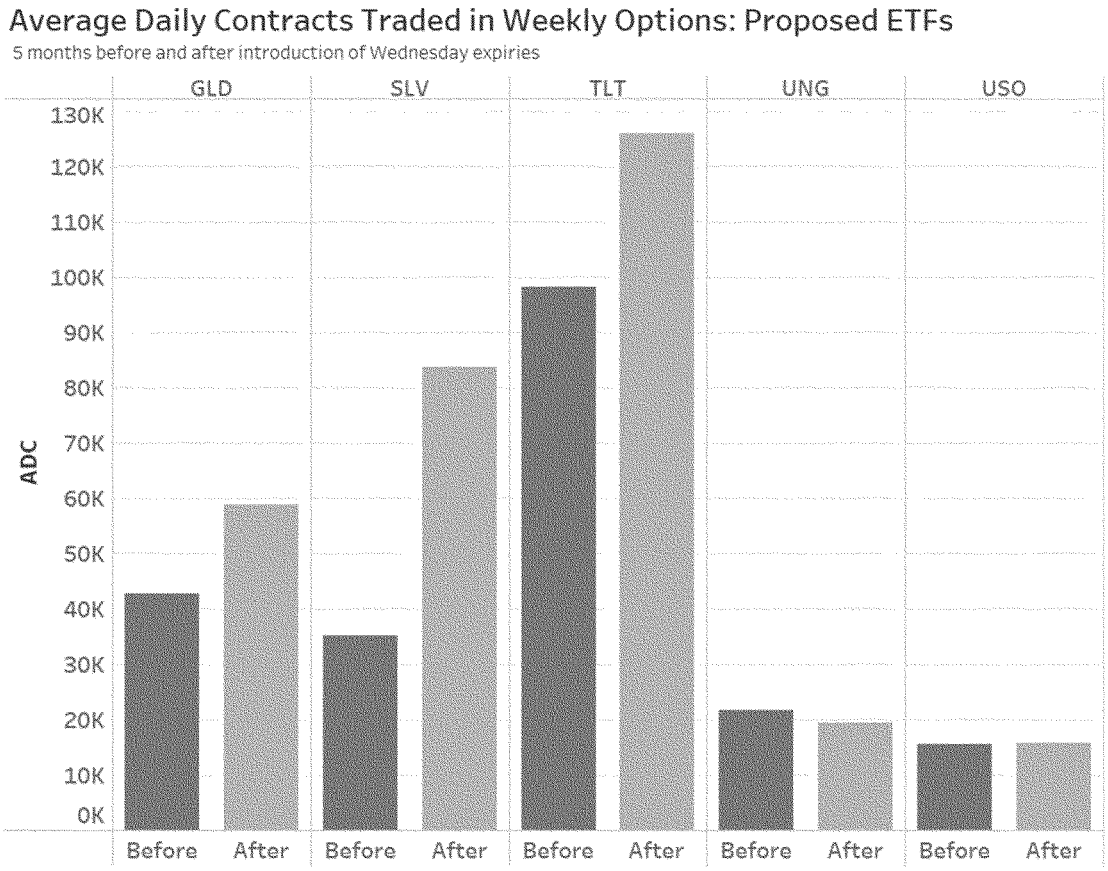
[19] *See* Securities Exchange Act Release No. 96281 (November 9, 2022), 87 FR 68769 (November 16, 2022) (SR–ISE–2022–18) (Approval Order for Tuesday and Thursday Expirations in SPY and QQQ). The Exchange began listing Tuesday and Thursday expirations in SPY and QQQ in mid-November 2022. *See* Options Trader Alert #2022–40.



The Exchange believes there is general demand for alternative expirations in GLD, SLV, TLT, UNG, and USO based on similar analysis. In particular, the Exchange looked at the average daily contracts traded in GLD, SLV, TLT, UNG, and USO five months before and five months after the introduction of Wednesday expirations to similarly assess whether there was new interest from adding these alternative expirations.[20] As shown below, there was a general volume increase in terms of average daily contracts traded in these five symbols in the five-month period following the introduction of Wednesday expirations.[21]

[20] *See supra* note 3.

[21] Note that UNG volume slightly decreased and USO volume showed little change in the five-month period following the introduction of Wednesday expirations.



The Exchange also looked at the lifecycle volume of GLD, SLV, TLT, UNG, and USO in terms of average daily contracts traded, going from 50 days before expiration to the expiration date, to see how that lifecycle volume changed before and after the introduction of Wednesday expirations. As shown below, there is a notable increase in volume in terms of average daily contracts traded as the expiration date approaches. This is consistent across all five symbols as well as before and after the addition of Wednesday expirations.

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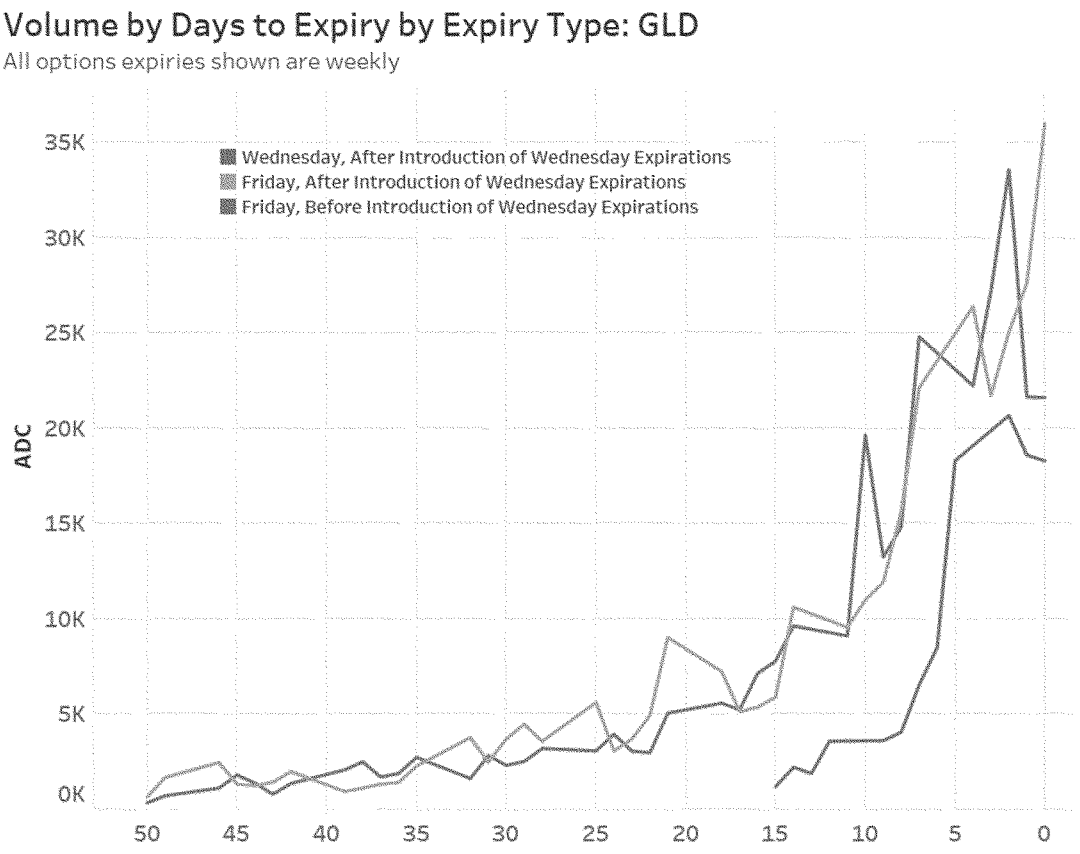
Volume by Days to Expiry by Expiry Type: GLD
All options expiries shown are weekly
Wednesday, After Introduction of Wednesday Expirations
Friday, After Introduction of Wednesday Expirations
Friday, Before Introduction of Wednesday Expirations
ADC
35K
30K
25K
20K
15K
10K
5K
0K
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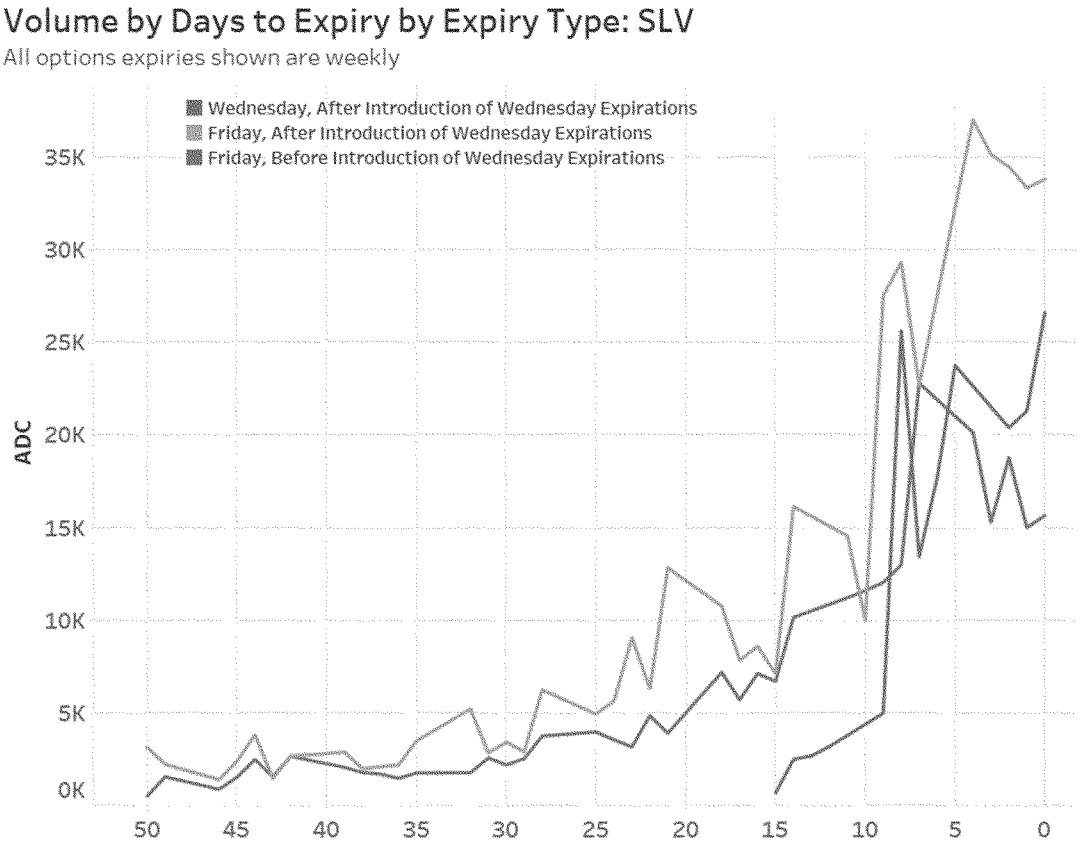
Volume by Days to Expiry by Expiry Type: SLV
All options expiries shown are weekly
Wednesday, After Introduction of Wednesday Expirations
Friday, After Introduction of Wednesday Expirations
Friday, Before Introduction of Wednesday Expirations
ADC
35K
30K
25K
20K
15K
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40
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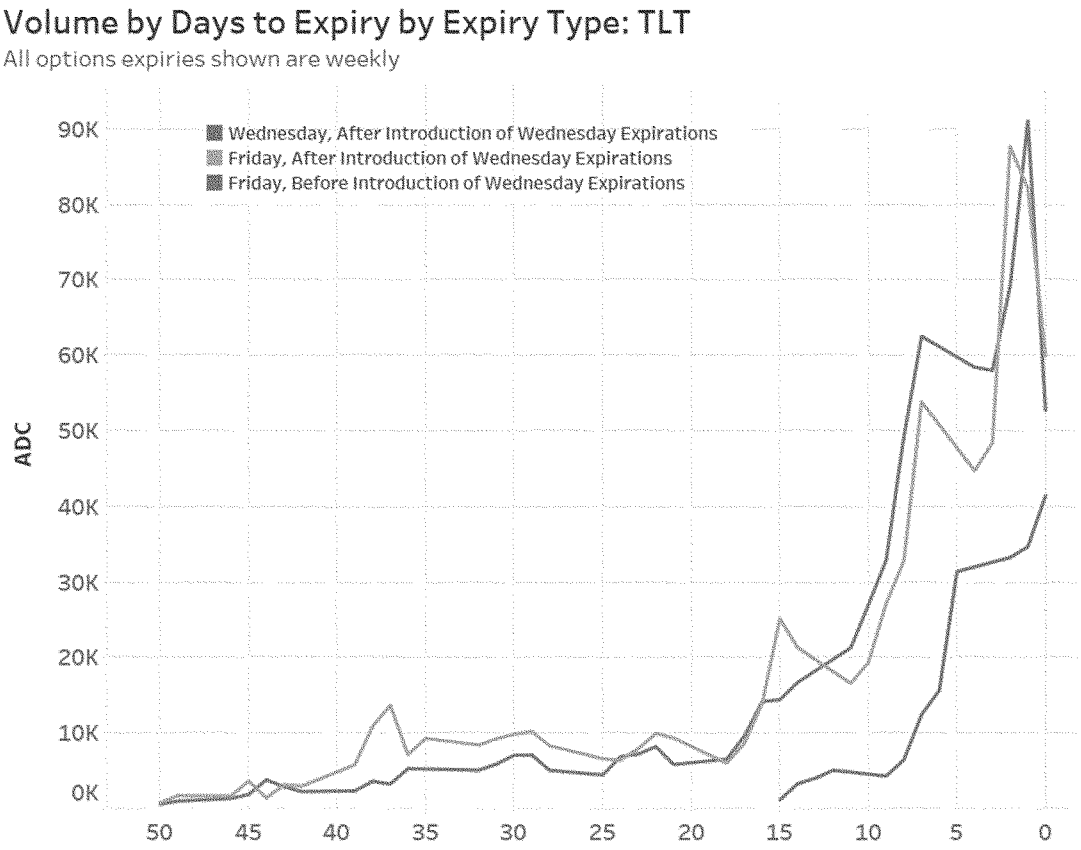
Volume by Days to Expiry by Expiry Type: TLT
All options expiries shown are weekly
Wednesday, After Introduction of Wednesday Expirations
Friday, After Introduction of Wednesday Expirations
Friday, Before Introduction of Wednesday Expirations
ADC
90K
80K
70K
60K
50K
40K
30K
20K
10K
0K
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15
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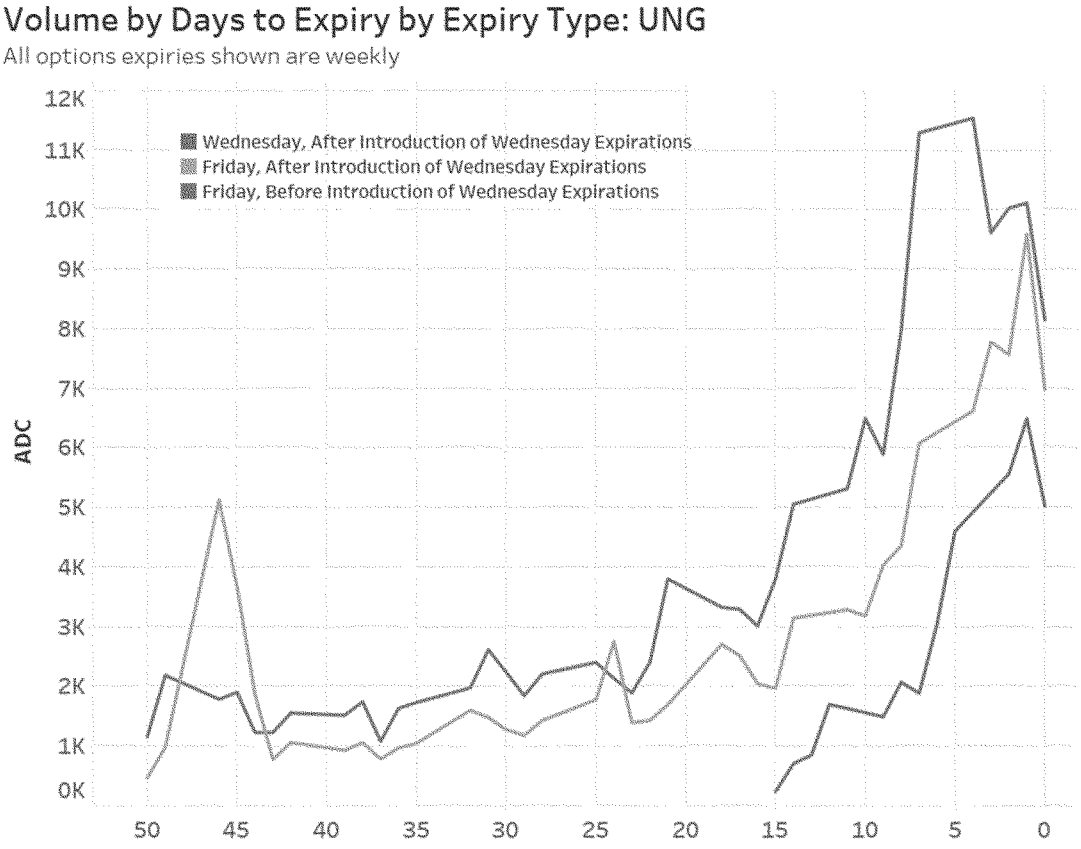
Volume by Days to Expiry by Expiry Type: UNG
All options expiries shown are weekly
Wednesday, After Introduction of Wednesday Expirations
Friday, After Introduction of Wednesday Expirations
Friday, Before Introduction of Wednesday Expirations
ADC
12K
11K
10K
9K
8K
7K
6K
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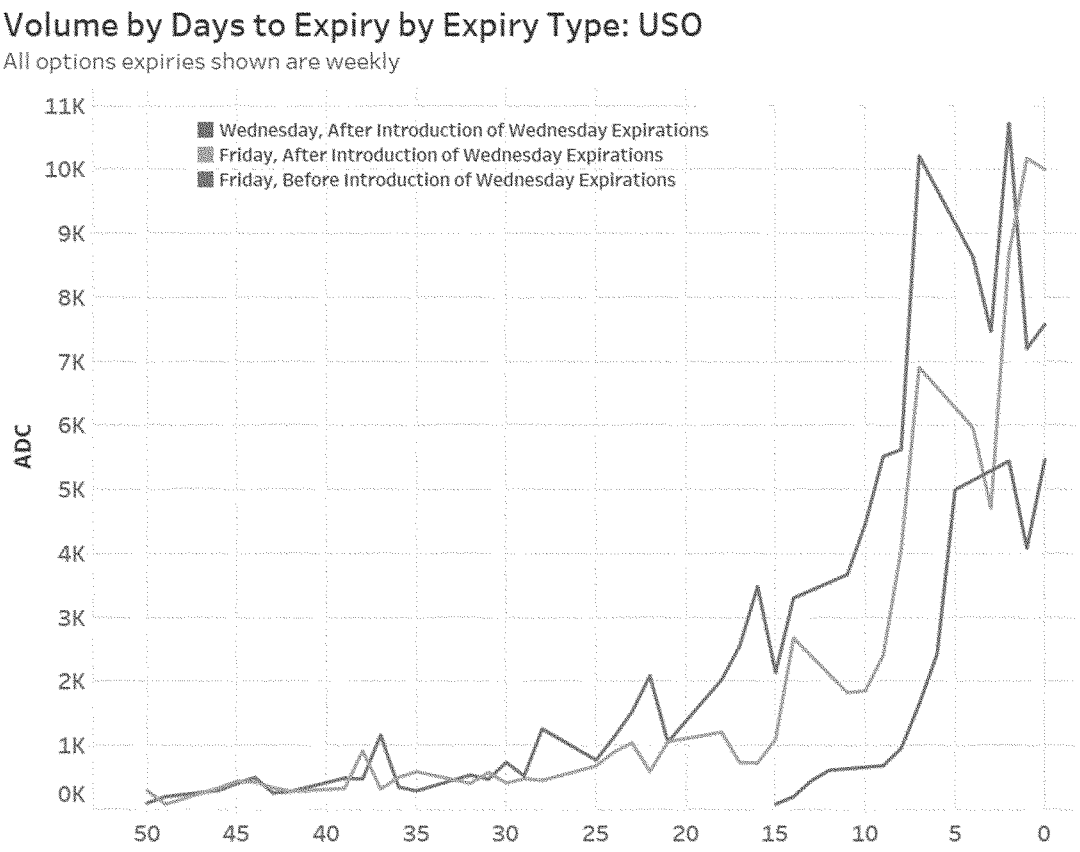

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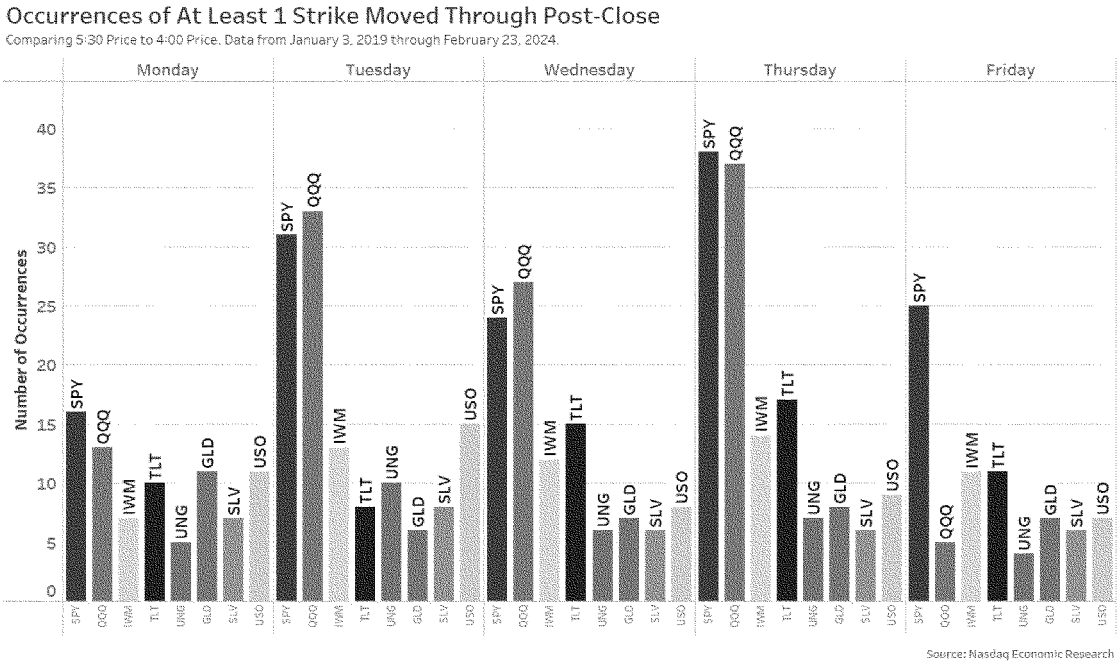
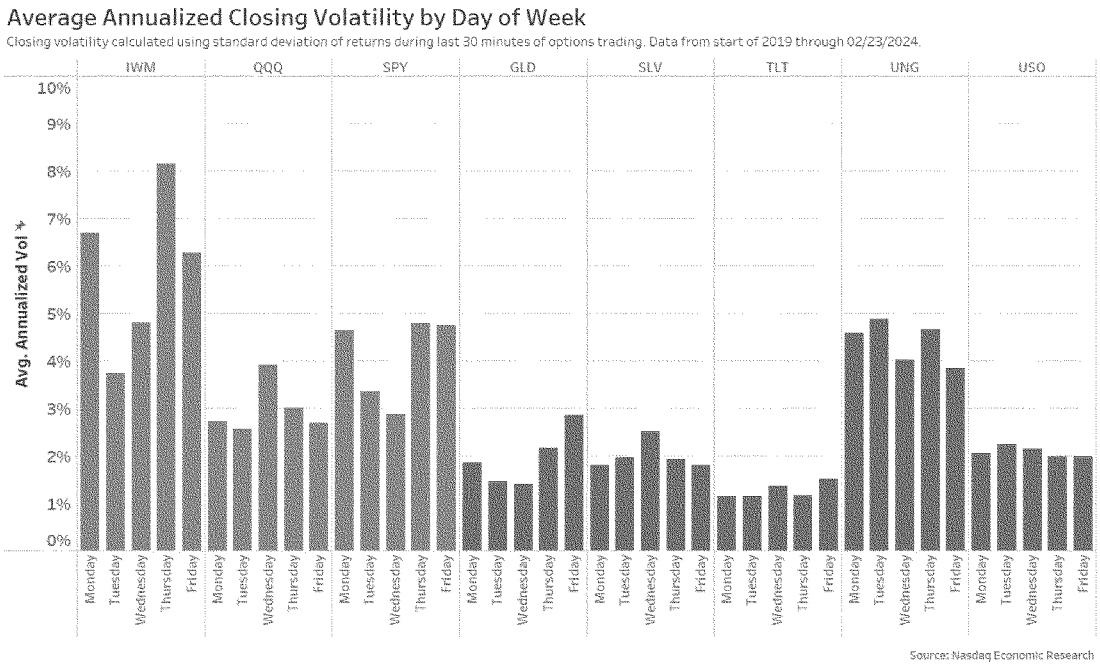
In addition, the below chart shows post-close movements between 4:00–5:30 p.m. Eastern Time, and indicates that GLD, SLV, TLT, UNG, and USO are generally less volatile (strike-wise) than SPY, QQQ, and IWM, where alternative expirations exist today.



Furthermore, the below chart shows that GLD, SLV, TLT, UNG, and USO are generally less volatile in the last 30 minutes of trading than SPY, QQQ, and IWM, which have alternative expirations today.



Because the Exchange proposes to limit the number of Monday Expirations for options on USO, UNG, GLD, SLV, and TLT to two expirations beyond the current week, the Exchange believes that the addition of these Monday ETP Expirations should encourage Market Makers to continue to deploy capital more efficiently and improve displayed market quality.[22]

Similar to SPY, QQQ and IWM Monday Expirations, the introduction of Monday ETP Expirations will, among other things, expand hedging tools available to market participants and allow for a reduced premium cost of buying portfolio protection. The Exchange believes that Monday ETP Expirations will allow market participants to hedge their portfolios with options on commodities (oil, natural gas, gold, and silver) as well as treasury securities, and tailor their investment and hedging needs more effectively.

Implementation

The Exchange proposes to implement this rule change within 30 days after Commission approval. The Exchange will issue an Options Trader Alert to notify Members of the implementation date.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[23] in general, and furthers the objectives of Section 6(b)(5) of the Act,[24] 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.

Similar to Monday expirations in SPY, QQQ, and IWM, the proposal to permit Monday ETP Expirations, subject to the proposed limitation of two expirations beyond the current week, would protect investors and the public interest by providing the investing public and other market participants more choice and flexibility to closely tailor their investment and hedging decisions in these options and allow for a reduced premium cost of buying portfolio protection, thus allowing them to better manage their risk exposure. The Exchange believes that there is general demand for alternative expirations based on the analysis discussed above, notably comparing the average daily contracts traded in options overlying SPY, QQQ, and the five ETPs five months before and after the introduction of alternative expirations on those symbols. As shown above, the Exchange saw a volume increase in SPY and QQQ in the five-month period following the introduction of Tuesday and Thursday expirations, which suggests there is indeed genuine new interest in these alternative expirations (as opposed to existing interest being cannibalized). The Exchange also saw a volume increase in the majority of the five ETPs in the five-month period following the introduction of Wednesday expirations, likewise indicating the existence of general demand for alternative expirations in these symbols.[25]

ISE represents that it has an adequate surveillance program in place to detect manipulative trading in the proposed option expirations, in the same way that it monitors trading in the current Short Term Option Series for Monday SPY, QQQ and IWM expirations. The Exchange also represents that it has the necessary system capacity to support the new expirations. Finally, the Exchange does not believe that any market disruptions will be encountered with the introduction of these option expirations. As discussed above, the Exchange believes that its proposal is a modest expansion of weekly expiration dates for GLD, SLV, USO, UNG, and TLT given that it will be limited to two Monday expirations beyond the current week. Furthermore, the above charts show less volatility in these five products (both in terms of post-close and during the last 30 minutes of trading) compared to SPY, QQQ, and IWM, which have alternative expirations (including Monday expirations) today.

The Exchange believes that the proposal is consistent with the Act as

[22] Market Makers include Primary Market Makers and Competitive Market Makers. *See* ISE Options 1, Section 1(a)(21). Today, Primary Market Makers and Competitive Market Makers are required to quote a specified time in their assigned options series. *See* ISE Options 2, Section 5.

[23] 15 U.S.C. 78f(b).

[24] 15 U.S.C. 78f(b)(5).

[25] *See supra* note 21.

the proposal would overall add a small number of Monday ETP Expirations by limiting the addition of two Monday expirations beyond the current week. The addition of Monday ETP Expirations would remove impediments to and perfect the mechanism of a free and open market by encouraging Market Makers to continue to deploy capital more efficiently and improve displayed market quality.[26] The Exchange believes that the proposal will allow Members to expand hedging tools and tailor their investment and hedging needs more effectively in USO, UNG, GLD, SLV, and TLT as these funds are most likely to be utilized by market participants to hedge the underlying asset classes. As stated in the Wednesday Approval Order, the ETPs currently trade within ''complexes'' where, in addition to the underlying security, there are multiple instruments available for hedging. Given the multi-asset class nature of these products and available hedges in highly-correlated instruments, the Exchange believes that its proposal to add Monday expirations on these products will provide market participants with additional useful hedging tools for the underlying asset classes.

Similar to Monday SPY, QQQ, and IWM expirations, the introduction of Monday ETP Expirations is consistent with the Act as it will, among other things, expand hedging tools available to market participants and allow for a reduced premium cost of buying portfolio protection. The Exchange believes that Monday ETP Expirations will allow market participants to purchase options on USO, UNG, GLD, SLV, and TLT based on their timing as needed and allow them to tailor their investment and hedging needs more effectively, thus allowing them to better manage their risk exposure. Today, ISE lists Monday SPY, QQQ, and IWM Expirations.[27]

In particular, the Exchange believes the Short Term Option Series Program has been successful to date and that Monday ETP 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.

There are no material differences in the treatment of Monday SPY, QQQ and IWM expirations compared to the proposed Monday ETP Expirations. Given the similarities between Monday SPY, QQQ and IWM expirations and the proposed Monday ETP Expirations, the Exchange believes that applying the provisions in Supplementary Material .03 to Options 4, Section 5 that currently apply to Monday SPY, QQQ and IWM expirations is justified. For example, the Exchange believes that allowing Monday ETP Expirations and monthly Exchange Traded Product expirations in the same week will benefit investors and minimize investor confusion by providing Monday ETP Expirations in a continuous and uniform manner.

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.

While the proposal will expand the Short Term Options Expirations to allow Monday ETP Expirations to be listed on ISE,[28] the Exchange believes that this limited expansion for Monday expirations for options on USO, UNG, GLD, SLV, and TLT will not impose an undue burden on competition; rather, it will meet customer demand. The Exchange believes that Members will continue to be able to expand hedging tools and tailor their investment and hedging needs more effectively in USO, UNG, GLD, SLV, and TLT.

Similar to Monday SPY, QQQ and IWM expirations, the introduction of Monday ETP 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 allow for a reduced premium cost of buying portfolio protection. The Exchange believes that Monday ETP Expirations will allow market participants to purchase options on USO, UNG, GLD, SLV, and TLT based on their timing as needed and allow them to tailor their investment and hedging needs more effectively.

The Exchange does not believe the proposal will impose any burden on inter-market competition, as nothing prevents the other options exchanges from proposing similar rules to list and trade Monday ETP Expirations.[29] Further, the Exchange does not believe the proposal will impose any burden on intra-market 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

No written comments were either solicited or received.

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 the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–ISE–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–ISE–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

[26] Today, Primary Market Makers and Market Makers are required to quote a specified time in their assigned options series. *See* ISE Options 2, Section 5.

[27] *See* ISE Supplementary Material .03 at Options 4, Section 5.

[28] As noted above, Nasdaq, Phlx, BX, GEMX and MRX incorporate ISE Options 4, Section 5 by reference, so the proposed changes herein will apply to those markets as well.

[29] *See supra* note 28.

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–ISE–2024–21 and should be submitted on or before June 20, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024–11801 Filed 5–29–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100224; File Nos. SR–NYSEARCA–2023–70; SR–NYSEARCA–2024–31; SR–NASDAQ–2023–045; SR–CboeBZX–2023–069; SR–CboeBZX–2023–070; SR–CboeBZX–2023–087; SR–CboeBZX–2023–095; SR–CboeBZX–2024–018]

Self-Regulatory Organizations; NYSE Arca, Inc.; The Nasdaq Stock Market LLC; Cboe BZX Exchange, Inc.; Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, To List and Trade Shares of Ether-Based Exchange-Traded Products

May 23, 2024.

I. Introduction

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder (''Rule 19b–4''),[2] each of NYSE Arca, Inc. (''NYSE Arca''), The Nasdaq Stock Market LLC (''Nasdaq''), and Cboe BZX Exchange, Inc. (''BZX'', and together with NYSE Arca and Nasdaq, the ''Exchanges'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') proposed rule changes to list and trade shares of the following. NYSE Arca proposes to list and trade shares of (1) the Grayscale Ethereum Trust[3] and (2) the Bitwise Ethereum ETF[4] under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares); Nasdaq proposes to list and trade shares of (3) the iShares Ethereum Trust[5] under Nasdaq Rule 5711(d) (Commodity-Based Trust Shares); and BZX proposes to list and trade shares of (4) the VanEck Ethereum Trust,[6] (5) the ARK 21Shares Ethereum ETF,[7] (6) the Invesco Galaxy Ethereum ETF,[8] (7) the Fidelity Ethereum Fund,[9] and (8) the Franklin Ethereum ETF[10] under BZX Rule 14.11(e)(4) (Commodity-Based Trust Shares). Each filing was subject to notice and comment.[11]

Each of the foregoing proposed rule changes, as modified by their respective amendments, is referred to herein as a ''Proposal'' and collectively as the ''Proposals.'' Each trust (or series of a trust) described in a Proposal is referred to herein as a ''Trust'' and collectively as the ''Trusts.'' As described in more detail in the Proposals' respective amended filings,[12] each Proposal seeks to list and trade shares of a Trust that would hold spot ether,[13] in whole or in part.[14] This order approves the Proposals on an accelerated basis.[15]

II. Discussion and Commission Findings

After careful review, the Commission finds that the Proposals are consistent with the Exchange Act and rules and regulations thereunder applicable to a national securities exchange.[16] In

[30] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Amendment No. 2 to Proposed Rule Change to List and Trade Shares of the Grayscale Ethereum Trust under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) (SR–NYSEARCA–2023–70), filed May 21, 2024, available at *https://www.sec.gov/comments/sr-nysearca-2023-70/srnysearca202370-475871-1363474.pdf* (''Grayscale Amendment'').

[4] *See* Amendment No. 1 to Proposed Rule Change to List and Trade Shares of the Bitwise Ethereum ETF under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) (SR–NYSEARCA–2024–31), filed May 21, 2024, available at *https://www.sec.gov/comments/sr-nysearca-2024-31/srnysearca202431-475891-1363514.pdf* (''Bitwise Amendment'').

[5] *See* Amendment No. 2 to Proposed Rule Change to List and Trade Shares of the iShares Ethereum Trust under Nasdaq Rule 5711(d) (Commodity-Based Trust Shares) (SR–NASDAQ–2023–045), filed May 22, 2024, available at *https://www.sec.gov/comments/sr-nasdaq-2023-045/srnasdaq2023045-475851-1363454.pdf* (''iShares Amendment'').

[6] *See* Amendment No. 2 to Proposed Rule Change to List and Trade Shares of the VanEck Ethereum Trust under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares (SR–CboeBZX–2023–069), filed May 21, 2024, available at *https://www.sec.gov/comments/sr-cboebzx-2023-069/srcboebzx2023069-475811-1363394.pdf* (''VanEck Amendment'').

[7] *See* Amendment No. 2 to Proposed Rule Change to List and Trade Shares of the ARK 21Shares Ethereum ETF under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares (SR–CboeBZX–2023–070), filed May 21, 2024, available at *https://www.sec.gov/comments/sr-cboebzx-2023-070/srcboebzx2023070-475812-1363414.pdf* (''ARK Amendment'').

[8] *See* Amendment No. 1 to Proposed Rule Change to List and Trade Shares of the Invesco Galaxy Ethereum ETF under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares (SR–CboeBZX–2023–087), filed May 21, 2024, available at *https://www.sec.gov/comments/sr-cboebzx-2023-087/srcboebzx2023087-475831-1363395.pdf* (''Invesco Amendment'').

[9] *See* Amendment No. 2 to Proposed Rule Change to List and Trade Shares of the Fidelity Ethereum Fund under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares (SR–CboeBZX–2023–095), filed May 21, 2024, available at *https://www.sec.gov/comments/sr-cboebzx-2023-095/srcboebzx2023095-475791-1363374.pdf* (''Fidelity Amendment'').

[10] *See* Amendment No. 1 to Proposed Rule Change to List and Trade Shares of the Franklin Ethereum ETF, a Series of the Franklin Ethereum Trust, under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares (SR–CboeBZX–2024–018), filed May 21, 2024, available at *https://www.sec.gov/comments/sr-cboebzx-2024-018/srcboebzx2024018-475813-1363434.pdf* (''Franklin Amendment'').

[11] Comments received on SR–NYSEARCA–2023–70 are available at *https://www.sec.gov/comments/sr-nysearca-2023-70/srnysearca202370.htm.* Comments received on SR–NYSEARCA–2024–31 are available at *https://www.sec.gov/comments/sr-nysearca-2024-31/srnysearca202431.htm.* Comments received on SR–NASDAQ–2023–045 are available at *https://www.sec.gov/comments/sr-nasdaq-2023-045/srnasdaq2023045.htm.* Comments received on SR–CboeBZX–2023–069 are available at *https://www.sec.gov/comments/sr-cboebzx-2023-069/srcboebzx2023069.htm.* Comments received on SR–CboeBZX–2023–070 are available at *https://www.sec.gov/comments/sr-cboebzx-2023-070/srcboebzx2023070.htm.* Comments received on SR–CboeBZX–2023–087 are available at *https://www.sec.gov/comments/sr-cboebzx-2023-087/srcboebzx2023087.htm.* Comments received on SR–CboeBZX–2023–095 are available at *https://www.sec.gov/comments/sr-cboebzx-2023-095/srcboebzx2023095.htm.* Comments received on SR–CboeBZX–2024–018 are available at *https://www.sec.gov/comments/sr-cboebzx-2024-018/srcboebzx2024018.htm.*

[12] *See supra* notes 3–10.

[13] Ether is a digital asset that is native to, and minted and transferred via, a distributed, open-source protocol used by a peer-to-peer computer network through which transactions are recorded on a public transaction ledger known as ''Ethereum.'' The Ethereum protocol governs the creation of new ether and the cryptographic system that secures and verifies transactions on Ethereum.

[14] All of the Trusts propose to hold spot ether. Additionally, all of the Trusts, except the Grayscale Ethereum Trust, propose to hold cash, and some Trusts also propose to hold cash equivalents, as described in their respective amended filings. *See* Bitwise Amendment at 5; iShares Amendment at 4; VanEck Amendment at 21; ARK Amendment at 20; Invesco Amendment at 22; Fidelity Amendment at 22; Franklin Amendment at 21.

[15] *See infra* Section III.

[16] In approving the Proposals, the Commission has considered the Proposals' impacts on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f). *See also infra* note 61 and accompanying text, discussing comments received regarding the efficiency of spot ether exchange-traded products (''ETPs''). *See also* Letter from Ryan Posey, dated Mar. 20, 2024, regarding SR–CboeBZX–2023–095 (''Posey Letter'') (stating that ''[t]he history of [exchange-traded funds] in other asset classes demonstrates how competition drives fees down''). Additionally, a commenter states that the Commission should approve spot ether ETPs, but not all at once, so as not to ''delay the innovators

Continued

particular, the Commission finds that the Proposals are consistent with Section 6(b)(5) of the Exchange Act,[17] which requires, among other things, that the Exchanges' rules be designed to ''prevent fraudulent and manipulative acts and practices'' and, ''in general, to protect investors and the public interest;'' and with Section 11A(a)(1)(C)(iii) of the Exchange Act,[18] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities.

A. Exchange Act Section 6(b)(5)

When considering proposals to list bitcoin-based commodity trusts and bitcoin-based trust issued receipts, the Commission has explained that one way an exchange that lists bitcoin-based ETPs can meet the obligation under Exchange Act Section 6(b)(5) that its rules be designed to prevent fraudulent and manipulative acts and practices is by demonstrating that the exchange has a comprehensive surveillance-sharing agreement with a regulated market of significant size related to the underlying or reference assets.[19] Such an agreement would assist in detecting and deterring fraud and manipulation related to that underlying asset.

The Commission has also consistently recognized, however, that this is not the *exclusive* means by which an ETP listing exchange can meet this statutory obligation.[20] A listing exchange could, alternatively, demonstrate that ''other means to prevent fraudulent and manipulative acts and practices will be sufficient'' to justify dispensing with a surveillance-sharing agreement with a regulated market of significant size.[21] Applying this same analytical framework to the spot ether to be held by the Trusts, the Commission finds that sufficient ''other means'' of preventing fraud and manipulation in this context have been demonstrated.

Each Exchange has a comprehensive surveillance-sharing agreement with the Chicago Mercantile Exchange (''CME'') via their common membership in the Intermarket Surveillance Group.[22] This facilitates the sharing of information that is available to the CME through its surveillance of its markets, including its surveillance of the CME ether futures market. Spot ether, however, does not trade on the CME and the CME does not engage in surveillance of spot ether markets. As with the proposals approved in the Spot Bitcoin ETP Approval Order, this raises questions regarding the sufficiency of a surveillance-sharing agreement with the CME in preventing fraud and manipulation when the proposed ETPs hold spot ether.[23] If a would-be manipulator of a spot ether ETP engages in misconduct (such as fraud, manipulation, or other trading abuses) on the CME itself, the CME's surveillance can be reasonably expected to detect such misconduct. But if the would-be manipulator is not transacting on the CME itself, the impacts of its misconduct would not necessarily be surveilled by the CME unless the misconduct also impacts the CME ether futures market. Thus, when assessing the sufficiency of a surveillance-sharing agreement with the CME, it is critical to establish whether, and to what extent, fraud or manipulation that impacts the spot ether market also impacts the CME ether futures market.[24]

In the Spot Bitcoin ETP Approval Order, the Commission concluded that having a comprehensive surveillance-sharing agreement with a U.S.-regulated market that, based on evidence from robust correlation analysis, is consistently highly correlated with the ETPs' underlying assets (spot bitcoin) constituted ''other means'' sufficient to satisfy the Exchange Act Section 6(b)(5) standard.[25] Specifically, given the consistently high correlation between the CME bitcoin futures market and a sample of spot bitcoin markets—confirmed through robust correlation analysis using data at hourly, five-minute, and one-minute intervals—the Commission was able to conclude that fraud or manipulation that impacts prices in spot bitcoin markets would likely similarly impact CME bitcoin futures prices. And because the CME's surveillance can assist in detecting those impacts on CME bitcoin futures prices, the Exchanges' comprehensive surveillance-sharing agreement with the CME can be reasonably expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of those proposals. The Commission indicated that the ''robustness'' of its correlation analysis rested on the pre-requisites of (1) the correlations being calculated with respect to bitcoin futures that trade on the CME, a U.S. market regulated by the Commodity Futures Trading Commission (''CFTC''), (2) the lengthy sample period of price returns for both the CME bitcoin futures market and the spot bitcoin market, (3) the frequent intra-day trading data in both the CME bitcoin futures market and the spot bitcoin market over that lengthy sample period, and (4) the consistency of the correlation results throughout the lengthy sample period.[26]

in order to allow free-riding copycats a free hand.'' *See* Letter from James J. Angel, Georgetown University, dated Apr. 5, 2024, regarding SR–NYSEARCA–2023–70 (''Angel Letter''), at 3–4. The Commission believes that it is appropriate to approve all of the Proposals at the same time in order to foster competition by potentially providing investors with several spot ether-based ETPs from which to choose. The shares of any Trust, however, may not begin trading on its applicable Exchange unless and until its corresponding registration statement becomes effective.

[17] 15 U.S.C. 78f(b)(5).

[18] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[19] *See, e.g.,* Order Granting Accelerated Approval of Proposed Rule Changes, as Modified by Amendments Thereto, to List and Trade Bitcoin-Based Commodity-Based Trust Shares and Trust Units, Securities Exchange Act Release No. 99306 (Jan. 10, 2024), 89 FR 3008 (Jan. 17, 2024) (SR–NYSEARCA–2021–90; SR–NYSEARCA–2023–44; SR–NYSEARCA–2023–58; SR–NASDAQ–2023–016; SR–NASDAQ–2023–019; SR–CboeBZX–2023–028; SR–CboeBZX–2023–038; SR–CboeBZX–2023–040; SR–CboeBZX–2023–042; SR–CboeBZX–2023–044; SR–CboeBZX–2023–072) (''Spot Bitcoin ETP Approval Order''); Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 2, To List and Trade Shares of the Teucrium Bitcoin Futures Fund Under NYSE Arca Rule 8.200–E, Commentary .02 (Trust Issued Receipts), Securities Exchange Act Release No. 94620 (Apr. 6, 2022), 87 FR 21676 (Apr. 12, 2022) (SR–NYSEARCA–2021–53). The Commission has provided an illustrative definition for ''market of significant size'' to include a market (or group of markets) as to which (a) there is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to successfully manipulate the ETP, so that a surveillance-sharing agreement would assist in detecting and deterring misconduct, and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market. *See* Order Setting Aside Action by Delegated Authority and Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, To List and Trade Shares of the Winklevoss Bitcoin Trust, Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579, 37594 (Aug. 1, 2018) (SR–BatsBZX–2016–30) (''Winklevoss Order'').

[20] *See* Winklevoss Order, 83 FR at 37580; Spot Bitcoin ETP Approval Order, 89 FR at 3009.

[21] *See* Spot Bitcoin ETP Approval Order, 89 FR at 3009 (quoting Winklevoss Order, 83 FR at 37580).

[22] *See id.* at 3009.

[23] *See id.*

[24] *See id.*

[25] *See id.* at 3009–11. To be clear, this does *not* mean that such U.S.-regulated market is of ''significant size'' related to the ETP's underlying or reference asset. In particular, the Commission did *not* conclude in the Spot Bitcoin ETP Approval Order that the CME bitcoin futures market is of ''significant size'' related to spot bitcoin. *See id.* at 3010–11 (''[B]ecause the CME's surveillance can assist in detecting those impacts on CME bitcoin futures prices, the Exchanges' comprehensive surveillance-sharing agreement with the CME—a U.S.-regulated market whose bitcoin futures market is consistently highly correlated to spot bitcoin, *albeit not of 'significant size' related to spot bitcoin*—can be reasonably expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the Proposals.'') (emphasis added).

[26] *See id.* at 3010 n.38.

Several of the Proposals and some commenters offered correlation analyses in the ether context. Some Proposals provided correlation results that used data at a daily frequency. For example, the ARK Amendment finds a correlation between the daily returns of CME ether futures and daily returns on certain spot ether trading platforms of more than 99.89%; [27] the VanEck Amendment, Invesco Amendment, and Franklin Amendment find daily correlation of 99.8%; [28] and the iShares Amendment finds a daily correlation of 99.93%.[29] However, as explained in the Spot Bitcoin ETP Approval Order, calculating correlation using only *daily* price observations provides no information on how prices in the two markets are associated—if at all—*throughout* the trading day; and calculating correlation for only the full sample period does not provide evidence of a *consistently* high correlation over time.[30]

The Fidelity Amendment performed rolling 90-day correlations between daily returns of CME ether futures and six spot ether trading platforms and found correlations ranged between 94% and 99.8%.[31] As indicated above, however, calculating correlations using only daily price observations—even on a rolling basis—provides no information on how prices are associated—if at all—*throughout* the trading day. The Fidelity Amendment also examined correlation using hourly returns data, and found such correlations for the full sample period to be above 98%.[32] While the filing does not provide rolling correlations using the hourly data, the filing examined the ''distribution of hourly returns'' and finds that at least 97.9% of the hourly returns of the spot ether platforms and the CME ether futures market are within 50 basis points. The filing stated that ''[t]his suggests a high degree of similarity in price movements between the regulated exchange and the spot platforms for most hours.'' [33]

The use of hourly data, however, provides no indication of how prices move at finer increments. For example, the results provide no indication of whether price movements—including price manipulations—in ether spot markets that persist for only a few minutes or less are likely to be reflected in CME ether futures prices. While the Fidelity Amendment's results may suggest a high degree of similarity in price movements between the CME ether futures market and the spot ether platforms ''*for most hours,*'' the results suggest nothing about the degree of similarity in price movements *for most minutes* within the hours.

Two commenters and one Proposal examined correlation between the CME ether futures market and spot ether trading platforms at hourly, five-minute, and one-minute intervals. The Coinbase Letter used price returns data from March 1, 2021, through January 31, 2024, for the CME ether futures market and the Coinbase platform.[34] This commenter calculated Pearson correlation statistics [35] for the full sample period as well as for rolling three-month segments within the sample period. The commenter's correlation results for the full sample period are 99.3% using data at an hourly interval, 96.2% using data at a five-minute interval, and 84.7% using data at a one-minute interval.[36] The commenter states that these results ''show an even greater correlation than what was reported by the Commission'' in the Spot Bitcoin ETP Approval Order with respect to the CME bitcoin futures market and spot bitcoin trading platforms.[37] The commenter also sought to replicate the same correlation analysis of the bitcoin market that the Commission performed for the Spot Bitcoin ETP Approval Order. The commenter's replication results also found greater correlation than what was reported in the Spot Bitcoin ETP Approval Order.[38]

The CF Benchmarks Letters used price returns data from February 2, 2022, through February 2, 2024, for the CME ether futures market and the Coinbase, Kraken, and LMAX Digital platforms.[39] This commenter also calculated Pearson correlation statistics for its full sample period as well as for rolling three-month segments within that sample period. This commenter's correlation results for the full sample period are no less than 98.0% using data at an hourly interval, 91.5% using data at a five-minute interval, and 84.9% using data at a one-minute interval.[40] The commenter states that these results are ''on the whole stronger'' than those that the Commission reported for the bitcoin market in the Spot Bitcoin ETP Approval Order.[41]

The Bitwise Amendment used price returns data from August 1, 2021, through March 20, 2024, for the CME ether futures market and the Coinbase and Kraken platforms.[42] This filing also calculated Pearson correlation statistics for its full sample period as well as for rolling three-month segments within that sample period. This filing's correlation results for the full sample period are no less than 98.6% using data at an hourly interval, 90.0% using data at a five-minute interval, and 70.9% using data at a one-minute interval.[43]

The Commission undertook to verify the Bitwise Amendment's and these two commenters' correlation results for certain spot ether markets. For robust [44] results, the Commission used stationary time series of price returns data at hourly, five-minute, and one-minute intervals for the spot ETH/USD trading pair on Coinbase and Kraken, as well as for the closest-to-maturity CME ether futures contract, over a similarly lengthy sample period (October 1, 2021, through March 29, 2024).[45] Pearson correlation

[27] *See* ARK Amendment at 14 (using data from Jan. 1, 2022, through Feb. 1, 2024).

[28] *See* VanEck Amendment at 13; Invesco Amendment at 14; Franklin Amendment at 13 (using data from Sept. 1, 2022, through Sept. 1, 2023).

[29] *See* iShares Amendment at 26 (using data from Oct. 13, 2022, through Oct. 13, 2023). Some commenters also assert that ether markets are highly correlated, but the commenters provide no evidence for this assertion. *See* Letter from Parker Jamieson, dated Mar. 12, 2024, regarding SR–CboeBZX–2023–095 (''Jamieson Letter''); Posey Letter.

[30] *See* Spot Bitcoin ETP Approval Order, 89 FR at 3009 n.30.

[31] *See* Fidelity Amendment at 16 (the filing does not provide the exact range for its data sample, but based on the chart at 16, the range appears to be approximately July 2021 through Jan. 2024).

[32] *See id.* at 17–18.

[33] *See id.* at 18.

[34] *See* Letter from Paul Grewal, Chief Legal Officer, Coinbase Global, Inc., dated Feb. 21, 2024, regarding SR–NYSEARCA–2023–70 (''Coinbase Letter''), at 20–22.

[35] Pearson correlation is a measure of linear association between two variables and indicates the magnitude as well as direction of this relationship. The value can range between −1 (suggesting a strong negative association) and 1 (suggesting a strong positive association). Correlation should not be interpreted as an indication of a causal relationship or whether one variable leads or lags the other.

[36] *See* Coinbase Letter at 21. The Coinbase Letter's rolling correlation results ranged between 98.1% and 99.7% using data at an hourly interval, 93.8% and 97.1% using data at a five-minute interval, and 80.4% and 88% using data at a one-minute interval.

[37] *See id.*

[38] *See id.*

[39] *See* Letters from CF Benchmarks, dated Mar. 22, 2024, regarding SR-CboeBZX–2024–018, and dated Apr. 11, 2024, regarding SR–NASDAQ–2023–045 (''CF Benchmarks Letters''), at 5–6.

[40] *See id.* at 6. The CF Benchmarks Letters' rolling correlation results ranged between 96.1% and 99.4% using data at an hourly interval, 81.3% and 94.7% using data at a five-minute interval, and 81.0% and 88.1% using data at a one-minute interval.

[41] *See id.* at 6.

[42] *See* Bitwise Amendment at 18–19.

[43] *See id.* The Bitwise Amendment's rolling correlation results ranged between 95.7% and 99.3% using data at an hourly interval, 86.8% and 92.9% using data at a five-minute interval, and 65.0% and 79.5% using data at a one-minute interval.

[44] *See also infra* note 49.

[45] Data were sourced from the CME via the SEC's Market Information Data Analytics System

Continued

statistics were calculated for the full sample period as well as for rolling three-month segments within the sample period. The Commission's correlation analysis utilized frequent intra-day trading data over the lengthy sample period on this subset of spot ether platforms [46] and—crucially—on the CME ether futures market as well.[47]

The results of the Commission's analysis confirm that the CME ether futures market has been consistently highly correlated with this subset of the spot ether market throughout the past 2.5 years. The correlation between the CME ether futures market and this subset of spot ether platforms for the full sample period is no less than 96.2 percent using data at an hourly interval, 85.7 percent using data at a five-minute interval, and 67.1 percent using data at a one-minute interval. The rolling three-month correlation results range between 86.4 and 98.4 percent using data at an hourly interval, 75.8 and 90.2 percent using data at a five-minute interval, and 58.6 and 75.9 percent using data at a one-minute interval.

FULL-SAMPLE AND POST-MERGE CORRELATIONS BETWEEN CERTAIN SPOT ETHER MARKETS AND THE CME ETHER FUTURES MARKET

[MIDAS and Kaiko Data]

	Coinbase			Kraken		
	Hourly	5 Minutes	1 Minute	Hourly	5 Minutes	1 Minute
Full Sample: October 1, 2021, through March 29, 2024	96.2	85.7	67.1	96.3	86.5	69.0
Rolling Three-Month Correlations Over the Full Sample Period:						
Maximum	98.4	90.1	74.5	98.4	90.2	75.9
Minimum	86.4	75.8	58.6	86.6	77.1	61.6
The Commission also examined correlation between the CME ether futures market and the Coinbase and Kraken spot ether trading platforms at hourly, five-minute, and one-minute intervals, using the same data sources and methodology (see note 45), for the period after the Ethereum Network changed from a Proof-of-Work to a Proof-of-Stake consensus mechanism in September 2022 (''post-Merge''). The results indicate that correlation has been similarly high and consistent during just the post-Merge period.						
Post-Merge Sample: September 16, 2022, through March 29, 2024	94.1	84.1	68.0	94.1	85.0	69.9
Rolling Three-Month Correlations Over the Post-Merge Sample:						
Maximum	98.4	88.3	73.1	98.4	89.3	75.9
Minimum	86.4	75.8	61.0	86.6	77.1	62.8

The Commission further examined correlation between the CME ether futures market and the Coinbase and Kraken spot ether trading platforms at hourly, five-minute, and one-minute intervals in a recent month, March 2024, sourcing CME ether futures market data from Refinitiv.[48] The results indicate similar correlation: no less than 97.6 percent using data at an hourly interval, 86.0 percent using data at a five-minute interval, and 62.5 percent using data at a one-minute interval.

CORRELATIONS BETWEEN CERTAIN SPOT ETHER MARKETS AND THE CME ETHER FUTURES MARKET

[Refinitiv and Kaiko Data]

	Coinbase			Kraken		
	Hourly	5 Minutes	1 Minute	Hourly	5 Minutes	1 Minute
March 2024	97.6	86.0	62.5	97.7	87.5	67.0

(''MIDAS'') for the closest-to-maturity CME ether futures contract price and from Kaiko for the ETH/USD prices on Coinbase and Kraken. The MIDAS CME ether futures data are limited to the 3:00 a.m.–5:00 p.m. ET, Monday through Friday, trading hours. All data sets used in the Commission's analysis are publicly available (although some require subscriptions). One-minute, five-minute, and hourly price *level* time series were created using the last trade price over the given interval for the spot ETH/USD pairs and the closest-to-maturity CME ether futures contract. For those time intervals during which there were no trades in the closest-to-maturity CME ether futures contracts or spot ether, the last trade price for the closest-to-maturity CME ether futures contract (or last trade price for spot ether, as applicable) was used as the price for such time interval. Each price *level* time series was then log differenced to create price *returns* time series. The stationarity of each price *returns* time series was confirmed through Augmented Dickey-Fuller tests.

[46] The spot ether market is a 24-hour, global marketplace. However, due to the unregulated and fragmented nature of the spot ether market, there are no authoritative published figures for spot ether trading. Nonetheless, multiple sources of pricing information for the spot ether market are available 24 hours per day on public websites and through subscription services. *See, e.g.,* Grayscale Amendment at 46 (stating that real-time price and volume data for ether is available by subscription from Reuters and Bloomberg).

[47] The CME ether futures market, which is regulated by the CFTC, has developed since its inception in February 2021 into an active market, growing from $64.3 million in average monthly open interest in February 2021 to $965.6 million in average monthly open interest in April 2024 (source: Refinitiv). Real-time trade information, including prices, for the CME ether futures market is made available through CME at: *https://www.cmegroup.com/markets/cryptocurrencies/ether/ether.quotes.html#venue=globex* and *https://www.cmegroup.com/markets/cryptocurrencies/ether/micro-ether.quotes.html#venue=globex. But see infra* note 49.

[48] Data were sourced from Refinitiv for the closest-to-maturity CME ether futures contract price and from Kaiko for the ETH/USD prices on Coinbase and Kraken. The Refinitiv CME ether futures data cover the CME's full 23 trading hours. All data sets used in the Commission's analysis are publicly available (although some require subscriptions). The Commission used the same methodology as summarized in note 45 above.

The results of the Commission's robust correlation analysis [49] provide empirical evidence that prices generally move in close (although not perfect) alignment between the spot ether market and the CME ether futures market.[50] As such, based on the record before the Commission and the correlation analyses in the record, including the Commission's own analysis, the Commission is able to conclude that fraud or manipulation that impacts prices in spot ether markets would likely similarly impact CME ether futures prices. And because the CME's surveillance can assist in detecting those impacts on CME ether futures prices, the Exchanges' comprehensive surveillance-sharing agreement with the CME—a U.S.-regulated market whose ether futures market is consistently highly correlated to spot ether, albeit *not* of ''significant size'' related to spot ether—can be reasonably expected to assist in surveilling for fraudulent and manipulative acts and practices in the specific context of the Proposals.[51]

B. Exchange Act Section 11A(a)(1)(C)(iii)

Each Proposal sets forth aspects of its proposed ETP, including the availability of pricing information, transparency of portfolio holdings, and types of surveillance procedures, that are consistent with other ETPs that the Commission has approved.[52] This includes commitments regarding: the availability via the relevant securities information processor of quotation and last-sale information for the shares of each Trust; the availability on the websites of each Trust of certain information related to the Trusts' intra-day indicative values (''IIV'') and net asset values; the dissemination of IIV by one or more major market data vendors, updated every 15 seconds throughout the Exchanges' regular trading hours; the Exchanges' surveillance procedures and ability to obtain information regarding trading in the shares of the Trusts; the conditions under which the Exchanges would implement trading halts and suspensions; and the requirements of registered market makers in the shares of each Trust.[53] In addition, in each Proposal, the applicable Exchange deems the shares of the applicable Trust to be equity securities, thus rendering trading in such shares subject to that Exchange's existing rules governing the trading of equity securities.[54] Further, the applicable listing rules of each Exchange require that all statements and representations made in its filing regarding, among others, the description of the applicable Trust's holdings, limitations on such holdings, and the applicability of that Exchange's listing rules specified in the filing, will constitute continued listing requirements.[55] Moreover, each Proposal states that: its issuer has represented to the applicable Exchange that it will advise that Exchange of any failure to comply with the applicable continued listing requirements; pursuant to obligations under Section 19(g)(1) of the Exchange Act, that Exchange will monitor for compliance with the continued listing requirements; and if the applicable Trust is not in compliance with the applicable listing requirements, that Exchange will commence delisting procedures.[56]

[49] The robustness of the Commission's correlation analysis rests on the pre-requisites of (1) the correlations being calculated with respect to ether futures that trade on *the CME,* a U.S. market regulated by the CFTC, (2) the lengthy sample period of price returns for both the CME ether futures market and the spot ether market, (3) the frequent intra-day trading data in both the CME ether futures market and the spot ether market over that lengthy sample period, and (4) the consistency of the correlation results throughout the lengthy sample period. The relatively low frequency of trading in CME ether futures, however, makes condition (3) particularly difficult to assess. Over the Commission's full sample period from October 1, 2021, through March 29, 2024, using MIDAS data (*see* note 45 above), front-month CME ether futures traded on average only 3.05 times per minute, and did not trade during 47% of the one-minute intervals. For comparison, over this same sample, front-month CME bitcoin futures traded on average 5.11 times per minute, and did not trade during 37% of the one-minute intervals. As explained in note 45 above, the Commission (1) used prior prices for the 47% of minutes during which front-month CME ether futures did not trade, which likely affected the correlation results. Alternatively, the Commission could have (2) dropped this 47% of minutes from the sample, but this also likely would have affected the correlation results. As the portion of no-trade minutes increases, the correlation results from both methodologies (1) and (2) become increasingly unreliable, because a larger and larger percentage of data is either dropped altogether (methodology (2)) or estimated with prior prices, potentially from distant past time intervals (methodology (1)). Consequently, with respect to future proposed spot ETPs, if trading on the regulated market is even less frequent, it may be more difficult to use correlation analysis to establish the sufficiency of a surveillance-sharing agreement with the regulated market.

[50] Correlation should not be interpreted as an indicator of a causal relationship or whether one variable leads or lags the other.

[51] One commenter argues that the Commission's use of correlation as a basis for approval is ''problematic'' because (1) it relies on a subset of spot markets which may not be representative of the entirety of the spot markets worldwide; (2) the fact that prices between the spot market and the CME futures market ''generally move in close alignment does not account for the times when the prices are not aligned,'' and thus ''the entire premise that price correlation leads to reliable detection of manipulation is fatally flawed;'' and (3) ''the fact that two variables are correlated in the past does not mean they will continue to be correlated in the future.'' *See* Letter from Dennis M. Kelleher, Co-Founder, President, and CEO, and Stephen W. Hall, Legal Director and Securities Specialist, Better Markets, Inc., dated Jan. 12, 2024, regarding SR–CboeBZX–2023–070 and SR–CboeBZX–2023–069 (''Better Markets Letter 1''), at 6–7. Regarding (1), the Commission selected the spot ether trading platforms of Coinbase and Kraken because these platforms have the largest volume of ETH/USD spot trading; whereas on other platforms, ETH trading typically occurs through so-called ''stablecoins'' and thus has prices that may be affected by USD/stablecoin rate fluctuations. Regarding (3), the Commission assessed the consistency of correlation over the full sample period through rolling 90-day correlations. The Commission does not detect any trends in the rolling correlations that would lead it to expect that the correlation would not be similarly high in the future. Both the post-Merge correlations and the March 2024 correlations using Refinitiv data indicate that correlations have recently been similar to the full sample period. Regarding (2), the Commission does not consider the use of correlation analysis in the context of the Proposals to be ''fatally flawed.'' However, the Commission agrees that the *lower* the frequency of trading in the CME futures market, the *greater* the risk that a price movement in spot markets would not be similarly reflected in a price movement in the CME futures market, notwithstanding seemingly high correlation results. For this reason, the Commission has explained that *robust* correlation analysis requires, among others, that there be *frequent* intra-day trading data in the CME futures market (*see* Spot Bitcoin ETP Approval Order, 89 FR at 3010 n.38).

[52] *See, e.g.,* Spot Bitcoin ETP Approval Order, 89 FR at 3011; Securities Exchange Act Release No. 61220 (Dec. 22, 2009), 74 FR 68895 (Dec. 29, 2009) (SR–NYSEARCA–2009–94) (Order Granting Approval of Proposed Rule Change Relating To Listing and Trading Shares of the ETFS Palladium Trust); Securities Exchange Act Release No. 94518 (Mar. 25, 2022), 87 FR 18837 (Mar. 31, 2022) (SR–NYSEARCA–2021–65) (Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of the Sprott ESG Gold ETF Under NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares)).

[53] *See* ARK Amendment at 28–30, 33–39; Bitwise Amendment at 19–23; Fidelity Amendment at 25–28, 31–37; Franklin Amendment at 25–28, 30–36; Grayscale Amendment at 45–49; Invesco Amendment at 25–27, 30–36; iShares Amendment at 12–16, 34–41; VanEck Amendment at 25–28, 30–36.

[54] *See* ARK Amendment at 36; Bitwise Amendment at 21; Fidelity Amendment at 34; Franklin Amendment at 34; Grayscale Amendment at 46; Invesco Amendment at 33; iShares Amendment at 37; VanEck Amendment at 34.

[55] *See* Nasdaq Rule 5711(d)(iii); NYSE Arca Rule 8.201–E(e)(2)(vii); BZX Rule 14.11(a).

[56] *See* ARK Amendment at 38; Bitwise Amendment at 23; Fidelity Amendment at 36; Franklin Amendment at 35; Grayscale Amendment at 49; Invesco Amendment at 35; iShares Amendment at 33; VanEck Amendment at 35.

The Commission therefore finds that the Proposals, as with other ETPs that the Commission has approved,[57] are reasonably designed to promote fair disclosure of information that may be necessary to price the shares of the Trusts appropriately, to prevent trading when a reasonable degree of transparency cannot be assured, to safeguard material non-public information relating to the Trusts' portfolios, and to ensure fair and orderly markets for the shares of the Trusts.

C. Other Comments

One commenter asserts that the Commission should approve the Proposals because CME ether futures exchange-traded funds (''ETFs'') registered under the Investment Company Act of 1940 (''1940 Act'') are already trading on national securities exchanges ''and possess much more potential for manipulation of the underlying asset.'' [58] Another commenter states that the Commission should approve the Proposals because ''[t]here is no difference between the [spot bitcoin ETP] approval and the [spot ether ETPs] at this point.'' [59]

The Commission has considered and, for the reasons described above, is approving the Proposals on their own merits and under the standards applicable to them; namely, the standards provided by Section 6(b)(5) and Section 11A(a)(1)(C)(iii) of the Exchange Act.[60] As described above, based on the record before the Commission and the Commission's own correlation analysis, the Commission concludes that fraud or manipulation that impacts prices in spot ether markets would likely similarly impact CME ether futures prices, such that a surveillance-sharing agreement with the CME can be reasonably expected to assist in surveilling for fraud and manipulation that may impact the proposed spot ether ETPs.

Some commenters state that the Commission should approve the Proposals for a variety of investor protection reasons, including that spot ether ETPs would be a less costly and more efficient,[61] more convenient and secure,[62] and more regulated [63] way to gain exposure to spot ether. The Exchanges make similar investor protection arguments in support of approval.[64]

Another commenter disagrees that the ETP investment vehicle would protect investors, stating that the value of an investment in a spot ether ETP would be subject to the same risks of fraud and manipulation in the spot ether market as holding ether directly, and that ETPs are not subject to the Commission's examination authority, custody requirements, or conflicts of interest rules of ETFs registered under the 1940 Act.[65] This commenter further states that any purported investor protections from an ETP compared to an ''even-worse over-the-counter market'' do not neutralize concerns about fraud and manipulation.[66]

This commenter also states that the price volatility of ether means that spot ether ETPs would threaten retail investors by exposing them to an unstable asset.[67] The commenter further states that approving spot ether ETPs ''would threaten not just investors but also the broader financial system'' by ''further entangl[ing] the crypto industry with traditional finance and aggravat[ing]'' risks similar to risks that the commenter claims are posed by spot bitcoin ETPs, such as bitcoin price volatility and dislocations between the price of a spot bitcoin ETP and bitcoin that can ''cause stress for institutions heavily exposed to'' or reliant on spot bitcoin ETPs.[68]

The Commission has considered these potential benefits and concerns in the broader context of whether the Proposals meet the applicable requirements of the Exchange Act,[69] including the requirement in Section 6(b)(5) [70] that the Exchanges' rules be designed to ''prevent fraudulent and manipulative acts and practices.'' For the reasons described above, the Commission has determined that the Proposals meet such requirements.

The Commission also finds that the Proposals are consistent with the Section 6(b)(5) requirement that the Exchanges' rules be designed to protect investors and the public interest because, in addition to the factors discussed in Section II.A and II.B above, existing rules and standards of conduct would apply to recommending and advising investments in the shares of the Trusts. For example, when broker-dealers recommend ETPs to retail customers, Regulation Best Interest (''Reg BI'') would apply.[71] Reg BI requires broker-dealers to, among other things, exercise reasonable diligence, care, and skill when making a recommendation to a retail customer to: (1) understand potential risks, rewards, and costs associated with the recommendation and have a reasonable basis to believe that the recommendation could be in the best interest of at least some retail customers; and (2) have a reasonable basis to believe the recommendation is in the best interest of a particular retail customer based on that retail customer's investment profile.[72] In addition, investment advisers have a fiduciary duty under the 1940 Act comprised of a duty of care and a duty of loyalty. These obligations require the adviser to act in the best interest of its client and

[57] *See supra* note 52.

[58] *See* Letter from Patrick Turley, dated Apr. 3, 2024, regarding SR–NASDAQ–2023–045 (''Turley Letter'').

[59] *See* Jamieson Letter.

[60] 15 U.S.C. 78f(b)(5); 15 U.S.C. 78k–1(a)(1)(C)(iii).

[61] *See, e.g.,* Posey Letter; Letter from William Entriken, dated Oct. 31, 2023, regarding SR–NYSEARCA–2023–70; Letter from Brent Wickenheiser, dated Apr. 3, 2024, regarding SR–NYSEARCA–2023–70 (''Wickenheiser Letter''); Letter from Dirk Hooley, dated Apr. 3, 2024, regarding SR–NYSEARCA–2023–70; Letter from Kevin Thompson, dated Apr. 3, 2024, regarding SR–NASDAQ–2023–045 (''Thompson Letter'').

[62] *See, e.g.,* Posey Letter; Wickenheiser Letter; Thompson Letter; Turley Letter; Letter from Anonymous, dated Apr. 3, 2024, regarding SR–CboeBZX–2023–095; Letter from Anonymous, dated Apr. 5, 2024, regarding SR–NASDAQ–2023–045.

[63] *See, e.g.,* Posey Letter; Thompson Letter; Angel Letter at 7–8.

[64] *See, e.g.,* ARK Amendment at 8–13; iShares Amendment at 18–20, 33–34; Bitwise Amendment at 17. However, another commenter states that the Commission should approve the Proposals because ''when it comes to crypto, things happen so fast that there is no legitimate protection possible.'' *See* Letter from El Norro, dated Dec. 1, 2023, regarding SR–CboeBZX–2023–095 (''Norro Letter'').

[65] *See* Better Markets Letter 1 at 4. While many of the Trusts use ''ETF'' or ''Fund'' in their names, none is registered under the 1940 Act.

[66] *See id*. *See also* Letter from Senator Jack Reed and Senator Laphonza Butler, dated Mar. 11, 2024. *But see* Letter from Representatives French Hill, Josh Gottheimer, Tom Emmer, Wiley Nickel, and Mike Flood, dated May 22, 2024.

[67] *See* Letter from Benjamin L. Schiffrin, Director of Securities Policy, Better Markets, Inc., dated May 15, 2024, regarding SR–CboeBZX–2023–069 and SR–CboeBZX–2023–070 (''Better Markets Letter 2''), at 4–7.

[68] *See id*. at 8. The commenter, however, provided no data on financial institutions' exposure to spot bitcoin ETPs or likely exposure to spot ether ETPs.

[69] *See also* Winklevoss Order, 83 FR at 37602.

[70] 15 U.S.C. 78f(b)(5).

[71] Exchange Act rule 15*l*–1(a).

[72] Exchange Act rules 15*l*–1(a)(2)(ii)(A) and (B). Separately, under Reg BI's Conflict of Interest Obligation, broker-dealers must establish, maintain, and enforce written policies and procedures reasonably designed to, among other things, identify and disclose or eliminate all conflicts of interest associated with a recommendation and mitigate conflicts of interest at the associated person level. *See* Exchange Act rules 15*l*–1(a)(2)(iii)(A) and (B). To the extent that broker-dealers recommend ETPs to customers who are not retail customers covered by Reg BI, FINRA Rule 2111 requires, in part, that a member broker-dealer or associated person ''have a reasonable basis to believe that a recommended transaction or investment strategy involving a security or securities is suitable for the customer, based on the information obtained through the reasonable diligence of the [broker-dealer] or associated person to ascertain the customer's investment profile.''

not subordinate its client's interest to its own.[73]

Some commenters contend that the Commission should disapprove the Proposals because the nature of ether and the Ethereum Network makes them inherently susceptible to fraud and manipulation.[74] Other commenters argue that the nature of ether and the Ethereum Network makes them inherently resistant to fraud and manipulation.[75] The Commission acknowledges commenters' concerns regarding fraud and manipulation. Pursuant to Section 19(b)(2) of the Exchange Act, however, the Commission must approve a proposed rule change filed by a national securities exchange if it finds that the proposed rule change is consistent with the applicable requirements of the Exchange Act.[76] For the reasons described above, the Commission finds that the Proposals satisfy the requirements of the Exchange Act, including the requirement in Section 6(b)(5)[77] that the Exchanges' rules be designed to ''prevent fraudulent and manipulative acts and practices.''

Commenters also address, among other things: investor demand for spot ether ETPs;[78] environmental considerations of Ethereum's proof-of-stake consensus mechanism;[79] whether to permit a Trust to stake its ether;[80] and the potential disadvantage from Commission disapproval of spot ether ETPs to U.S. innovation[81] and to U.S. investors compared to those in other countries.[82] Ultimately, however, for the reasons described above, the Commission is approving the Proposals because it finds that the Proposals satisfy the requirements of the Exchange Act, including the requirement in Section 6(b)(5)[83] that the Exchanges' rules be designed to ''prevent fraudulent and manipulative acts and practices.''

III. Accelerated Approval of the Proposals

The Commission finds good cause to approve the Proposals prior to the 30th day after the date of publication of notice of the Exchanges' amended filings[84] in the **Federal Register**. The amended filings clarified the descriptions of the Trusts; further described the terms of the Trusts; and conformed various representations in the amended filings to the applicable Exchange's listing standards and to representations that the Exchanges have made for other ETPs that the Commission has approved.[85] These changes do not raise any novel regulatory issues. Further, the changes assist the Commission in evaluating the Proposals and in determining that they are consistent with the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange, as discussed above. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Exchange Act,[86] to approve the Proposals on an accelerated basis.

IV. Conclusion

This approval order is based on all of the Exchanges' representations and descriptions in their respective amended filings, which the Commission has carefully evaluated as discussed

[73] *See* Commission Interpretation Regarding Standard of Conduct for Investment Advisers, Investment Advisers Act Release No. 5248 (June 5, 2019), 84 FR 33669 (July 12, 2019), at 33671; Investment Company Act Release No. 34084 (Nov. 2, 2020), 85 FR 83162 (Dec. 21, 2020), at 83217 (discussing the best interest standard of conduct for broker-dealers and the fiduciary obligations of investment advisers in the context of all ETPs).

[74] *See, e.g.,* Better Markets Letter 1 at 3 (asserting that relays are responsible for adding blocks of transactions to the Ethereum Blockchain, and recently one infrastructure provider exited the network, which left ''only four other major relay players to handle most Ethereum blocks and raises concern of potential problems, ranging from censorship of transactions to stealing of other key operators' profits''; that in addition to relays, the Ethereum Network is run by ''parties called builders, which compile most transactions into blocks, and validators, which order blocks into a blockchain,'' but that both ''builder and validator functions are dominated by a handful of participants''; and that ''[a] validator controlling 34% could potentially falsify transactions'' and one validator currently controls 32.3% of validator power and four builders account for the majority of blocks built); Letter from Robert, dated Apr. 23, 2024, regarding CboeBZX–2023–095 (stating that proof-of-stake is centralizing because as the ''pile of [validators'] ether token increases, so does their ability to capture control over the network''; and that ''the founding entities never relinquished control over the network'' despite the Ethereum Foundation's ''deceptive affinity marketing'' to the contrary); Letter from Brandon, dated Apr. 4, 2024, regarding SR–NYSEARCA–2023–70 (''Control of the network will inevitably centralize . . . because only the largest holders are the ones rewarded with new coins''; and ''the entire [Ethereum Blockchain] can be manipulated by the foundation, such as after the DAO attack where the chain was rolled back by the organization''); Letter from James Keeton, dated Apr. 3, 2024, regarding SR–NASDAQ–2023–045 (''[T]he merge to proof of stake in 2022 solidified the lack of decentralization of this blockchain''); Letter from Anonymous, dated Mar. 5, 2024, regarding SR–NASDAQ–2023–045 (''Proof of stake is just another mechanism for more increased centralization and control over the network by the biggest stakers.''); Letter from Luther, dated Apr. 3, 2024, regarding SR–NASDAQ–2023–045 (''The Ethereum [F]oundation is the centralized entity that controls the protocol . . . [T]hey regularly push out hard forks to their centralized node infrastructure to make protocol changes. In a truly decentralized system this would not be possible.'').

[75] *See, e.g.,* Coinbase Letter at 2 (asserting that the technological and operational security mechanisms inherent in the Ethereum Blockchain significantly limit ether's susceptibility to fraud and manipulation); Letter from Laura Brookover, Matt Corva, and William C. Hughes, Consensys Software Inc., dated Mar. 29, 2024, regarding SR–NASDAQ–2023–045, SR–CboeBZX–2023–087, and SR–CboeBZX–2023–095 (''Consensys Letter''), at 2–7 (arguing that Ethereum's proof-of-stake consensus mechanism ''has several built-in protections providing additional security against fraud and manipulation,'' including: its block finality model provides increased reliability and integrity; the division of labor between two groups of block validators, proposers and attesters, ''serves as a check and balance against error and manipulation;'' the cost to an attacker group of obtaining the percentage of Ethereum nodes required to compromise the network is greater than for the Bitcoin Network; and the ''slashing'' that ''penalizes validators who violate protocol rules by docking their stakes . . . serves as both a punitive measure and a deterrent.'' This commenter also states that the ''active and sizable developer community'' enhances Ethereum's resilience against attacks; the redundancy afforded by independent open source software clients means that ''network integrity is maintained even if one software client fails due to a bug or malicious exploit;'' and the ''inherent transparency'' of Ethereum's public protocol development ''forms a significant barrier to fraud and manipulation at the protocol level.''); Letter from Chris McCullough, dated Apr. 3, 2024, regarding SR–NASDAQ–2023–045 (citing unspecified ''advanced safeguards inherent in Ethereum's design''); Letter from Anonymous, dated Mar. 24, 2024, regarding SR–NASDAQ–2023–045 (''Anonymous Letter''), at 4 (arguing that the decentralization of ether software clients ''helps mitigate the risks posed by bugs, although some concentration is still observed in a few clients''); Letter from Nathan Yang, dated Apr. 7, 2024, regarding SR–NYSEARCA–2024–31.

[76] *See* Exchange Act Section 19(b)(2)(C), 15 U.S.C. 78s(b)(2)(C). The Commission does not apply a ''cannot be manipulated'' standard; rather, the Commission examines whether a proposal meets the requirements of the Exchange Act. *See, e.g.,* Winklevoss Order, 83 FR at 37582. The Commission does not understand the Exchange Act to require that a particular product or market be immune from manipulation. Rather, the inquiry into whether the rules of an exchange are designed to prevent fraudulent and manipulative acts and practices and, in general, to protect investors and the public interest, has long focused on the mechanisms in place for the detection and deterrence of fraud and manipulation.

[77] 15 U.S.C. 78f(b)(5).

[78] *See, e.g.,* Jamieson Letter; Letter from John, dated Apr. 4, 2024, regarding SR–CboeBZX–2023–095 (''John Letter''); Letter from Johanes Swenberg, dated Apr. 3, 2024, regarding SR–CboeBZX–2023–095; Letter from Shaun Cumby, dated Apr. 3, 2024, regarding SR–NASDAQ–2023–045.

[79] *See, e.g.,* Anonymous Letter at 2; Consensys Letter at 6; John Letter; Letter from Brett, dated Apr. 4, 2024, regarding SR–NASDAQ–2023–045.

[80] *See, e.g.,* Better Markets Letter 2 at 7–8; Anonymous Letter at 3; Turley Letter. The Proposals under consideration by the Commission in this order do not contemplate staking of the Trusts' ether. Accordingly, the relative benefits or drawbacks of staking are outside the scope of this order. Any future proposal of a Trust to, directly or indirectly, engage in action where any portion of the Trust's ether becomes subject to the Ethereum proof-of-stake validation or is used to earn additional ether or generate income or other earnings would require the applicable Exchange to submit a proposed rule change under Rule 19b–4.

[81] *See, e.g.,* Turley Letter.

[82] *See, e.g.,* Norro Letter.

[83] 15 U.S.C. 78f(b)(5).

[84] *See supra* notes 3–10.

[85] *See also supra* Section II.B.

[86] 15 U.S.C. 78s(b)(2).

above.[87] For the reasons set forth above, including the Commission's correlation analysis, the Commission finds, pursuant to Section 19(b)(2) of the Exchange Act,[88] that the Proposals are consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange, and in particular, with Section 6(b)(5) and Section 11A(a)(1)(C)(iii) of the Exchange Act.[89]

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[90] that the Proposals (SR–NYSEARCA–2023–70; SR–NYSEARCA–2024–31; SR–NASDAQ–2023–045; SR–CboeBZX–2023–069; SR–CboeBZX–2023–070; SR–CboeBZX–2023–087; SR–CboeBZX–2023–095; SR–CboeBZX–2024–018) be, and hereby are, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[91]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2024–11804 Filed 5–29–24; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-Day notice.

SUMMARY: The Small Business Administration (SBA) is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act and OMB procedures, SBA is publishing this notice to allow all interested member of the public an additional 30 days to provide comments on the proposed collection of information.

DATES: Submit comments on or before July 1, 2024.

ADDRESSES: Written comments and recommendations for this information collection request should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Small Business Administration''; ''Currently Under Review,'' then select the ''Only Show ICR for Public Comment'' checkbox. This information collection can be identified by title and/or OMB Control Number.

FOR FURTHER INFORMATION CONTACT: You may obtain a copy of the information collection and supporting documents from the Agency Clearance Office at *Curtis.Rich@sba.gov;* (202) 205–7030, or from *www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: For SBA financial assistance programs, SBA Form 413 Personal Financial Statement (PFS) collects information regarding the assets and liabilities of certain owners, officers and guarantors of the small business applicant benefiting from such assistance and is used when analyzing the applicant's repayment abilities or creditworthiness. SBA's Surety Bond Guaranty Program uses the Form 413 PFS information during the claim recovery process. The information is also collected from applicants and participants in SBA's 8(a) Business Development (BD) and Women-Owned Small Business (WOSB) Program certification process to determine whether they meet the economic disadvantage requirements of the program.

All program offices use the same Form 413. SBA plans to revise and clarify the instructions for the Form 413 to ensure the public will be aware of the specific submission process for each program office. SBA will update the Form 413 to include recent rule and policy updates related to its thresholds for inflation. Lastly, the Form 413 may undergo additional formatting changes to make it easier to address mandatory Federal government 508 accessibility compliance.

Solicitation of Public Comments:

Comments may be submitted 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.

OMB Control Number: 3245–0188.

Title: Personal Financial Statement.

Description of Respondents: 7(a) and 504 loan Program applicants, Surety Bond Program recovery claimants, Disaster Loan Program business applicants 8(a)/BD and WOSB Program applicants.

SBA Form Numbers: SBA Forms 413(a) loan program, 413 (504) loan program, 413 Disaster and 413 8(a) BD program.

Estimated Number of Respondents: 251,934.

Estimated Annual Responses: 251,934.

Estimated Annual Hour Burden: 344,174.

Curtis Rich,

Agency Clearance Officer.

[FR Doc. 2024–11797 Filed 5–29–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20349 and #20350; Indiana Disaster Number IN–20001]

Administrative Declaration of a Disaster for the State of Indiana

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of indiana dated 05/23/2024.

Incident: Severe Storms and Tornado.

Incident Period: 05/07/2024.

DATES: Issued on 05/23/2024.

Physical Loan Application Deadline Date: 07/22/2024.

Economic Injury (EIDL) Loan Application Deadline Date: 02/24/2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by

[87] *See supra* notes 3–10. In addition, the shares of the Trusts in SR–NYSEARCA–2023–70 and NYSEARCA–2024–31 must comply with the requirements of NYSE Arca Rule 8.201–E (Commodity-Based Trust Shares) to be listed and traded on NYSE Arca on an initial and continuing basis; the shares of the Trust in SR–NASDAQ–2023–045 must comply with the requirements of Nasdaq Rule 5711(d) (Commodity-Based Trust Shares) to be listed and traded on Nasdaq on an initial and continuing basis; and the shares of the Trusts in SR–CboeBZX–2023–069, SR–CboeBZX–2023–070, SR–CboeBZX–2023–087, SR–CboeBZX–2023–095, and SR–CboeBZX–2024–018 must comply with the requirements of BZX Rule 14.11(e)(4) (Commodity-Based Trust Shares) to be listed and traded on BZX on an initial and continuing basis.

[88] 15 U.S.C. 78s(b)(2).

[89] 15 U.S.C. 78f(b)(5); 15 U.S.C. 78k–1(a)(1)(C)(iii).

[90] 15 U.S.C. 78s(b)(2).

[91] 17 CFR 200.30–3(a)(12).

email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Franklin

Contiguous Counties:

Indiana: Dearborn, Decatur, Fayette, Ripley, Rush, Union

Ohio: Butler, Hamilton

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.375
Homeowners without Credit Available Elsewhere	2.688
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20349C and for economic injury is 203500.

The States which received an EIDL Declaration are Indiana, Ohio.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2024–11820 Filed 5–29–24; 8:45 am]

BILLING CODE 8026–09–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2024–0016]

Agency Information Collection Activities: Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, Mail Stop 3253 Altmeyer, 6401 Security Blvd., Baltimore, MD 21235, Fax: 833–410–1631, Email address: *OR.Reports.Clearance@ssa.gov*

Or you may submit your comments online through *https://www.reginfo.gov/public/do/PRAmain* by clicking on Currently under Review—Open for Public Comments and choosing to click on one of SSA's published items. Please reference Docket ID Number [SSA–2024–0016] in your submitted response.

SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than July 1, 2024. Individuals can obtain copies of these OMB clearance packages by writing to the *OR.Reports.Clearance@ssa.gov.*

1. Development of Participation in a Vocational Rehabilitation or Similar Program—20 CFR 404.316(c), 404.337(c), 404.352(d), 404.1586(g), 404.1596, 404.1597(a), 404.327, 404.328, 416.1321(d), 416.1331(a)–(b), and 416.1338, 416.1402—0960–0282. State Disability Determination Services (DDS) determine if Social Security disability payment recipients whose disability ceased and who participate in vocational rehabilitation programs may continue to receive disability payments. To do this, DDSs need information about the recipients, the types of program participation, and the services they receive under the rehabilitation program. SSA uses Form SSA–4290 to collect this information. The respondents are State employment networks, vocational rehabilitation agencies, or other providers of educational or job training services.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office or for teleservice centers (minutes) **	Total annual opportunity cost (dollars) ***
SSA–4290–F5 (By mail)	2,400	1	40	1,600	* $21.27		*** $34,032
SSA–4290–F5 (Telephone)	600	1	30	300	* 21.27	** 19	*** 10,422
Totals	3,000			1,900			*** 44,454

* We based this figure on average Social and Human Service Assistant's hourly salary, as reported by (*https://www.bls.gov/oes/current/oes211093.htm*).

** We based this figure on the average FY 2024 wait times for field offices phone calls, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Application to Collect a Fee for Payee Services—20 CFR 404.2040a & 416.640a—0960–0719. Sections 205(j) and 1631(a) of the Social Security Act (Act) allow SSA to authorize certain organizational representative payees to collect a fee for providing payee services. Before an organization may collect this fee, they complete and submit Form SSA–445. SSA uses the information to determine whether to authorize or deny permission to collect fees for payee services. The respondents are private sector businesses, or State and local government offices, applying to become a fee-for-service organizational representative payee.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden hours (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Private sector business	80	1	13	17	* $18.48	** $314
State/local government offices	10	1	10	2	* 18.48	** 37
Totals	90			19		** 351

* We based these figures on average Personal Care and Service Occupations hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes390000.htm*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. Screen Pop—20 CFR 401.45—0960–0790. Section 205(a) of the Act requires SSA to verify the identity of individuals who request a record or information pertaining to themselves, and to establish procedures for disclosing personal information. SSA established Screen Pop, an automated telephone process, to speed up verification for such individuals. Accessing Screen Pop, callers enter their Social Security number (SSN) using their telephone keypad or speech technology prior to speaking with a National 800 Number Network (N8NN) agent. The automated Screen Pop application collects the SSN and routes it to the ''Start New Call'' Customer Help and Information (CHIP) screen. Functionality for the Screen Pop application ends once the SSN connects to the CHIP screen and the SSN routes to the agent's screen. When the call connects to the N8NN agent, the agent can use the SSN to access the caller's record as needed. The respondents for this collection are individuals who contact SSA's N8NN to speak with an agent.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time for teleservice centers (minutes) **	Total annual opportunity cost (dollars) ***
Screen Pop	51,933,760	1	1	865,563	* $31.48	** 19	*** $544,958,276

* We based this figure on average U.S. worker's hourly wages, as reported by Bureau of Labor Statistics data (*https://www.bls.gov/oes/current/oes_nat.htm#00-00000*).

** We based this figure on the average FY 2024 wait times for teleservice centers, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete.*

4. Electronic Consent Based Social Security Number Verification—20 CFR 400.100—0960–0817. The electronic Consent Based Social Security Number Verification (eCBSV) is a fee-based SSN verification service which allows permitted entities (a financial institution as defined by section 509 of the Gramm-Leach-Bliley Act, 42 U.S.C. 405(b)(4), and Pub. L. 115–174; or service provider, subsidiary, affiliate, agent, subcontractor, or assignee of a financial institution), to verify that an individual's name, date of birth (DOB), and SSN match our records based on the SSN holder's signed, including electronic consent in connection with a credit transaction or any circumstance described in section 604 of the Fair Credit Reporting Act (15 U.S.C. 1681b).

Background

SSA established the eCBSV service in response to section 215 of the Economic Growth, Regulatory Relief, and Consumer Protection Act of 2018 (Banking Bill), Public Law 115–174. Permitted entities are able to submit the SSN, name, and DOB of the number holder in connection with a credit transaction, or any circumstances described in section 604 of the Fair Credit Reporting Act to SSA for verification via an application programming interface. eCBSV allows SSA to verify permitted entities who submit SSN, name, and DOB matches, or does not match, the data contained in SSA's records. After obtaining number holders' consents, a permitted entity submits the names, DOBs, and SSNs of number holders to the eCBSV service. SSA matches the information against our Master File, using SSN, name, and DOB. The eCBSV service responds in real time with a match, or no match indicator (and an indicator if our records show that the number holder died). SSA does not provide specific information on what data elements did not match, nor does SSA provide any SSNs or other identifiable information. The verification does not authenticate the identity of the number holders or conclusively prove the number holders we verify are who they are claiming to be.

Consent Requirements

Under the eCBSV process, the permitted entities do not submit the number holder's consent forms to SSA. SSA requires each permitted entity to retain a valid consent for each SSN verification request submitted for a period of 5 years. SSA allows the permitted entities to retain the consent in an electronic format, and SSA requires a wet or electronic signature on the consent. Permitted entities may request verification of a number holder's SSN on behalf of a financial institution pursuant to the terms of the Banking Bill; the user agreement between SSA and the PE; and the SSN Holder's consent. The permitted entity ensures the financial institution agrees to the terms in the user agreement to only use the SSN verification for the purpose stated in the consent, and prohibits public entities from further using or disclosing the SSN verification. This relationship is subject to the terms in the user agreement between SSA and the PE.

Compliance Review

SSA requires each permitted entity to undergo compliance reviews which an SSA approved certified public accountant (CPA) conducts. The compliance reviews ensure the permitted entities meet all terms and conditions of the user agreement, including obtaining valid consent from number holders. The permitted entities pay all compliance review costs through the eCBSV fees. In general, SSA requests annual reviews with additional reviews

as necessary. The CPA follows review standards established by the American Institute of Certified Public Accountants and contained in the Generally Accepted Government Auditing Standards (GAGAS).

Initially, SSA only allowed 10 permitted entities access to use the service, with an estimated 307,000,000 requests. Now, with the open enrollment, eCBSV is available to all interested permitted entities, as defined in section 215 of the Banking Bill with an estimated annual 77,000,000 requests, and 20 participating public entities. The respondents are permitted entities; members of the public who consent to SSN verifications; and CPAs who provide compliance review services.

Type of Request: Revision of an OMB-approved information collection.

Requirement	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
(a) People whose SSNs SSA will verify—Reading and Signing	76,000,000	1	3	3,800,000	* $13.30	** $50,540,000
(a) Sending in the verification request, calling our system, getting a response	76,000,000	1	1	1,266,667	* 43.55	** 55,163,348
(c) CPA Compliance Review and Report ***	21	1	4,800	1,680	* 43.65	** 73,332
Totals	152,000,021			5,068,347		** 105,776,680

* We based these figures on average Business and Financial operations occupations (*https://www.bls.gov/oes/current/oes130000.htm*), and Accountants and Auditors hourly salaries (*https://www.bls.gov/oes/current/oes132011.htm*), as reported by Bureau of Labor Statistics data, and average DI payments, as reported in SSA's disability insurance payment data (*https://mwww.ba.ssa.gov/legislation/2024FactSheet.pdf*).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

*** The enrollment process occurs automatically through the eCBSV Customer Connection, and entails providing consent for SSA to verify the EIN; electronically signing the eCBSV User Agreement, and the permitted entities certification; selecting their annual tier level; and linking to pay.gov to make payment for services.

**** SSA uses one CPA firm (an SSA-approved contractor) to conduct compliance reviews and prepare written reports of findings on the permitted entities.

Cost Burden

The public cost burden depends on the number of permitted entities using the service and the annual transaction volume. SSA based the current tier fee schedule below on 20 participating public entities in fiscal year (FY) 2023 submitting an anticipated annual volume of 65 million transactions. For FY 2024, we are maintaining the current tier structure, based our analysis, which estimated 20 participating public entities with an anticipated annual volume of 52 million. Since our analysis and initial estimate, one permitted entity noted the potential for a significant increase in volume in FY 2024. The total cost for developing and operating the service is $62 million through FY 2023. Of this amount, $37 million remains unrecovered/unreimbursed. The current subscription tier structure and associated fees intend to recover these costs over a four-year period, assuming projected enrollments and transaction volumes meet these projections. SSA uses the fee to allocate for forecasted systems and operational expenses; agency oversight; and overhead necessary to sustain the service.

eCBSV Tier Fee Schedule

Tier	Annual transaction threshold	Annual fee
1	Up to 10,000 (1–10,000)	$7,000
2	Up to 200,000 (10,001–200,000)	130,000
3	Up to 1 million (200,001–1 million)	630,000
4	Up to 2.5 million (1,000,001–2.5 million)	1,500,000
5	Up to 5 million (2,500,001–5 million)	3,000,000
6	Up to 10 million (5,000,001–10 million)	4,500,000
7	Up to 15 million (10,000,001–15 million)	5,000,000
8	Up to 20 million (15,000,001–20 million)	6,250,000
9	Up to 25 million (20,000,001–25 million)	7,250,000
10	Up to 75 million (25,000,001–200 million)	8,250,000

SSA calculates fees based on forecasted systems and operational expenses, agency oversight, overhead, and Certified Public Accountant audit contract costs.

Section 215(h)(1)(B) of the Banking Bill requires that the Commissioner shall ''periodically adjust'' the price paid by users to ensure that amounts collected are sufficient to fully offset the costs of administering the eCBSV system. SSA will monitor costs incurred to provide eCBSV services on at least and annual basis, and will revise the tier fee schedule accordingly. SSA will notify permitted entities of the tier fee schedule in effect at the renewal of the eCBSV user agreements; when a permitted entity begins a new 365-day agreement period; and via notice in the **Federal Register**. SSA will govern permitted entities renewals by the tier in effect at the time of renewal.

Dated: May 23, 2024.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2024–11803 Filed 5–29–24; 8:45 am]

BILLING CODE 4191–02–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Extension of Certain Exclusions: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Notice.

SUMMARY: In prior notices, the U.S. Trade Representative modified the actions in the section 301 investigation of China's acts, policies, and practices related to technology transfer, intellectual property, and innovation by excluding from additional duties certain products of China. The current 429 product specific exclusions (352 previously reinstated exclusions and 77 COVID-related exclusions) are scheduled to expire on May 31, 2024. This notice announces the U.S. Trade Representative's determination to provide a 14-day transition period for all current exclusions, extending them through June 14, 2024, and to extend certain exclusions through May 31, 2025.

DATES: To provide a transition period, this notice extends all exclusions scheduled to expire on May 31, 2024, through June 14, 2024. Those exclusions receiving further extension are listed in Annex C to this notice and are extended through May 31, 2025.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Senior Associate General Counsel Philip Butler or Assistant General Counsel Edward Marcus at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusions, contact *traderemedy@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

In the course of this investigation, the U.S. Trade Representative has imposed additional duties on products of China in four tranches. *See* 83 FR 28719 (June 20, 2018); 83 FR 40823 (August 16, 2018); 83 FR 47974 (September 21, 2018), as modified by 83 FR 49153 (September 28, 2018); and 84 FR 43304 (August 20, 2019), as modified by 84 FR 69447 (December 18, 2019) and 85 FR 3741 (January 22, 2020).

For each tranche of additional duties, the U.S. Trade Representative established a process by which interested persons could request the temporary exclusion of particular products subject to the action. These exclusions were granted for a limited time and, with few exceptions, most expired in 2019 and 2020.

Reinstated Exclusions

On October 8, 2021, the U.S. Trade Representative invited the public to submit comments on whether to temporarily reinstate certain exclusions previously granted and extended. *See* 86 FR 56345 (October 8, 2021). On March 28, 2022, the U.S. Trade Representative determined to temporarily reinstate 352 expired exclusions through December 31, 2022. *See* 87 FR 17380 (March 28, 2022) (March 28 notice). The 352 exclusions were subsequently extended through September 30, 2023. *See* 87 FR 78187 (December 21, 2022).

COVID-Related Exclusions

On March 25, 2020, USTR requested public comments on proposed modifications to exclude from additional duties certain medical-care products related to the U.S. response to COVID. *See* 85 FR 16987 (March 25, 2020). In light of ongoing efforts to combat COVID, on December 29, 2020, USTR announced 99 product exclusions for medical-care products and products related to the U.S. COVID response. *See* 85 FR 85831 (December 20, 2020) (December 20 notice). For additional background on previous COVID-related extensions, see prior notices issued in the investigation, including: 86 FR 13785 (March 10, 2021), 86 FR 63438 (November 16, 2021), 87 FR 33871 (June 3, 2022), and 87 FR 73383 (November 29, 2022). On May 17, 2023, the U.S. Trade Representative determined to extend 77 of the COVID-related exclusions through September 30, 2023. *See* 88 FR 31580 (May 17, 2023).

Four-Year Review

In accordance with section 307(c)(3) of the Trade Act of 1974 (19 U.S.C. 2417(c)(3)), on September 8, 2022, USTR announced that it would be conducting a review of the July 6, 2018 and August 23, 2018 actions, as modified. *See* 87 FR 26797 (May 5, 2022); 87 FR 55073 (September 8, 2022). In a notice published on October 17, 2022 (87 FR 62914), USTR announced that it was opening a docket on November 15, 2022, for interested persons to submit comments on the review, including whether certain tariff headings (including those with product-specific exclusions) should remain covered by the actions.

To allow for consideration under the statutory review, on September 11, 2023, the U.S. Trade Representative determined to extend all current exclusions through December 31, 2023. *See* 88 FR 62423 (September 11, 2023).

Consideration of Further Extension of Exclusions

In light of public comments submitted in the four-year review, on December 29, 2023, USTR invited public comments on whether to further extend any of the current exclusions and announced an interim extension of the exclusions through May 31, 2024. *See* 88 FR 90225 (December 29, 2023) (the December 29 notice).

The December 29 notice provided that, in considering possible extensions, USTR would evaluate each exclusion on a case-by-case basis, with the focus of the evaluation on the availability of products covered by the exclusion from sources outside of China, efforts undertaken to source products covered by the exclusion from the United States or third countries, and whether further extension of a particular exclusion would aid in shifting sourcing outside of China. *See* 88 FR 90225. The notice also provided that USTR would consider the impact on U.S. interests of extending or not extending an exclusion and the goal of obtaining the elimination of China's acts, policies, and practices covered in the investigation.

USTR opened a 30-day docket on January 22, 2024, and requested that commenters address the availability of products covered by the exclusion outside of China, plans to shift their sourcing outside of China in 2024, efforts undertaken to source products from the United States or third countries, and why additional time is needed to shift sourcing out of China and the timeline, if any, expected for sourcing to shift outside of China.

B. Determination to Further Extend Certain Exclusions

Based on evaluation of the factors set out in the December 29 notice, and pursuant to sections 301(b), 301(c), and 307(a) of the Trade Act of 1974, as amended, the U.S. Trade Representative has determined to further modify the action to extend the exclusions listed in Annex C to this notice through May 31, 2025. The U.S. Trade Representative has found that extending these exclusions will support efforts to shift sourcing out of China, or provide additional time where, despite efforts to source products from alternative sources, availability of the product outside of China remains limited.

The U.S. Trade Representative has determined not to extend the remaining exclusions beyond the 14-day transition period. These exclusions are listed in

Annex D to this notice. The list includes 102 exclusions where no public comments requested further extension. For the remaining exclusions, public comments do not demonstrate that further extending the exclusion would aid efforts to shift sourcing out of China in the near term or do not demonstrate that products covered by the exclusion are unavailable outside of China.

For example, the U.S. Trade Representative has declined to further extend exclusions where comments indicated that importers had no plans to shift sourcing out of China in 2024 (or at all). Similarly, the U.S. Trade Representative has declined to further extend exclusions where, despite more than four years of temporary exclusion, commenters reported that they had taken few or no steps to shift sourcing out of China. This includes comments that, without further explanation, asserted that they were considering alternative sources, or reported plans to shift sourcing, but failed to adequately explain efforts undertaken or why additional time was needed.

The U.S. Trade Representative also declined to further extend exclusions where opposing comments indicated availability from domestic sources or third country sources. This includes opposing comments from domestic producers reporting available capacity and opposing comments from importers who previously benefitted from the exclusion reporting successful efforts to shift to alternative sources. Extending these exclusions may undercut those efforts, including recent investments in domestic capacity.

The U.S. Trade Representative also declined to extend exclusions where claims of unavailability were based on the product being unavailable at the price of Chinese sources. In many instances, comments simply asserted that products were unavailable because China remained the lowest cost source. Extending those exclusions would likely delay the commenters' efforts to find alternative sourcing and continue their dependence on Chinese suppliers and products, which undermines the goal of obtaining the elimination of China's acts, policies, and practices covered in the investigation.

Similarly, many comments asserted that a product was unavailable outside of China due to costs associated with finding alternative sources or based on the limited availability of certain product specifications or comparable quality outside of China. Without additional explanation of efforts undertaken or how further extending the exclusion would aid efforts to shift sourcing, the U.S. Trade Representative declined to extend these exclusions.

The U.S. Trade Representative's consideration to extend certain exclusions takes into account public comments submitted in response to the December 29 notice, public comments submitted in the four-year review, confidential import data provided by U.S. Customs and Border Protection, the advice of advisory committees, and the advice of the interagency section 301 Committee.

As stated above, to provide a transition period for the expiring exclusions, the U.S. Trade Representative has determined to extend all current exclusions through June 14, 2024. *See* Annex A and Annex B to this notice. The exclusions listed in Annex C to this notice are further extended through May 31, 2025. The exclusions listed in Annex D are not being extended beyond the 14-day transition period.

The extensions announced in the notice are available for any product that meets the description in the product exclusion. Further, the scope of each exclusion and modification is governed by the scope of the ten-digit Harmonized Tariff Schedule of the United States (HTSUS) subheadings and product descriptions in the Annexes of this notice. U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

Juan Millan,

Acting General Counsel, Office of the United States Trade Representative.

BILLING CODE 3390–F4–P

Annex A

The U.S. Trade Representative has determined to extend all exclusions previously extended under heading 9903.88.67 and U.S. notes 20(ttt)(i), 20(ttt)(ii), 20(ttt)(iii), and 20(ttt)(iv) to subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS). See 88 FR 90225 (December 29, 2023). The extension is effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern standard time on June 1, 2024, and before 11:59 p.m. eastern daylight time on June 14, 2024. Effective on June 1, 2024, the article description of heading 9903.88.67 of the HTSUS is modified by deleting ''May 31, 2024,'' and by inserting "June 14, 2024,'' in lieu thereof.

Annex B

The U.S. Trade Representative has determined to extend all exclusions previously extended under heading 9903.88.68 and U.S. notes 20(uuu)(i), 20(uuu)(ii), 20(uuu)(iii), and 20(uuu)(iv) to subchapter III of chapter 99 of the HTSUS. See 88 FR 90225 (December 29, 2023). The extension is effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern standard time on June 1, 2024, and before 11:59 p.m. eastern daylight time on June 14, 2024. Effective on June 1, 2024, the article description of heading 9903.88.68 of the HTSUS is modified by deleting ''June 1, 2024,'' and by inserting ''June 15, 2024,'' in lieu thereof.

Annex C

A. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on June 15, 2024 and before 11:59 p.m. eastern daylight time on May 31, 2025, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

1. by inserting the following new heading 9903.88.69 in numerical sequence, with the material in the new heading inserted in the columns of the HTSUS labeled "Heading/Subheading", "Article Description", and "Rates of Duty 1-General", respectively:

Heading/ Subheading	Article Description	Rates of Duty		
		1		2
		General	Special	
"9903.88.69	Effective with respect to entries on or after June 15, 2024 and through May 31, 2025, articles the product of China, as provided for in U.S. note 20(vvv) to this subchapter, each covered by an exclusion granted by the U.S. Trade Representative	The duty provided in the applicable subheading"		

2. by inserting the following new U.S. note 20(vvv) to subchapter III of chapter 99 in numerical sequence:

"(vvv)(i) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.01 and provided for in U.S. notes 20(a) and 20(b) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.01. See 83 Fed. Reg. 40823 (August 16, 2018) and 83 Fed. Reg. 47326 (September 18, 2018). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that, as provided in heading 9903.88.69, the additional duties provided for in heading 9903.88.01 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

1) 8483.50.9040
2) 8607.21.1000
3) 9030.90.4600
4) Pump casings and bodies (described in statistical reporting number 8413.91.9080 prior to January 1, 2019; described in statistical reporting number 8413.91.9095 effective January 1, 2019 through December 31, 2019; described in statistical reporting number 8413.91.9085 or 8413.91.9096 effective January 1, 2020)
5) Pump covers (described in statistical reporting number 8413.91.9080 prior to January 1, 2019; described in statistical reporting number 8413.91.9095 effective January 1, 2019 through December 31, 2019; described in statistical reporting number 8413.91.9085 or 8413.91.9096 effective January 1, 2020)
6) Pump parts, of plastics, each valued not over $3 (described in statistical reporting number 8413.91.9080 prior to January 1, 2019; described in statistical reporting number 8413.91.9095 effective January 1, 2019 through December 31, 2019; described in statistical reporting number 8413.91.9085 or 8413.91.9096 effective January 1, 2020)
7) Compressors, other than screw type, used in air conditioning equipment in motor vehicles, each valued over $88 but not over $92 per unit (described in statistical reporting number 8414.30.8030)
8) Rotary compressors, each exceeding 746 W but not exceeding 2,238 W, with a cooling capacity ranging from 2.3 kW to 5.5 kW (described in statistical reporting number 8414.30.8060)
9) Heat exchanger plates, cores, finned tubes, cones, shells, bonnets, flanges and baffles (described in statistical reporting number 8419.90.3000)

10) Chemically etched dies of steel, steel-rule cutting dies, movable magnetic dies, embossing folders and plastic embossing diffusers, of a kind used in manually-powered roller machines for etching or stenciling a single sheet of cardstock, paper, leather, flexible magnet, plastics, metallic foil, vellum, felt or fabric, such sheets measuring not more than 50.8 cm in width or length (described in statistical reporting number 8420.99.9000)
11) Cutting pads, platforms, base plates, pads, shims, trays, which function as guides for hand-operated table-top calendering machines of a width not exceeding 51 cm (described in statistical reporting number 8420.99.9000)
12) Machinery for filtering water, submersible, powered by batteries, manually operated, such machinery designed for use in pools, basins, aquariums, spas or similar contained bodies of water (described in statistical reporting number 8421.21.0000)
13) Air purification equipment, electrically powered, weighing less than 36 kg (described in statistical reporting number 8421.39.8015 prior to January 27, 2022; described in statistical reporting number 8421.39.0115 effective January 27, 2022)
14) Disposable plastic filters of a kind suitable for filtering and dehumidifying a patient's breath in a medical device such as a gas analyzer (described in statistical reporting number 8421.39.8090 prior to January 27, 2022; described in statistical reporting number 8421.39.0190 effective January 27, 2022)
15) Filter housings, covers, or couplings, the foregoing of steel and comprising parts of machinery or apparatus for filtering liquids (described in statistical reporting number 8421.99.0040 prior to January 27, 2022; described in statistical reporting number 8421.99.0140 effective January 27, 2022)
16) Counterweight castings of iron or steel designed for use on fork lift and other works trucks (described in statistical reporting number 8431.20.0000)
17) Tines, carriages, and other goods handling apparatus and parts designed for use on fork lift and other works trucks (described in statistical reporting number 8431.20.0000)
18) Animal feeding machinery (described in statistical reporting number 8436.80.0090)
19) Parts of animal feeding machinery (described in statistical reporting number 8436.99.0090)
20) Reject doors, pin protectors, liners, front walls, grates, hammers, rotor and end disc caps, and anvil and breaker bars, of iron or steel, the foregoing parts of metal shredders (described in statistical reporting number 8479.90.9496 prior to January 27, 2022; described in statistical reporting number 8479.90.9596 effective January 27, 2022)
21) Ball type angle cock valve bodies, of cast iron, for oleohydraulic or pneumatic transmissions (described in statistical reporting number 8481.90.9020)
22) Valve bodies, of aluminum, of valves for oleohydraulic or pneumatic transmissions (described in statistical reporting number 8481.90.9020)
23) Angle cock handle assemblies, of iron and steel, each measuring 11.43 cm by 21.59 cm by 5.08 cm and weighing 0.748 kg (described in statistical reporting number 8481.90.9040)
24) Pipe brackets of aluminum, each with 4 ports, the foregoing measuring 27.9 cm x 20.3 cm x 17.8 cm and weighing 11.34 kg, designed for installation into air brake control valves (described in statistical reporting number 8481.90.9040)
25) Electric motors, AC, permanent split capacitor type, not exceeding 16 W (described in statistical reporting number 8501.10.4020)

26) DC electric motors, of an output of less than 18.65 W, other than brushless, measuring less than 38 mm in diameter (described in statistical reporting number 8501.10.4060)
27) DC motors, of an output exceeding 37.5 W but not exceeding 74.6 W, valued over $2 but not over $30 each (described in statistical reporting number 8501.31.2000)
28) AC motors, multi-phase, of rolled steel frame construction (described in statistical reporting number 8501.51.4040)
29) AC motors, multi-phase, of an output of 186.5 kW or more but not exceeding 373 kW, having a cast iron frame construction (described in statistical reporting number 8501.53.8040)
30) Dual layer printed circuit board assemblies, each valued over $30 but not over $35 (described in statistical reporting number 8504.90.7500)
31) Ring terminals, for a voltage not exceeding 1,000 V (described in statistical reporting number 8536.90.4000)
32) Weather station sets, each consisting of a monitoring display and outdoor weather sensors, having a transmission range of not over 140 m and valued not over $50 per set (described in statistical reporting number 9015.80.8080)
33) Disposable electrocardiograph (ECG) electrodes (described in statistical reporting number 9018.11.9000)
34) Ultrasonic scanning apparatus, each having dimensions not exceeding 122 cm by 77 cm by 127 cm, whether or not presented with transducer (described in statistical reporting number 9018.12.0000)
35) Blood pressure monitors suitable for use by medical professionals (described in statistical reporting number 9018.19.9530)
36) Digital peak flow meters suitable for use by medical professionals (described in statistical reporting number 9018.19.9550)
37) Fingertip pulse oximeters suitable for use by medical professionals (described in statistical reporting number 9018.19.9550)
38) Disposable surface electrodes for Intra-operative neuromonitoring ("IONM") systems, each composed of a surface electrode pad, an insulated wire, and a standard DIN 42802 connector (described in statistical reporting number 9018.19.9560)
39) Parts and accessories of capnography monitors (described in statistical reporting number 9018.19.9560)
40) Anesthetic instruments and appliances suitable for use in medical or surgical sciences, and parts and accessories of the foregoing (described in statistical reporting number 9018.90.3000)
41) Electrosurgical cautery pencils with electrical connectors (described in statistical reporting number 9018.90.6000)
42) Combined positron emission tomography/computed tomography (PET/CT) scanners which utilize multiple PET gantries (frames) on a common base (described in statistical reporting number 9022.12.0000)
43) Radiation therapy systems, each encased by steel-based structural shell with gantry cover comprising three pairs of plastics-based panels (described in statistical reporting number 9022.14.0000)
44) X-ray tube housings and parts thereof (described in statistical reporting number 9022.90.4000)
45) Multi-leaf collimators of radiotherapy systems based on the use of X-ray (described in statistical reporting number 9022.90.6000)

46) Printed circuit board assemblies, of a kind designed for use in X-ray apparatus (described in statistical reporting number 9022.90.6000)
47) Thermostats designed for air conditioning or heating systems, not designed to connect to the internet, the foregoing designed for wall mounting (described in statistical reporting number 9032.10.0030)

(ii) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.02 and provided for in U.S. notes 20(c) and 20(d) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.02. See 83 Fed. Reg. 40823 (August 16, 2018) and 83 Fed. Reg. 47326 (September 18, 2018). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that, as provided in heading 9903.88.69, the additional duties provided for in heading 9903.88.02 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

1) 9025.19.8010
2) 9025.19.8020
3) 9025.19.8085
4) Acrylic acid-2-acrylamido-2-methylpropanesulfonic acid-acrylic ester (AA/AMPS/HPA) terpolymers, presented in dry form (described in statistical reporting number 3906.90.5000)
5) Rolls of polyethylene film coated with a solvent acrylic adhesive (described in statistical reporting number 3919.10.2055)
6) Polyethylene film, 20.32 to 198.12 cm in width, and 30.5 to 2000.5 m in length, coated on one side with solvent acrylic adhesive, clear or in transparent colors, whether or not printed, in rolls (described in statistical reporting number 3919.90.5040 or 3919.90.5060)
7) Films coated on one or both sides with polyvinylidene chloride (PVdC) or polyvinyl alcohol (PVOH), whether or not having a primer layer between the base and coating; any of the foregoing having a total thickness greater than 0.01 mm but not greater than 0.03 mm (described in statistical reporting number 3920.62.0090)
8) Gas (natural or liquid propane (LP)) engines each having a displacement of more than 2 liters but not more than 2.5 liters (described in statistical reporting number 8407.90.9010)
9) Dispensers of hand-cleaning or hand-sanitizing solutions, whether employing a manual pump or a proximity-detecting battery-operated pump, each article weighing not more than 3 kg (described in statistical reporting number 8424.89.9000)
10) Electric motors, with an output of 18.65 W or more but not exceeding 37.5 W, with attached cables, designed for use in adjusting motor vehicle seats (described in statistical reporting number 8501.10.6080)
11) DC electric motors, 24 V, with an output not exceeding 515 W, measuring not over 95 mm in outside diameter, not over 155 mm in length and with a shaft not over 30 mm in length (described in statistical reporting number 8501.31.4000)
12) DC electric motors, with an output exceeding 74.6 W but not exceeding 735 W, containing lead wires and an electrical connector (described in statistical reporting number 8501.31.4000)
13) DC motors with a power output exceeding 74.6 W but not exceeding 230 W, measuring less than 105 mm in diameter and 50 mm or more but not over 100 mm in length (described in statistical reporting number 8501.31.4000)

14) DC motors, of an output exceeding 74.6 W but not exceeding 735 W, each valued not over $18 (described in statistical reporting number 8501.31.4000)
15) Ground Fault Circuit Interrupters (GFCIs), Appliance Leakage Current Interrupters (ALCIs), Leakage Current Detection Interrupters (LCDIs), and Arc Fault Circuit Interrupters (AFCIs) (described in statistical reporting number 8536.30.8000)
16) Electronic AC passive infrared (PIR) motion sensing switches (described in statistical reporting number 8536.50.7000)
17) Position or speed sensors for motor vehicle transmission systems, each valued not over $12 (described in statistical reporting number 8543.70.4500)
18) Apparatus using passive infrared detection sensors designed for turning lights on and off (described in statistical reporting number 8543.70.9960 prior to January 27, 2022; described in statistical reporting number 8543.70.9860 effective January 27, 2022)
19) Liquid leak detectors (described in statistical reporting number 8543.70.9960 prior to January 27, 2022; described in statistical reporting number 8543.70.9860 effective January 27, 2022)
20) Robots, programmable, measuring not more than 40 cm high by 22 cm wide by 27 cm deep, incorporating an LCD display, camera and microphone but without "hands" (described in statistical reporting number 8543.70.9960 prior to January 27, 2022; described in statistical reporting number 8543.70.9860 effective January 27, 2022)
21) Motorcycles (including mopeds), with reciprocating internal combustion piston engine of a cylinder capacity not exceeding 50 cc, valued not over $500 each (described in statistical reporting number 8711.10.0000)
22) Portable, wireless enabled, electrical gas monitors (described in statistical reporting number 9027.10.2000)

(iii) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.03 and provided for in U.S. notes 20(e) and 20(f) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.03, and by which particular products classified in heading 9903.88.04 and provided for in U.S. note 20(g) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.04. See 83 Fed. Reg. 47974 (September 21, 2018) and 84 Fed. Reg. 29576 (June 24, 2019). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that, as provided in heading 9903.88.69, the additional duties provided for in heading 9903.88.03 or in heading 9903.88.04 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

1) 0304.72.5000
2) 0304.83.1015
3) 0304.83.1020
4) 0304.83.5015
5) 0304.83.5020
6) 0304.83.5090
7) 3808.94.5010
8) 3923.21.0095
9) 5603.92.0090 prior to July 1, 2022; 5603.92.0070 or 5603.92.0095 effective July 1, 2022
10) 5603.93.0090
11) 6505.00.8015
12) 8424.90.9080
13) 8425.31.0100

14) King crab meat, frozen in blocks each weighing at least 1 kg but not more than 1.2 kg, in airtight containers (described in statistical reporting number 1605.10.2010)
15) Snow crab meat (C. opilio), frozen in blocks, in airtight containers each with net weight of not more than 1.2 kg (described in statistical reporting number 1605.10.2022)
16) Dungeness crab meat, frozen in blocks, in airtight containers with net weight of not more than 1.2 kg (described in statistical reporting number 1605.10.2030)
17) Crab meat (other than King crab, Snow crab, Dungeness or swimming crabs), frozen in blocks, in airtight containers with net weight of not more than 1.5 kg (described in statistical reporting number 1605.10.2090)
18) Sodium metal (CAS No. 7440-23-5), in bulk solid form (described in statistical reporting number 2805.11.0000)
19) Sodium adipate (1,4-butanedicarboxylic acid, disodium salt) (IUPAC name: disodium hexanedioate) (CAS No. 7486-38-6) (described in statistical reporting number 2917.12.5000)
20) N-(n-Butyl)thiophosphoric triamide (IUPAC name: N-Diaminophosphinothioylbutan-1-amine) (CAS No. 94317-64-3) (described in statistical reporting number 2929.90.5090 prior to January 1, 2024; described in statistical reporting number 2929.90.5095 effective January 1, 2024)
21) Supported nickel-based catalysts, of a kind used for methanation, desulfurization, hydrogenation, pre-reforming or reforming of organic chemicals or for protection of hydrotreating catalysts from arsine poisoning (described in statistical reporting number 3815.11.0000)
22) Supported catalysts for polymerization (described in statistical reporting number 3815.19.0000)
23) Supported catalysts of copper oxide or zinc oxide as the active ingredients for arsine removal (described in statistical reporting number 3815.19.0000)
24) Supported catalysts with copper carbonate or zinc carbonate as the active ingredients for low temperature desulfurization (described in statistical reporting number 3815.19.0000)
25) Supported catalysts with metal sulfide as the active substance for mercury removal (described in statistical reporting number 3815.19.0000)
26) Supported catalysts with molybdenum compounds as the active substance for hydrogenation (described in statistical reporting number 3815.19.0000)
27) Supported catalysts with zinc oxide as the active substance (described in statistical reporting number 3815.19.0000)
28) One-piece stoppers, of polypropiolactone ("PPL") or polylactic acid ("PLA") polymers, each comprising a disc-shaped top attached to a rounded, tapered plug with a protruding stirrer, measuring at least 55 mm but not more than 120.7 mm in overall length, and weighing at least 0.6 g but not more than 1.1 g each, of a kind used with lids for beverage containers (described in statistical reporting number 3923.50.0000)
29) Backpacks with outer surface of textile materials of man-made fibers, each measuring at least 35 cm but not more than 75 cm in height, at least 19 cm but not more than 34 cm in width, and at least 5 cm but not more than 26 cm in depth (described in statistical reporting number 4202.92.3120)
30) Silk fabrics, containing 85 percent or more by weight of silk or of silk waste other than noil silk, the foregoing not printed, not jacquard woven, measuring over 127 cm in width (described in statistical reporting number 5007.20.0065)
31) Silk fabrics, containing 85 percent or more by weight of silk or of silk waste other than noil silk, the foregoing not printed, not jacquard woven, measuring 107 cm or

more but not over 127 cm in width (described in statistical reporting number 5007.20.0085)

32) Long pile knit fabrics, of acrylic pile on polyester ground, valued not over $16 per m2 (described in statistical reporting number 6001.10.2000)

33) Sandstone known as brown wave, of a kind used in outdoor living spaces, containing one textured side and up to four chiseled edges with a density of 2,750 kg/m3 (described in statistical reporting number 6802.99.0060 prior to July 1, 2023; described in statistical reporting number 6802.99.0090 effective July 1, 2023)

34) Sandstone with a flamed finish on one side and a length of 200 mm or more but not over 3,100 mm, a width of 100 mm or more but not over 1,380 mm and a thickness of 30 mm or more but not over 180 mm (described in statistical reporting number 6802.99.0060 prior to July 1, 2023; described in statistical reporting number 6802.99.0090 effective July 1, 2023)

35) Grinding beads of yttria-stabilized zirconia (described in statistical reporting number 6909.11.2000)

36) Screen protectors of tempered safety glass, transparent, cut, and treated, with adhesive on one side, in rectangular sheets, each weighing at least 6 g but not more than 77 g, each measuring not less than 2.8 cm but not more than 28 cm in height, not less than 1.9 cm but not more than 21 cm in width, and not more than 0.1 cm in thickness (described in statistical reporting number 7007.19.0000)

37) Sheets of tempered safety glass, coated with silicone oxide, having a surface area of less than 2.5 m2, designed to be placed over solar cell panels for protection from external damage (described in statistical reporting number 7007.19.0000)

38) Rear-view mirrors of convex glass for motor vehicles, each measuring not less than 1.75 mm and not more than 2.4 mm in thickness, not less than 125 mm and not more than 210 mm in length, not less than 97 mm and not more than 180 mm in width, weighing not less than 74 g and not more than 188 g (described in statistical reporting number 7009.10.0000)

39) Rear-view mirrors of flat glass for motor vehicles, each measuring not less than 1.75 mm but not more than 2.4 mm in thickness, not less than 163 mm but not more than 210 mm in length, not less than 107 mm but not more than 167 mm in width and weighing not less than 80 g but not more than 188 g (described in statistical reporting number 7009.10.0000)

40) Tiles of non-recycled glass on a vinyl mesh backing, in a grid pattern of not less than 304 mm by 304 mm and not exceeding 305 mm by 305 mm, for mosaics or other decorative or construction purposes (described in statistical reporting number 7016.10.0000)

41) Cable hooks of steel, each weighing not less than 0.2 kg, measuring not less than 9 cm in length, not less than 5 cm in width and not less than 1 cm in height with spring loaded closure gate (described in statistical reporting number 7326.90.8688)

42) Kitchen and table implements of iron or steel, non-electric, including but not limited to peelers, graters and whisks (described in statistical reporting number 8205.51.3030)

43) Cooling medium pumps for internal combustion piston engines of the motor vehicles of headings 8703 or 8704 (described in statistical reporting number 8413.30.9090)

44) DC blowers for use in motor vehicle climate control systems, each measuring no less than 323 mm by 122 mm by 102 mm and no more than 357 mm by 214 mm by 167 mm (described in statistical reporting number 8414.59.6540)

45) DC centrifugal radial blowers, each measuring not less than 345 mm by 122 mm by 102 mm and not more than 355 mm by 173 mm by 145 mm, of an output of 100 W to

285 W, and weighing at least 1.80 kg but no more than 2.72 kg (described in statistical reporting number 8414.59.6560)

46) Electric display cases incorporating refrigerating equipment designed for commercial use, each with a glass front to display the food or drink being stored (described in statistical reporting number 8418.50.0080)

47) Printed circuit assemblies for rendering images onto computer screens ("graphics processing modules") (described in statistical reporting number 8473.30.1180)

48) Printed circuit assemblies to enhance the graphics performance of automatic data processing (ADP) machines ("accelerator modules") (described in statistical reporting number 8473.30.1180)

49) Printed circuit assemblies, constituting unfinished logic boards (described in statistical reporting number 8473.30.1180)

50) Parts and accessories of machines of heading 8471, whether or not incorporating fan hubs or LEDs but not incorporating other goods of heading 8541 or 8542 (described in statistical reporting number 8473.30.5100)

51) Electric gear motors, single phase AC, of an output of 74.6 W or more but not exceeding 228 W, each with a spring, a coupling, and a locking connector, the assembly measuring not more than 30 cm in length, not more than 11 cm in width, not more than 16 cm in height (described in statistical reporting number 8501.40.4020)

52) AC motors, single phase, each of an output exceeding 74.6 W but not exceeding 335 W, measuring not more than 13 cm in diameter and not more than 13 cm in height and with a shaft measuring not more than 39 cm in length (described in statistical reporting number 8501.40.4040)

53) Power adapters for a weather sensor or weather station display (described in statistical reporting number 8504.40.9580)

54) Starter motors for internal combustion gasoline engines designed for use in the lawn, automotive, watercraft, motorcycle, industrial and garden industries (described in statistical reporting number 8511.40.0000)

55) Electric fireplaces, weighing not more than 55 kg (described in statistical reporting number 8516.29.0090)

56) Printed circuit boards, each with a base wholly of plastics impregnated glass, not flexible, with 4 layers of copper (described in statistical reporting number 8534.00.0020)

57) Printed circuit boards, each with a base wholly of plastics impregnated glass, not flexible, with 2 layers of copper (described in statistical reporting number 8534.00.0040)

58) Gas ignition safety controls, measuring 3.8 to 5.3 cm in height, 6.4 to 10.1 cm in width and 13.2 to 13.9 cm in depth; weighing 160 g to 380 g each; and valued not over $26 each; of a kind used in patio heaters, agricultural heaters or clothes dryers (described in statistical reporting number 8537.10.9170)

59) Digital sound processing apparatus capable of connecting to a wired or wireless network for the mixing of sound, each capable of mixing 16, 24, 32 or 64 channel, each measuring not more than 17 cm in height, not more than 60 cm in depth, and not more than 83 cm in width (described in statistical reporting number 8543.70.9100)

60) Insulated electric conductors for a voltage not exceeding 1,000 V, fitted with connectors of a kind used for telecommunications, each valued over $0.35 but not over $2 (described in statistical reporting number 8544.42.2000)

61) Insulated conductors, not of a kind used for telecommunications, for a voltage not exceeding 1,000 V, each with polyvinyl chloride (PVC) covers and connectors at

each end in bundles of 3, 5 or 6 for use in connecting patients to monitoring devices (described in statistical reporting number 8544.42.9090)

62) Junction box assemblies, of a kind used in solar panels, incorporating three bypass diodes and two insulated cables fitted with connectors, for a voltage not more than 1,000 V (described in statistical reporting number 8544.42.9090)
63) Park gear blanks of Society of Automotive Engineers ("SAE") 1520 carbon steel (described in statistical reporting number 8708.40.7570)
64) Stator shafts of Stahlwerk Annahutte ZF34C grade carbon steel (described in statistical reporting number 8708.40.7570)
65) Wheeled trailers suitable for towing behind an adult bicycle, each comprising a frame of aluminum with a hitch mechanism, weighing not more than 17.5 kg, with a capacity of not more than 46 kg, with those trailers designated for carrying children meeting ASTM International standard F1975 (described in statistical reporting number 8716.40.0000)
66) Upholstered seats with wooden frames other than chairs, not of cane, osier, bamboo or similar materials, each measuring at least 144 cm but no more than 214 cm in width, at least 81 cm but no more than 89 cm in height and at least 81 cm but not more than 163 cm in depth (described in statistical reporting number 9401.61.6011)
67) Unassembled upholstered chairs with metal frames, other than household chairs, with seats and backs having a shell of plastics or wood and measuring at least 48 cm but not more than 61 cm in width (described in statistical reporting number 9401.71.0031)
68) Hunting stands of steel or aluminum (including ladder stands, pod stands, hang-on stands and climbing stands), each of which allows one or more hunters to ascend to a height and sit while waiting for game animals to appear (described in statistical reporting number 9401.79.0035)
69) Parts of chairs of unfinished plywood, including bodies, legs and arms (described in statistical reporting number 9401.90.4080 prior to January 27, 2022; described in statistical reporting number 9401.91.9090 effective January 27, 2022)
70) Baby crib liners, each composed of two pieces of multi-layer warp polyester knit mesh without any padding, one measuring no more than 29 cm by 283 cm and the other measuring no more than 29 cm by 210 cm (described in statistical reporting number 9403.90.6005 prior to January 27, 2022; described in statistical reporting number 9403.99.5005 effective January 27, 2022)

(iv) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.15 and provided for in U.S. notes 20(r) and (s) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.15. See 84 Fed. Reg. 43304 (August 20, 2019), 84 Fed. Reg. 45821 (August 30, 2019), 84 Fed. Reg. 57144 (October 24, 2019) and 85 Fed. Reg. 3741 (January 22, 2020). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that, as provided in heading 9903.88.69, the additional duties provided for in heading 9903.88.15 shall not apply to the following particular products, which are provided for in the following enumerated statistical reporting numbers:

1) 0505.10.0050
2) 0505.10.0055
3) 3401.19.0000
4) 3926.90.9910
5) 5504.10.0000

6) 6210.10.5010
7) 6210.10.5090
8) 6506.10.6030
9) Sodium alginate resins (CAS No. 9005-38-3) (described in statistical reporting number 3913.10.0000)
10) Single-use sterile drapes and covers of plastics, of a kind used to protect the sterile field in surgical operating rooms (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
11) Sterile decanters of polystyrene plastics, each of a kind used to transfer aseptic fluids or medication to and from sterile bags, vials or glass containers (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
12) Babies' sleep sacks of cotton interlock knitted fabric, sleeveless, each with neck opening and two-way zipper (described in statistical reporting number 6111.20.6070)
13) Babies' sleep sacks, knitted, of cotton, each with neck opening and two-way zipper (described in statistical reporting number 6111.20.6070)
14) Dust covers of knitted polyester fabric, designed for bed mattresses and pillows (described in statistical reporting number 6302.10.0020)
15) Protective covers of cotton for pillows, not knitted or crocheted, of cotton, not napped or printed, each with full encasement construction and zipper opening (described in statistical reporting number 6302.31.9040)
16) Cold packs consisting of a single-use, instant, endothermic chemical reaction cold pack combined with a textile exterior lining (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
17) Laparotomy sponges of cotton (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
18) Athletic, recreational and sporting headgear comprising shells of polyvinyl chloride, polycarbonate plastic or acrylonitrile butadiene styrene, each with an inner liner of expanded polypropylene or expanded polystyrene, designed for use with bicycles (described in statistical reporting number 6506.10.6045)
19) Sewing machines of the household type, each weighing not more than 22.5 kg, having a touch screen control, a sewing light, a presser foot lifter and an automatic needle threader (described in statistical reporting number 8452.10.0090)
20) Liquid crystal display ("LCD") modules, not capable of receiving or processing a broadcast television signal, each with a video display diagonal measuring not more than 191 cm (described in statistical reporting number 9013.80.9000 prior to January 27, 2022, described in statistical reporting number 8524.11.9000 effective January 27, 2022)
21) Television liquid crystal display ("LCD") main board assemblies, each consisting of a printed circuit board containing a television tuner and audio and video components (described in statistical reporting number 8529.90.1300)
22) Protective Articles (described in statistical reporting number 9004.90.0000 prior to January 1, 2021; described in statistical reporting number 9004.90.0010 or 9004.90.0090 effective January 1, 2021)
23) Prism binoculars, other than for use with infrared light, comprising a plastic, aluminum or magnesium alloy body with a rubber jacket, with magnification ranging from at least 4X but not more than 22X and aperture ranging from at least 21 mm but not more than 56 mm (described in statistical reporting number 9005.10.0040)

24) Parts of child safety seats (described in statistical reporting number 9401.90.1085 prior to January 27, 2022; described in statistical reporting number 9401.91.1500 or 9401.99.1085 effective January 27, 2022)
25) Pillow shells of cotton, each filled with goose or duck down (described in statistical reporting number 9404.90.1000 prior to January 1, 2023; described in statistical reporting number 9404.90.1060 or 9404.90.1090 effective January 1, 2023)".

3. by amending the last sentence of the first paragraph of U.S. note 20(a) to subchapter III of chapter 99 by:
   a. by deleting "or (16)" and by inserting "(16)" in lieu thereof; and

   b. by inserting"; or (17) heading 9903.88.69 and U.S. note 20(vvv)(i) to subchapter III of chapter 99" after the phrase "U.S. note 20(uuu)(i) to subchapter III of chapter 99", where it appears at the end of the sentence.

4. By amending U.S. note 20(b) to subchapter III of chapter 99 by:

   a. by deleting "or (16)" and by inserting "(16)" in lieu thereof; and

   b. by inserting"; or (17) heading 9903.88.69 and U.S. note 20(vvv)(i) to subchapter III of chapter 99" after the phrase "U.S. note 20(uuu)(i) to subchapter III of chapter 99", where it appears at the end of the sentence.

5. by amending the last sentence of the first paragraph of U.S. note 20(c) to subchapter III of chapter 99 by:

   a. by deleting "or (10)" and by inserting "(10)" in lieu thereof; and

   b. by inserting"; or (11) heading 9903.88.69 and U.S. note 20(vvv)(ii) to subchapter III of chapter 99" after the phrase "U.S. note 20(uuu)(ii) to subchapter III of chapter 99", where it appears at the end of the sentence.

6. by amending U.S. note 20(d) to subchapter III of chapter 99 by:

   a. by deleting "or (10)" and by inserting "(10)" in lieu thereof; and

   b. by inserting"; or (11) heading 9903.88.69 and U.S. note 20(vvv)(ii) to subchapter III of chapter 99" after the phrase "U.S. note 20(uuu)(ii) to subchapter III of chapter 99", where it appears at the end of the sentence.

7. by amending the last sentence of the first paragraph of U.S. note 20(e) to subchapter III of chapter 99 by:

   a. by deleting "or (19)" and by inserting "(19)" in lieu thereof; and

   b. by inserting"; or (20) heading 9903.88.69 and U.S. note 20(vvv)(iii) to subchapter III of chapter 99" after the phrase "U.S. note 20(uuu)(iii) to subchapter III of chapter 99", where it appears at the end of the sentence.

8. by amending U.S. note 20(f) to subchapter III of chapter 99 by:

    a. by deleting "or (19)" and by inserting "(19)" in lieu thereof; and
    b. by inserting"; or (20) heading 9903.88.69 and U.S. note 20(vvv)(iii) to subchapter III of chapter 99" after the phrase "U.S. note 20(uuu)(iii) to subchapter III of chapter 99", where it appears at the end of the sentence.

9. by amending U.S. note 20(g) to subchapter III of chapter 99 by:

    a. by deleting “or (10)” and by inserting “(10)” in lieu thereof; and
    b. by inserting “or (11) heading 9903.88.69 and U.S. note 20(vvv)(iii) to subchapter III of chapter 99” after the phrase “U.S. note 20(ttt)(iii) to subchapter III of chapter 99”, where it appears at the end of the first sentence.

10. by amending the last sentence of the first paragraph of U.S. note 20(r) to subchapter III of chapter 99:

    a. by deleting "or (13)" and by inserting "(13)" in lieu thereof; and

    b. by inserting", or (14) heading 9903.88.69 and U.S. note 20(vvv)(iv) to subchapter III of chapter 99" after "U.S. note 20(uuu)(iv) to sub chapter III of chapter 99".

11. by amending the article description of heading 9903.88.01:

    a. by deleting "9903.88.67 or";

    b. by inserting in lieu thereof "9903.88.67,"; and

    c. by inserting "or 9903.88.69," after "9903.88.68,"

12. by amending the article description of heading 9903.88.02:

    a. by deleting "9903.88.67 or";

    b. by inserting in lieu thereof "9903.88.67,"; and

    c. by inserting "or 9903.88.69," after "9903.88.68,"

13. by amending the article description of heading 9903.88.03:

    a. by deleting “9903.88.67 or”;

    b. by inserting in lieu thereof “9903.88.67,” and

    c. by inserting “or 9903.88.69,” after 9903.88.68,”

14. by amending the article description of heading 9903.88.04:

a. by deleting "9903.88.66 or";

b. by inserting in lieu thereof "9903.88.66," and

c. by inserting "or 9903.88.69," after 9903.88.67,"

15. by amending the article description of heading 9903.88.15:

a. by deleting "9903.88.67 or";

b. by inserting in lieu thereof "9903.88.67," and

c. by inserting "or 9903.88.69," after 9903.88.68,".

Annex D

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(i)(1)		8412.21.0045
20(ttt)(i)(7)		Direct acting and spring return pneumatic actuators, each rated at a maximum pressure of 10 bar and valued over $68 but not over $72 per unit (described in statistical reporting number 8412.39.0080)
20(ttt)(i)(8)		Centrifugal pumps, submersible, other than for use with machines for making cellulosic pulp, paper or paperboard; the foregoing pumps rated not over 1.5 KW (described in statistical reporting number 8413.70.2004)
20(ttt)(i)(9)		Breast pumps, whether or not with accessories or batteries (described in statistical reporting number 8413.81.0040)
20(ttt)(i)(10)		Housings for water pumps of subheading 8413.30.90 (as described in subheading 8413.91.9010)
20(ttt)(i)(16)		Solar water heaters incorporating glass tube heat collectors and including glass tubes and stands with tanks (described in statistical reporting number 8419.19.0040 prior to January 27, 2022; described in statistical reporting number 8419.12.0000 effective January 27, 2022)
20(ttt)(i)(18)		Thermal roll laminators, each valued not over $450 (described in statistical reporting number 8420.10.9040)
20(ttt)(i)(19)		Roller machines designed for cutting, etching or embossing paper, foil or fabric, manually powered (described in statistical reporting number 8420.10.9080)
20(ttt)(i)(20)		Roller machines with dies for embossing paper, manually powered (described in statistical reporting number 8420.10.9080)
20(ttt)(i)(23)		Filtering or purifying machinery or apparatus of a kind used for waste water treatment (described in statistical reporting number 8421.21.0000)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(i)(24)		Hand-held ultraviolet water purifiers, powered by batteries (described in statistical reporting number 8421.21.0000)
20(ttt)(i)(26)		Filters designed to remove sulfites from wine (described in statistical reporting number 8421.22.0000)
20(ttt)(i)(29)		Parts of swimming pool vacuum cleaners (described in statistical reporting number 8421.99.0040 prior to January 27, 2022; described in statistical reporting number 8421.99.0140 effective January 27, 2022)
20(ttt)(i)(30)		Ratchet winches designed for use with textile fabric strapping (described in statistical reporting number 8425.39.0100)
20(ttt)(i)(31)		Garage door opener/closers (described in statistical reporting number 8428.90.0290 prior to January 27, 2022; described in statistical reporting number 8428.90.0390 effective January 27, 2022)
20(ttt)(i)(32)		Pile drivers, diesel powered (described in statistical reporting number 8430.10.0000)
20(ttt)(i)(35)		Welded frames designed to support conveyor rollers (described in statistical reporting number 8431.39.0010)
20(ttt)(i)(36)		Vulcanized rubber tracks, each incorporating cords and cleats of steel, designed for use on construction equipment (described in statistical reporting number 8431.49.9095)
20(ttt)(i)(39)		Automated data processing storage units (other than magnetic disk drive units), not assembled in cabinets for placing on a table or similar place, not presented with any other unit of a system (described in statistical reporting number 8471.70.6000)
20(ttt)(i)(2)		8481.10.0090
20(ttt)(i)(44)		Armatures designed for use in hydraulic solenoid valves (described in statistical reporting number 8481.90.9040)
20(ttt)(i)(45)		C-poles, of steel, designed for use in hydraulic solenoid control valves (described in statistical reporting number 8481.90.9040)
20(ttt)(i)(46)		Metering spools, of aluminum, designed for use in hydraulic solenoid control valves (described in statistical reporting number 8481.90.9040)
20(ttt)(i)(48)		Poles, of steel, designed for use in hydraulic solenoid control valves (described in statistical reporting number 8481.90.9040)
20(ttt)(i)(49)		Push pins, of steel, designed for use in hydraulic solenoid control valves (described in statistical reporting number 8481.90.9040)
20(ttt)(i)(50)		Retainers, of steel, designed for use in hydraulic solenoid control valves (described in statistical reporting number 8481.90.9040)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(i)(51)		Coupling covers, including center members, flanged hubs, sleeves and shoes (described in statistical reporting number 8483.90.8010)
20(ttt)(i)(55)		DC motors, electronically commutated, three-phase, eight-pole of a kind used in HVAC systems, of an output of 750 W, valued not over $100 each (described in statistical reporting number 8501.31.6000)
20(ttt)(i)(58)		AC multi-phase motors, each of an output exceeding 300 kW but not exceeding 310 kW, fitted with pulleys and brakes to raise and lower passenger elevators (described in statistical reporting number 8501.53.8040)
20(ttt)(i)(60)		Speed drive controllers for electric motors, each such controller measuring 100 mm or more but not over 130 mm in length, 40 mm or more but not over 125 mm in width and 24 mm or more but not over 85 mm in height (described in statistical reporting number 8504.40.4000)
20(ttt)(i)(59)		Regenerative speed drive controllers for controlling speed of electric motors for elevators (described in statistical reporting number 8504.40.4000)
20(ttt)(i)(62)		Speed drive controllers for electric motors, each such controller measuring 100 mm or more but not over 130 mm in length, 40 mm or more but not over 125 mm in width and 24 mm or more but not over 85 mm in height (described in statistical reporting number 8504.40.4000)
20(ttt)(i)(4)		8525.60.1010
20(ttt)(i)(63)		Aluminum electrolytic capacitors, each valued not over $3.20 (described in statistical reporting number 8532.22.0085)
20(ttt)(i)(64)		Rotary switches, rated at over 5 A, measuring not more than 5.5 cm by 5.0 cm by 3.4 cm, each with 2 to 8 spade terminals and an actuator shaft with D-shaped cross section (described in statistical reporting number 8536.50.9025)
20(ttt)(i)(65)		Rotary switches, single pole, single throw (SPST), rated at over 5 A, each measuring not more than 14.6 cm by 8.9 cm by 14.1 cm (described in statistical reporting number 8536.50.9025)
20(ttt)(i)(66)		Modular light switches, for a voltage not exceeding 1,000 V, presented in polyethylene terephthalate (PET) housings, designed for use with a backplate (described in statistical reporting number 8536.50.9065)
20(ttt)(i)(67)		Switches designed for use in motor vehicles, driver or passenger activated (described in statistical reporting number 8536.50.9065)
20(ttt)(i)(68)		Coaxial connectors, for a voltage not exceeding 1,000 V, valued over $0.20 but not over $0.30 each (described in statistical reporting number 8536.69.4010)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(i)(69)		Butt splice connectors, for a voltage not exceeding 1,000 V, each valued not over $3 (described in statistical reporting number 8536.90.4000)
20(ttt)(i)(71)		Twist-on wire connectors, for a voltage not exceeding 1,000 V, each valued not over $0.03 (described in statistical reporting number 8536.90.4000)
	20(uuu)(i)(2)	S-band and X-band linear accelerators designed for use in radiation surgery or radiation therapy equipment (described in statistical reporting number 8543.10.0000)
20(ttt)(i)(72)		Zinc anodes for use with machines and apparatus for electroplating, electrolysis or electrophoresis (described in statistical reporting number 8543.30.9080)
20(ttt)(i)(73)		Stereoscopic microscopes, not provided with a means for photographing the image, valued not over $500 per unit (described in statistical reporting number 9011.10.8000)
20(ttt)(i)(74)		Adapter rings, tubes and extension sleeves, stands and arm assemblies, stages and gliding tables, eyeguards and focusing racks, all the foregoing designed for use with compound optical microscopes (described in statistical reporting number 9011.90.0000)
20(ttt)(i)(75)		Depth-sounding apparatus, each valued not over $50 (described in statistical reporting number 9014.80.2000)
20(ttt)(i)(77)	20(uuu)(i)(8)	Bismuth germanate crystals with set dimensional and surface finish requirements and used as a detection element in Positron Emission Tomography (PET) detectors (described in statistical reporting number 9018.19.9560)
	20(uuu)(i)(9)	Magnetic resonance imaging ("MRI") patient enclosure devices, each incorporating radio frequency and gradient coils (described in statistical reporting number 9018.19.9560)
	20(uuu)(i)(12)	Otoscopes (described in statistical reporting number 9018.90.2000)
	20(uuu)(i)(13)	Anesthesia masks (described in statistical reporting number 9018.90.3000)
	20(uuu)(i)(16)	Printed circuit board assemblies designed for use in displaying operational performance of medical infusion equipment (described in statistical reporting number 9018.90.7580)
20(ttt)(i)(82)	20(uuu)(i)(18)	X-ray tables (described in statistical reporting number 9022.90.2500)
20(ttt)(i)(86)	20(uuu)(i)(22)	Vertical stands specially designed to support, contain or adjust the movement of X-ray digital detectors, or the X-ray tube and collimator in complete X-ray diagnostic systems (described in statistical reporting number 9022.90.6000)
	20(uuu)(i)(21)	Parts and accessories, of metal, for mobile X-ray apparatus (described in statistical reporting number 9022.90.6000)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
	20(uuu)(i)(23)	Thermoplastic masks of polycaprolactone for the use of immobilizing patients, during the use of alpha, beta or gamma radiations, for radiography or radiotherapy (described in statistical reporting number 9022.90.9500)
20(ttt)(i)(87)	20(uuu)(i)(24)	Inoculator sets of plastics, each consisting of a plate with multiple wells, a display tray, and a lid; when assembled, the set measuring 105 mm or more but not exceeding 108 mm in width, 138 mm or more but not exceeding 140 mm in depth, and 6.5 mm or less in thickness (described in statistical reporting number 9027.90.5650)
20(ttt)(i)(89)		Battery balancers designed for regulating voltage across batteries, other than for 6, 12 or 24 volt systems (described in statistical reporting number 9032.89.4000)
	20(uuu)(ii)(5)	Molded acrylonitrile-butadiene-styrene (ABS) tubes, of a kind used to effect the sterile transfer of fluid from a bag or vial to another container, each tube measuring 7.5 cm or more but not exceeding 23 cm in length, with an inner diameter of less than 0.65 cm and an outer diameter of less than 9 cm, one end having been angle-cut to form a spike, and having an integrated flange, less than 3 cm in diameter (splash guard) near the spike end and removable polyethylene caps on each end, put up in sterile packing (described in statistical reporting number 3917.29.0090)
20(ttt)(ii)(2)		Electrical tape of polyvinyl chloride, in rolls, measuring not more than 2 cm in width, not more than 20.2 m in length, and not more than 0.18 mm in thickness (described in statistical reporting number 3919.10.2020)
20(ttt)(ii)(3)		Transparent tape of plastics with an acrylic emulsion adhesive, in rolls measuring not over 4.8 cm in width, valued not over $.25 per square meter (described in statistical reporting number 3919.10.2030)
	20(uuu)(ii)(6)	Rectangular sheets of high-density or low-density polyethylene, 111.75 cm to 215.9 cm in width, and 152.4 cm to 304.8 cm in length, with a sticker attached to mark the center of each sheet, of a kind used in hospital or surgery center operating rooms (described in statistical reporting number 3920.10.0000)
20(ttt)(ii)(6)		Rolls of polyvinyl chloride, measuring 2.5 cm or more but not exceeding 5.1 cm in width and 182.9 m in length (described in statistical reporting number 3920.43.5000)
20(ttt)(ii)(8)		Printed film of polyvinyl chloride, laminated with foamed-polyvinyl chloride-coated polyester scrim, in rolls, of a kind used for lining shelves or drawers (described in statistical reporting number 3921.12.1100)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(ii)(9)	20(uuu)(ii)(7)	Sheets and strips consisting of both cross-linked polyethylene and ethylene vinyl acetate, of a width greater than 1 m but not greater than 1.5 m, and a length greater than 1.75 m but not greater than 2.6 m (described in statistical reporting number 3921.19.0000)
	20(uuu)(ii)(8)	Polyethylene sheet and film laminated with spunbond-spunbond-spunbond nonwoven polypropylene fabric, measuring 1.12 m or more but not over 1.52 m in width and 1.93 m or more but not over 2.29 m in length, and weighing 55 g/m² or more but not exceeding 88 g/m² (described in statistical reporting number 3921.90.1500)
20(ttt)(ii)(12)		Walk behind rotary tillers, electric powered, individually weighing less than 14 kg (described in statistical reporting number 8432.29.0060)
20(ttt)(ii)(13)		AC motors, of 18.65 W or more but not exceeding 37.5 W, each with attached actuators, crankshafts or gears (described in statistical reporting number 8501.10.6020)
20(ttt)(ii)(15)		DC electric motors, 12 V, with an output exceeding 74.6 W but not exceeding 735 W, with lead wires and electrical connector, measuring not over 75 mm outside diameter, with a housing not over 100 mm in length and a shaft not over 60 mm in length (described in statistical reporting number 8501.31.4000)
20(ttt)(ii)(16)		DC electric motors, 230 V, with an output not exceeding 140 W, measuring not more than 45 mm in diameter and not over 100 mm in length (described in statistical reporting number 8501.31.4000)
20(ttt)(ii)(24)		Wheel speed sensors for anti-lock motor vehicle braking systems, each valued not over $12 (described in statistical reporting number 8543.70.4500)
20(ttt)(ii)(28)		Monopolar conductors for a voltage exceeding 1,000 V, other than of copper and not fitted with connectors (described in statistical reporting number 8544.60.6000)
20(ttt)(ii)(29)		Follower block plates, designed for use with buffering/cushioning systems of freight railcars of heading 8606 (described in statistical reporting number 8607.30.1000)
20(ttt)(ii)(31)		Motorcycles with electric power for propulsion, each of a power not exceeding 1,000 W (described in statistical reporting number 8711.60.0000 prior to July 1, 2019; described in statistical reporting numbers 8711.60.0050 or 8711.60.0090, effective July 1, 2019)
20(ttt)(ii)(32)		Digital clinical thermometers (described in statistical reporting number 9025.19.8040 prior to July 1, 2020; described in statistical reporting number 9025.19.8010 or 9025.19.8020 effective July 1, 2020)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(ii)(33)		Digital clinical thermometers, valued not over $11 each (described in statistical reporting number 9025.19.8040 prior to July 1, 2020; described in statistical reporting number 9025.19.8010 or 9025.19.8020 effective July 1, 2020)
	20(uuu)(ii)(3)	9025.19.8060
20(ttt)(iii)(20)		Alaskan sole (yellowfin, rock or flathead), frozen in blocks, in cases with net weight of more than 4.5 kg (described in statistical reporting number 0304.83.5015)
20(ttt)(iii)(26)		1-Cyanoguanidine (Dicyandiamide) (CAS No. 461-58-5) (described in statistical reporting number 2926.20.0000)
	20(uuu)(iii)(11)	Disposable cloths of nonwoven textile materials impregnated, coated or covered with organic surface-active preparations for washing the skin, put up for retail sale (described in statistical reporting number 3401.30.5000 prior to January 27, 2022; described in statistical reporting number 3401.11.5000 effective January 27, 2022)
20(ttt)(iii)(28)		Artificial graphite, in powder form (described in statistical reporting number 3801.10.5000)
20(ttt)(iii)(29)		Artificial graphite, in powder or flake form, for manufacturing into the lithium-ion anode component of batteries (described in statistical reporting number 3801.10.5000)
20(ttt)(iii)(30)		Natural graphite, in powder form (described in statistical reporting number 3801.90.0000)
20(ttt)(iii)(31)		Herbicide consisting of 1,1'-dimethyl-4,4 '-bipyridinium dichloride (CAS No. 1910-42-5) (Paraquat concentrate in liquid form) up to45 percent concentration with application adjuvants (described in statistical reporting number 3808.93.1500)
	20(uuu)(iii)(1)	3808.94.1000
20(ttt)(iii)(33)		Plate-type supported catalysts (reaction accelerators) for reduction of nitrous oxides (NOx) with enhanced mercury oxidation, with oxides of base metals being the active substances, applied to a stainless steel mesh (described in statistical reporting number 3815.19.0000)
20(ttt)(iii)(34)		Plate-type supported catalysts (reaction accelerators) for reduction of nitrous oxides (NOx), with base metals being the active substances, applied on a titanium dioxide based ceramic material to a stainless steel mesh (described in statistical reporting number 3815.19.0000)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(42)		Mixtures of hydrofluorocarbons, containing 40 to 44 percent by weight of 1,1,1,2- tetrafluoroethane (CAS No. 811-97-2), 56 to 60 percent by weight of pentafluoroethane (CAS No. 354-33-6) and up to 2 percent by weight of lubricating oil (described in statistical reporting number 3824.78.0020 prior to January 27, 2022; described in statistical reporting number 3827.62.0000 effective January 27, 2022)
20(ttt)(iii)(43)		Refrigerant gas R-421B, comprising mixtures containing at least 83 percent but not more than 87 percent by weight of pentafluoroethane, at least 13 percent but not more than 17 percent by weight of 1,1,2,2-tetrafluoroethane, and at least 0.5 percent but not more than 2 percent by weight of lubricant (described in statistical reporting number 3824.78.0020 prior to January 27, 2022; described in statistical reporting number 3827.62.0000 effective January 27, 2022)
20(ttt)(iii)(41)	20(uuu)(iii)(12)	Mixtures containing N,Ndimethyldodecan-1-amine (CAS No. 112-18-5) and N,N- dimethyltetradecan-1-amine (CAS No. 112-75-4) (described in statistical reporting number 3824.99.9297 prior to January 27, 2022; described in 3824.99.9397 effective January 27, 2022)
	20(uuu)(iii)(13)	Silicon monoxide (SiO) (CAS No. 10097-28-6) in powder form (described in statistical reporting number 3824.99.9297 prior to January 27, 2022; described in statistical reporting number 3824.99.9397 effective January 27, 2022)
	20(uuu)(iii)(14)	Flexible gas sampling tubes, pipes and hoses, of polyvinyl chloride, with lock connectors at each end (described in statistical reporting number 3917.33.0000)
	20(uuu)(iii)(15)	Flexible oxygen tubes, pipes and hoses presented with integrated molded connectors, of polyvinyl chloride (described in statistical reporting number 3917.33.0000)
	20(uuu)(iii)(16)	Container units of plastics, each comprising a tub and lid therefore, configured or fitted for the conveyance, packing, or dispensing of wet wipes (described in statistical reporting number 3923.10.9000)
	20(uuu)(iii)(17)	Sacks and bags of polymers of ethylene, reclosable, qualifying as Class 1 medical devices by the U.S. Food and Drug Administration under product code NNI (described in statistical reporting number 3923.21.0030)
20(ttt)(iii)(44)	20(uuu)(iii)(18)	Injection molded polypropylene plastic caps or lids each weighing not over 24 grams designed for dispensing wet wipes (described in statistical reporting number 3923.50.0000)
20(ttt)(iii)(8)	20(uuu)(iii)(3)	3926.20.9050

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(46)		Endless synchronous belts of vulcanized rubber, molded polyurethane, neoprene, or welded urethane, each of an outside circumference of 60 cm or more but not more than 77 cm and a width of 2.5 cm or more but not exceeding 4 cm, weighing 0.18 kg or more but not exceeding 0.45 kg (described in statistical reporting number 4010.35.9000)
20(ttt)(iii)(47)		Messenger bags of polyester, each measuring not more than 50 cm by 38 cm by 11 cm, weighing not more than 2.5 kg (described in statistical reporting number 4202.12.8130)
20(ttt)(iii)(48)		Backpacks with hydration system, each measuring not more than 51 cm by 28 cm by 9 cm, weighing not more than 1 kg (described in statistical reporting number 4202.92.0400)
20(ttt)(iii)(50)		Duffel bags made predominantly of man-made fibers, weighing not more than 7 kg, with wheels (described in statistical reporting number 4202.92.3131)
20(ttt)(iii)(51)		Duffel bags of polyester, weighing not more than 7 kg (described in statistical reporting number 4202.92.3131)
20(ttt)(iii)(52)		Covers, of leather, designed for use with telecommunication devices (described in statistical reporting number 4205.00.8000)
	20(uuu)(iii)(4)	4819.50.4060
20(ttt)(iii)(53)		Plates, bowls or cups of molded or pressed bamboo pulp, each weighing at least 3 g but not more than 92 g (described in statistical reporting number 4823.70.0020)
20(ttt)(iii)(54)		Clamshell containers, pizza pans, lids, compartmentalized and other trays of molded or pressed bamboo pulp, each weighing at least 3 g but not more than 95 g (described in statistical reporting number 4823.70.0040)
20(ttt)(iii)(57)		Yarn of cashmere or camel hair, carded but not combed, not put up for retail sale (described in statistical reporting number 5108.10.8000)
20(ttt)(iii)(58)		Woven dyed fabrics of 100 percent textured polyester filament yarn, measuring 332.7 cm in width, weighing more than 170 g/m^2 (described in statistical reporting number 5407.52.2060)
20(ttt)(iii)(59)		Woven fabric of 100 percent textured polyester filaments, dyed, weighing more than 170 g/m^2, measuring not more than 310 cm in width (described in statistical reporting number 5407.52.2060)
20(ttt)(iii)(60)		Woven fabric of synthetic filament yarn containing 85 percent or more by weight of textured polyester filaments, dyed, measuring 249 cm in width, weighing more than 170 g/m^2 (described in statistical reporting number 5407.52.2060)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(61)		Woven dupioni fabric wholly of non-textured dyed polyester filaments, weighing not more than 170 g/m², measuring not more than 310 cm in width (described in statistical reporting number 5407.61.9930)
20(ttt)(iii)(62)		Woven fabric wholly of polyester, dyed, not flat, containing non-textured polyester filaments, weighing not more than 170 g/m², measuring not over 310 cm in width (described in statistical reporting number 5407.61.9930)
20(ttt)(iii)(63)		Woven fabric wholly of polyester, dyed, containing non-textured polyester filaments, weighing more than 170 g/m², measuring not over 310 cm in width (described in statistical reporting number 5407.61.9935)
20(ttt)(iii)(64)		Woven fabric containing by weight 47 percent of nylon and 53 percent of polyester, dyed, containing textured filaments, weighing not more than 170 g/m², measuring greater than 274 cm in width (described in statistical reporting number 5407.72.0015)
20(ttt)(iii)(65)		Polyester filament tow, measuring more than 50 ktex but not more than 275 ktex (described in statistical reporting number 5501.20.0000)
20(ttt)(iii)(66)		Polypropylene fiber tow, measuring more than 50 ktex but not more than 275 ktex (described in statistical reporting number 5501.40.0000)
20(ttt)(iii)(67)		Woven dyed fabrics wholly of spun polyester, weighing more than 240 g/m² and measuring not more than 310 cm in width (described in statistical reporting number 5512.19.0090)
20(ttt)(iii)(9)	20(uuu)(iii)(5)	5603.12.0090 prior to July 1, 2022; 5603.12.0070 or 5603.12.0095 effective July 1, 2022
20(ttt)(iii)(10)		5603.14.9090
20(ttt)(iii)(68)		Non-woven fabrics of polyethylene terephthalate (PET), in sheets measuring not more than 160 cm by 250 cm, weighing more than 1,800 g/m² but not more than 3,000 g/m² (described in statistical reporting number 5603.94.9090)
20(ttt)(iii)(69)		Rugs of hand-knotted pile, of nylon and polypropylene, measuring at least 1.2 m2 (described in statistical reporting number 5701.90.1010)
20(ttt)(iii)(70)		Woven dyed embroidery fabrics containing by weight 55 percent of polyester and 45 percent of nylon, weighing less than 115 g/m² and measuring 289 cm in width (described in statistical reporting number 5810.92.9080)
20(ttt)(iii)(72)		Knitted or crocheted fabrics of artificial staple fibers derived from bamboo (described in statistical reporting number 6003.40.6000)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(81)		Equipment for scaffolding, comprising powder coated or galvanized welded tubular steel frames, braces, guard rail systems, components and accessories, the foregoing for assembly into frame and brace configurations measuring at least 10 cm but not more than 3.3 m in height and at least 4 cm but not more than 8.8 m in width, weighing not more than 91 kg, with a load capacity not more than 2,750 kg (described in statistical reporting number 7308.40.0000)
20(ttt)(iii)(82)		Portable outdoor cooker kits, consisting of at least a burner and stand made from steel and/or cast iron, with an adjustable pressure regulator/hose combination for connecting the burner to a source of natural gas or a portable container of liquefied propane (described in statistical reporting number 7321.11.1060)
20(ttt)(iii)(83)		Grills composed of steel wire, each measuring 49 cm by 47 cm (19.25 inches by 18.5 inches), weighing 0.36 kg (0.80 lbs.), designed as cooking surface of barbecue grill (described in statistical reporting number 7321.90.6090)
20(ttt)(iii)(85)		Nickel hydroxy carbonate (CAS No. 12607-70-4) (described in statistical reporting number 7501.20.0000)
20(ttt)(iii)(86)		Mounting boards of aluminum for guitar sound modifying ("effect") devices, each consisting of an aluminum frame with above ground slots for the placement of devices and floor level slots for the on/off foot-operated pedal switches which control the modifying devices (described in statistical reporting number 7616.99.5190)
20(ttt)(iii)(88)		Automotive polishing attachments specially designed for use with a hand-held drill, each attachment including a 9.5 mm steel drive shaft, internal gear assembly, transverse hand brace and rotating disk components (described in statistical reporting number 8207.90.7585)
20(ttt)(iii)(89)		Bolt-on tips of carbon alloy steel of a kind used in tub or horizontal grinders (described in statistical reporting number 8207.90.7585)
20(ttt)(iii)(90)		Flat panel display mounting adapters of base metal (described in statistical reporting number 8302.50.0000)
20(ttt)(iii)(91)		Stamped and formed brackets of steel (described in statistical reporting number 8302.50.0000)
20(ttt)(iii)(92)		Gun safes with digital keypads, of base metal, each weighing at least 148 kg but not more than 422 kg, measuring at least 141 cm but not more than 183 cm in height, at least 55 cm but not more than 107 cm in width and at least 40 cm but not more than 71 cm in depth (described in statistical reporting number 8303.00.0000)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(93)		Parts suitable for use solely or principally with spark-ignition internal combustion piston engines of heading 8407 for marine propulsion (other than cast-iron parts, not advanced beyond cleaning, and machined only for the removal of fins, gates, sprues and risers or to permit location in finishing machinery or connecting rods) (described in statistical reporting number 8409.91.9290)
20(ttt)(iii)(94)		Hydraulic valve lifters of steel with rollers, suitable for use solely or principally with spark-ignition internal combustion piston engines (other than for aircraft engines, marine propulsion engines or for vehicles of subheading 8701.20, or headings 8702, 8703 or 8704), each measuring 5 cm or more but not over 13 cm in length and 2.5 cm or more but not over 3.9 cm in diameter and weighing 135 g or more but not over 410 g (described in statistical reporting number 8409.91.9990)
20(ttt)(iii)(95)		Solid valve lifters of steel, suitable for use solely or principally with spark-ignition internal combustion piston engines (other than for aircraft engines, marine propulsion engines or for vehicles of subheading 8701.20, or headings 8702, 8703 or 8704), each measuring 19 mm or more but not over 114 mm in length and 6 mm or more but not over 26 mm in diameter and weighing 20 g or more but not over 250 g (described in statistical reporting number 8409.91.9990)
20(ttt)(iii)(96)		Wind turbine hubs (described in statistical reporting number 8412.90.9081)
	20(uuu)(iii)(19)	Hand pumps (other than for fuel or lubricants, not fitted or designed to be fitted with a metering device), each used to dispense a metered quantity of liquid soap or sanitizer (described in statistical reporting number 8413.20.0000)
	20(uuu)(iii)(20)	Hand pumps for liquids (other than those of subheading 8413.11 or 8413.19) of acrylonitrile butadiene styrene (ABS) plastics (described in statistical reporting number 8413.20.0000)
20(ttt)(iii)(98)		Vacuum pumps, each composed of a cast aluminum body and an unalloyed steel cover, measuring not more than 85 mm in length, not more than 75 mm in width and not more than 96 mm in height, with a pump volume not more than 200 cc, for use in automotive braking systems (described in statistical reporting number 8414.10.0000)
20(ttt)(iii)(99)		Hand- or foot-operated air pumps, each weighing 400 g or more but not over 3 kg, with a maximum pressure of 1.52 MPa, imported with adapters for valves for tires and inner tubes (described in statistical reporting number 8414.20.0000)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(103)		Upright coolers incorporating refrigerating equipment, each measuring not more than 77 cm in width, not more than 78 cm in depth and not more than 200 cm in height, weighing not more than 127 kg, with one swing-type transparent glass door (described in statistical reporting number 8418.50.0080)
20(ttt)(iii)(104)		Compact portable shipping scales, of stainless steel, with a maximum weighing capacity of not more than 16 kg, with a digital display, weight below hook, and handles, measuring not less than 19 cm in width, not less than 21 cm in depth, not less than 3 cm in height but not more than 52 cm in width, not more than 41 cm in depth, not more than 13 cm in height (described in statistical reporting number 8423.81.0040)
20(ttt)(iii)(105)		Screw jacks and scissor jacks, each comprising a base, two lift arms and adjustable wheel pads, weighing at least 22 kg but not more than 42 kg, with a weight limit of not more than 342 kg (described in statistical reporting number 8425.49.0000)
20(ttt)(iii)(106)		Sewing machines, not of the household type, not specially designed to join footwear soles to uppers; each such machine weighing 45 kg or more but not over 140 kg, suitable for sewing leather (described in statistical reporting number 8452.29.9000)
20(ttt)(iii)(107)		Trackpad input units for automatic data processing (ADP) machines, each valued over $100 (described in statistical reporting number 8471.60.9050)
20(ttt)(iii)(112)		Ratchet tie down straps, each consisting of straps of textiles measuring not less than 25 mm and not more than 105 mm in width and not more than 12.5 m in length, steel hooks at opposite ends of the straps and a gear and pawl mechanism for adjusting the length of the whole (described in statistical reporting number 8479.89.9499 prior to January 27, 2022; described in statistical reporting number 8479.89.9599 effective January 27, 2022)
20(ttt)(iii)(113)		Hand-operated valves of plastics, each comprising a bottle lid, drinking spout and flavor dispensing valve (described in statistical reporting number 8481.80.5090)
20(ttt)(iii)(114)		Single phase AC electric motors (other than gear motors), of an output of 56 W or more but not exceeding 69 W, each measuring no more than 9 cm in length and no more than 11.5 cm in diameter, weighing no more than 2 kg, in a housing of base metals, with a switch (described in statistical reporting number 8501.40.2040)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(117)		Single-phase AC electric motors incorporating permanent split capacitors, each of an output range of 367 W or more but not exceeding 565 W, operating at not less than 115 V of alternating current (VAC) but not more than 230 VAC, capable of operating while submerged in water, each weighing at least 7 kg but not more than 11 kg, measuring not more than 10 cm in diameter and at least 22 cm but not exceeding 34 cm in length (described in statistical reporting number 8501.40.4040)
20(ttt)(iii)(118)		Single-phase AC electric motors, other than gear motors, whether or not incorporating permanent split capacitors, each of an output range of 746 W or more but not exceeding 1.13 kW, operating at not less than 115 V of alternating current (VAC) but not more than 250 VAC, capable of operating while submerged in water, each weighing at least 9 kg but not more than 12.5 kg, measuring not more than 10 cm in diameter and at least 25 cm but not exceeding 36 cm in length (described in statistical reporting number 8501.40.6040)
20(ttt)(iii)(119)		Power supplies for cable networks, that convert 120 V/60 Hz AC input to either 63 V AC or 87 V AC output, each measuring not more than 200 mm by 425 mm by 270 mm and weighing not more than 27.5 kg, containing printed circuit board assemblies, a transformer, and an oil filled capacitor (described in statistical reporting number 8504.40.8500)
20(ttt)(iii)(120)		Static converters of a kind used to charge telecommunication apparatus in cars or homes, valued not over $2 each (described in statistical reporting number 8504.40.8500)
20(ttt)(iii)(122)		Robotic vacuum cleaners designed for residential use, each with a self-contained electric motor of a power not exceeding 50 W and dust bag/receptacle capacity not exceeding 1 L, whether or not shipped with accessories (described in statistical reporting number 8508.11.0000)
20(ttt)(iii)(123)		Vacuum cleaners, bagless, upright, each with self-contained electric motor of a power not exceeding 1,500 W and having a dust receptacle capacity not exceeding 1 liter (described in statistical reporting number 8508.11.0000)
20(ttt)(iii)(125)		Projectors ("trumpets") of plastics for air horns (described in statistical reporting number 8512.90.2000)
20(ttt)(iii)(126)		Fan-forced portable electric heaters, each with a ceramic heating element (described in statistical reporting number 8516.29.0030)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(127)		Fan-forced, portable electric space heaters, each having a power consumption of not more than 1.5 kW and weighing more than 1.5 kg but not more than 17 kg, whether or not incorporating a humidifier or air filter (described in statistical reporting number 8516.29.0030)
20(ttt)(iii)(128)		Electric fireplace inserts and free-standing electric fireplace heaters, rated at 5,000 British thermal units (BTUs) (described in statistical reporting number 8516.29.0090)
20(ttt)(iii)(130)		Portable countertop air fryers of a kind used for domestic purposes (described in statistical reporting number 8516.60.4070)
20(ttt)(iii)(131)		Tubular electric heating resistors (described in statistical reporting number 8516.80.8000)
20(ttt)(iii)(132)		Closed-loop, digital, video security systems, each consisting of one 4-, 8- or 16-channel digital video recorder (DVR) that connects via cables to at least 2 but no more than 16 color television cameras in housings of plastics, cables and power adapters, put up for retail sale (described in statistical reporting number 8525.80.3010 prior to January 27, 2022; described in statistical reporting number 8525.83.0000 or 8525.89.3000 effective January 27, 2022)
20(ttt)(iii)(133)		Color video cameras for use with microscopes, each camera with C-mount lens mount, weighing not more than 87 g, measuring not more than 109 mm in length and 31 mm in diameter, presented with a cable measuring not more than 1.5 m in length (described in statistical reporting number 8525.80.3010 prior to January 27, 2022; described in statistical reporting number 8525.81.0000, 8525.82.0000, or 8525.89.3000 effective January 27, 2022)
20(ttt)(iii)(134)		Digital color video cameras for use with microscopes, each camera with 10 megapixel resolution, weighing not more than 175 g, measuring 63 mm by 37 mm in length, presented with USB cable, reduction lens, eyepiece adapters, software CD and calibration slide (described in statistical reporting number 8525.80.3010 prior to January 27, 2022; described in statistical reporting number 8525.81.0000, 8525.82.0000, or 8525.89.3000 effective January 27, 2022)
20(ttt)(iii)(135)		Digital color video cameras for use with microscopes, each camera with autofocus, C- mount lens mount, 1080p resolution, weighing not more than 450 g, measuring not more than 67 mm by 67 mm by 81 mm, presented with AC power adapter and power cable (described in statistical reporting number 8525.80.3010 prior to January 27, 2022; described in statistical reporting number 8525.81.0000, 8525.82.0000, or 8525.89.3000 effective January 27, 2022)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
	20(uuu)(iii)(21)	Indicator panels incorporating LEDs, designed for use in medical infusion equipment (described in statistical reporting number 8531.20.0040)
20(ttt)(iii)(137)		Printed circuit boards, with a base of glass reinforced epoxy laminate material that is compliant with NEMA grade FR-4 fire resistance, not flexible, with 10 layers, designed for use in a flow meter, and measuring not more than 6.35 cm by 6.35 cm by 0.1575 cm (described in statistical reporting number 8534.00.0020)
	20(uuu)(iii)(22)	Data input devices each with display capabilities of a kind used for magnetic resonance imaging ("MRI") equipment, computed tomography ("CT") equipment, intraoperative X-ray ("IXR") equipment or patient monitors (described in statistical reporting number 8537.10.9170)
20(ttt)(iii)(142)		Extension cords of copper wire with polyvinyl chloride (PVC) sheaths, for a voltage not exceeding 1,000 V, each measuring at least 9 m but not longer than 16 m in length, with National Electrical Manufacturers Association (NEMA) type 5-15P plug on one end and NEMA type 5-15R receptacle on the other (described in statistical reporting number 8544.42.9010)
20(ttt)(iii)(143)		Extension cords of copper wire with polyvinyl chloride (PVC) sheaths, for a voltage not exceeding 1,000 V, each measuring at least 4 m but not longer than 16 m in length, with National Electrical Manufacturers Association (NEMA) type TT-30P plug on one end and NEMA type TT-30R receptacle on the other or NEMA type 14-50P plug on one end and NEMA type 14-50R receptacle on the other, with handles on each end in the shape of loops (described in statistical reporting number 8544.42.9090)
20(ttt)(iii)(146)		Electrical insulators ("wire nuts") of plastics and steel (described in statistical reporting number 8546.90.0000)
20(ttt)(iii)(147)		Tire carrier attachments, roof racks, fender liners, side protective attachments, the foregoing of steel (described in statistical reporting number 8708.29.5060 prior to January 27, 2022; described in statistical reporting number 8708.29.5160 effective January 27, 2022)
20(ttt)(iii)(148)		Guide pins and guide bolts designed for use in brakes and servo-brakes of subheading 8708.30 (described in statistical reporting number 8708.30.5090)
20(ttt)(iii)(16)		8708.50.8500
20(ttt)(iii)(149)		Flange forgings of Society of Automotive Engineers ("SAE") 1035 carbon steel (described in statistical reporting number 8708.40.7570)
20(ttt)(iii)(150)		Hub forgings of Society of Automotive Engineers ("SAE") 1035 carbon steel (described in statistical reporting number 8708.40.7570)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(153)		Front output shafts of Society of Automotive Engineers ("SAE") 1045 carbon steel suitable for use in automatic transmission systems for passenger motor vehicles (described in statistical reporting number 8708.99.6890)
20(ttt)(iii)(154)		Hitches receivers of steel, not suitable for towing applications, each receiver to be clamped onto the rear bumper of a recreational vehicle, such bumpers being square in section and measuring not more than 102 mm on a side (described in statistical reporting number 8708.99.8180)
20(ttt)(iii)(17)		8712.00.1510
20(ttt)(iii)(18)		8712.00.1520
20(ttt)(iii)(19)		8712.00.1550
20(ttt)(iii)(155)		Bicycles, not motorized, each having aluminum- or magnesium- alloy wheels both measuring more than 69 cm but not more than 71 cm in diameter, tires of cross-sectional diameter of 3.5 cm, aluminum frame, a polyurethane/carbon fiber cord drive belt, 3-, 7- or 12-speed rear hub and twist shifter (described in statistical reporting number 8712.00.2500)
20(ttt)(iii)(156)		Single-speed bicycles having both wheels exceeding 63.5 cm in diameter, weighing less than 16.3 kg without accessories and not designed for use with tires having a cross-sectional diameter exceeding 4.13 cm (described in statistical reporting number 8712.00.2500)
20(ttt)(iii)(157)		Bicycles, not motorized, having both wheels exceeding 63.5 cm in diameter, each having no more than three speeds and a coaster brake (described in statistical reporting number 8712.00.3500)
20(ttt)(iii)(158)		Bicycle frames, of carbon fiber, valued not over $600 each (described in statistical reporting number 8714.91.3000)
20(ttt)(iii)(160)		Casters, with diameter (including, where appropriate, tires) of 20 cm or more but not over 23 cm (described in statistical reporting number 8716.90.3000)
20(ttt)(iii)(161)	20(uuu)(iii)(23)	Compound binocular optical microscopes (other than stereoscopic microscopes and microscopes for photomicrography, cinemicrography or microprojection), each with magnification of 40X or more but not exceeding 1,000X, weighing not more than 3 kg (described in statistical reporting number 9011.80.0000)
20(ttt)(iii)(162)	20(uuu)(iii)(24)	Compound optical microscopes (other than stereoscopic microscopes and microscopes for photomicrography, cinemicrography or microprojection), each with magnification of 40X or more but not exceeding 400X, weighing not more than 15 kg (described in statistical reporting number 9011.80.0000)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(163)		Parts and accessories of meteorological instruments and appliances, each consisting of a wind vane made of plastics and base metal weighing no more than 25 g (described in statistical reporting number 9015.90.0190)
20(ttt)(iii)(164)		Parts and accessories of meteorological instruments and appliances, each consisting of an assembly comprising 3 rotating wind cups, bearings, an internal aspirating fan and one or more solar panels (described in statistical reporting number 9015.90.0190)
20(ttt)(iii)(165)		Parts and accessories of meteorological instruments and appliances, each consisting of an assembly made of plastic and metal comprising 3 wind cups weighing no more than 35 g (described in statistical reporting number 9015.90.0190)
20(ttt)(iii)(166)		Metal casings for, and metal parts of, thermometers of subheading 9025.11.40 designed for use in heating, ventilation and air conditioning ("HVAC") equipment (described in statistical reporting number 9025.90.0600)
20(ttt)(iii)(167)		Hand-held card counters, each consisting of a plastic case containing a circuit board, rechargeable battery and controls, weighing less than 1 kg (described in statistical reporting number 9029.10.8000)
20(ttt)(iii)(168)		60-minute mechanical count-down kitchen timers (described in statistical reporting number 9106.90.8500)
20(ttt)(iii)(170)		Stackable upholstered metal chairs for religious worship settings, capable of interlocking with each other, each with attached holders and racks (described in statistical reporting number 9401.71.0031)
20(ttt)(iii)(173)		Unassembled non-upholstered chairs with metal frames (other than household chairs) with seats and backs having a shell of plastics or wood and measuring at least 48 cm but not more than 61 cm in width (described in statistical reporting number 9401.79.0050)
20(ttt)(iii)(177)		Foot assemblies of base metal and rubber, designed for folding chairs (described in statistical reporting number 9401.90.5081 prior to January 27, 2022; described in statistical reporting number 9401.99.9081 effective January 27, 2022)
20(ttt)(iii)(175)		Bench frames of cast aluminum, each measuring at least 42 cm but not more than 79 cm in height, and at least 52 cm but not more than 62 cm in width (described in statistical reporting number 9401.90.5081 prior to January 27, 2022; described in statistical reporting number 9401.99.9081 effective January 27, 2022)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(176)		Chair frames of metal, each with integral bookshelf, capable of being stacked (described in statistical reporting number 9401.90.5081 prior to January 27, 2022; described in statistical reporting number 9401.99.9081 effective January 27, 2022)
20(ttt)(iii)(178)		Household furniture of metal and high-pressure laminated bamboo (other than ironing boards, furniture for infants or children or bed frames) (described in statistical reporting number 9403.20.0050)
20(ttt)(iii)(180)		Display racks of powder coated steel, whether or not on casters, whether or not with LED lighting, each measuring at least 60 cm but not more than 125 cm in length, at least 60 cm but not more than 125 cm in width and at least 130 cm but not more than 225 cm in height, with slanted shelves with a lip at the front edge of each that measures 3 cm or more in height (described in statistical reporting number 9403.20.0080 prior to July 1, 2019; described in statistical reporting number 9403.20.0081 effective July 1, 2019 through June 30, 2022; described in statistical reporting number 9403.20.0082 effective July 1, 2022)
20(ttt)(iii)(179)		Adjustable wire shelving units of steel, other than for household use, comprising vertical poles, foot caps or casters, clips and shelves, each when fully assembled measuring at least 35 cm or more but not more than 183 m in width, at least 35 cm but not more than 77 cm in depth, and at least 137 cm but not more than 183 cm in height (described in statistical reporting number 9403.20.0081 prior to July 1, 2022; described in statistical reporting number 9403.20.0082 effective July 1, 2022?)
20(ttt)(iii)(181)		Foldable tables with frames of steel and/or aluminum, each measuring 25 cm or more but not over 156 cm in length, 30 cm or more but not over 80 cm in width and 37 cm or more but not over 113 cm in height, with a tabletop surface of aluminum (described in statistical reporting number 9403.20.0090)
20(ttt)(iii)(182)		Household furniture of high-pressure laminated bamboo, other than babies' or children's furniture (described in statistical reporting number 9403.82.0015)
20(ttt)(iii)(184)		Flameless pillar candles with LED lamps powered by batteries, each measuring at least 7.6 cm but not more than 20 cm in diameter and having a wax exterior (described in statistical reporting number 9405.40.8440 prior to January 27, 2022; described in statistical reporting number 9405.42.8440 effective January 27, 2022)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iii)(185)		Flexible strips, each having embedded light-emitting diodes electrically connected to a molded electrical end connector, each strip wound onto a reel measuring not more than 25 cm in diameter and not more than 1.5 cm in width (described in statistical reporting number 9405.40.8440 prior to January 27, 2022; described in statistical reporting number 9405.42.8440 effective January 27, 2022)
20(ttt)(iii)(186)		Garden, patio and table top wick burning torches for outdoor use (described in statistical reporting number 9405.50.4000)
20(ttt)(iii)(187)		Lamp shades of fabric over metal frame (described in statistical reporting number 9405.99.4090)
20(ttt)(iv)(5)	20(uuu)(iv)(3)	5210.11.4040
20(ttt)(iv)(6)	20(uuu)(iv)(4)	5210.11.6020
20(ttt)(iv)(10)		Shower heads of plastics, designed to be fixed, hand-held, height-adjustable or combinations thereof, and parts of such shower heads (described in statistical reporting number 3924.90.5650)
	20(uuu)(iv)(9)	Face shields of transparent plastics, whether or not assembled (described in statistical reporting number 3926.90.9950)
20(ttt)(iv)(13)		Sets of three polyvinyl chloride-coated foam pads, of plastics, of a kind used to assemble flotation work vests by passing adjustable straps with buckles through slots in the pads, each set comprising two irregularly shaped front/side pads and one rectangular back pad (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
20(ttt)(iv)(11)	20(uuu)(iv)(10)	Bowls of molded plastics, with clips for retaining guide wires during surgical procedures (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
20(ttt)(iv)(12)	20(uuu)(iv)(12)	Disposable graduated medicine dispensing cups of plastics (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)
	20(uuu)(iv)(11)	Coverings, of plastics, designed to fit over wound sites or casts thereby forming a protective seal for keeping the covered area dry and debris free while showering or bathing (described in statistical reporting number 3926.90.9990 prior to July 1, 2020; described in statistical reporting number 3926.90.9985 effective July 1, 2020)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iv)(16)		Wallpaper, other than described in subheading 4814.20.00, with floral, landscape, figure or abstract designs or solid backgrounds painted by hand, whether or not with applications of metal leaf (described in statistical reporting number 4814.90.0200)
20(ttt)(iv)(17)		Women's knit robes in chief weight of cotton, with hook and loop tab closure (described in statistical reporting number 6108.91.0030)
20(ttt)(iv)(18)		Babies' gowns of cotton knitted interlock fabric, each with sleeves, neck opening and elasticized bottom opening (described in statistical reporting number 6111.20.6070)
20(ttt)(iv)(21)		Babies' swaddle sacks of cotton knitted interlock fabric, each with sleeves and mitten cuffs (described in statistical reporting number 6111.20.6070)
20(ttt)(iv)(22)		Babies' blanket sleepers of polyester knitted fleece, sleeveless, each with two-way zipper (described in statistical reporting number 6111.30.5015)
20(ttt)(iv)(23)		Men's and boys' cotton terry bathrobes with muslin trim, each beltless but featuring a hook-and-loop tab (described in statistical reporting number 6207.91.1000)
20(ttt)(iv)(24)		Girls' cotton terry bathrobes with muslin trim, each beltless but featuring a hook-and-loop tab (described in statistical reporting number 6208.91.1020)
20(ttt)(iv)(25)		Girls' fleece bathrobes, each beltless but featuring a hook-and-loop tab (described in statistical reporting number 6208.92.0020)
20(ttt)(iv)(26)		Blankets (other than electric blankets) of cotton, woven, each measuring at least 116 cm but not more than 118 cm on an edge (described in statistical reporting number 6301.30.0010)
20(ttt)(iv)(27)		Blankets (other than electric blankets) of cotton, other than woven, each measuring at least 116 cm but not more than 118 cm on an edge (described in statistical reporting number 6301.30.0020)
20(ttt)(iv)(29)		Crib sheets of muslin cotton, fitted with elastic (described in statistical reporting number 6302.31.9020)
	20(uuu)(iv)(8)	6307.90.7200
	20(uuu)(iv)(16)	Hot packs of textile material, single-use (exothermic chemical reaction) (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
	20(uuu)(iv)(18)	Single-use blood pressure cuff sleeves of textile materials (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)

Reinstatement Note (87 FR 17380)	COVID Note (88 FR 31580)	Exclusion Product Description
20(ttt)(iv)(32)	20(uuu)(iv)(19)	Single-use stethoscope covers (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
	20(uuu)(iv)(20)	Woven gauze sponges of cotton in square or rectangular sizes (described in statistical reporting number 6307.90.9889 prior to July 1, 2020; described in statistical reporting number 6307.90.9891 effective July 1, 2020)
20(ttt)(iv)(35)		Tracking devices, each device measuring not more than 86 mm on a side (if rectangular) or 28 mm in diameter (if circular) and not more than 7.5 mm in thickness, not weighing more than 15 g, designed to be attached to another article and to establish a Bluetooth connection with another device for the purposes of providing relative location information (described in statistical reporting number 8517.62.0090)
20(ttt)(iv)(36)		Wireless communication apparatus that can receive audio data to be distributed to wireless speakers (described in statistical reporting number 8518.22.0000)

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee; Notice of Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The FAA announces multiple meetings of the Aviation Rulemaking Advisory Committee (ARAC). This notice announces the date, time, and location of these meetings. The meetings will be ''open to the public'' meeting notice requirements. The purpose of ARAC is to provide information, advice, and recommendations to the Secretary of Transportation, through the FAA Administrator, concerning rulemaking activities, such as aircraft operations, airman and air agency certification, airworthiness standards and certification, airports, maintenance, noise, and training.

DATES: The ARAC will host two public meetings, the first will take place June 13, 2024, from 2:00 p.m. to 4:00 p.m. Eastern Time. The second public meeting will be held on September 12, 2024, from 1:00 p.m. to 4:00 p.m. Eastern Time. The FAA must receive requests to attend the meeting at least two weeks in advance of the meeting.

ADDRESSES: Each meeting will be held at the Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, and virtually on Zoom. However, if the FAA is unable to hold the meeting in person due to circumstances outside of its control, the FAA will hold a virtual meeting, notifying registrants of the meeting details and posting any updates on the FAA Committee website. Members of the public who wish to observe the meeting must RSVP by emailing *9-awa-arac@faa.gov*. General committee information, including copies of the meeting minutes, will be available on the FAA Committee website (*https://www.faa.gov/regulations_policies/rulemaking/committees/documents/*) at least one week in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Aliah Duckett, Federal Aviation Administration, Office of Rulemaking, 800 Independence Avenue SW, Washington, DC 20591, *9-awa-arac@faa.gov* or (202) 267–6952. Any committee-related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

ARAC was established on January 22, 1991, under the Federal Advisory Committee Act (FACA) and pursuant to Title 5 of the United States Code (5 U.S.C. 1001 *et seq.*), as a discretionary committee. The purpose of ARAC is to provide information, advice, and recommendations to the Secretary of Transportation, through the FAA Administrator, concerning rulemaking activities, such as aircraft operations, airman and air agency certification, airworthiness standards and certification, airports, maintenance, noise, and training.

II. Agenda

The agendas for the June 13 and September 12, 2024, meetings will include the following:

- Welcome and Introductions
- Federal Advisory Committee Act (FACA) Statement
- Ratification of Minutes
- Status Updates and Recommendation Reports

A. ARAC
- Airman Certification System Working Group
- Training Standardization Working Group
- Part 65.101 Repairman Certificate Portability Working Group

B. Transport Airplane and Engine (TAE) Subcommittee

- Flight Test Harmonization Working Group
- Ice Crystal Icing Working Group
- Engine and Powerplant Interface Working Group

- Any Other Business
- FAA Update on Regulatory Activities
- Adjourn

Detailed agenda information will be posted on the FAA Committee website address listed in the **ADDRESSES** section at least one week in advance of the meeting.

III. Public Participation

The meeting will be open to the public for virtual or in-person attendance on a first-come, first-served basis, as there is limited space. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section and provide the following information: full legal name, country of citizenship, and name of your industry association or applicable affiliation. Please indicate if you plan to observe the meeting in person or virtually. The FAA will email registrants the meeting access information in a timely manner prior to the start of the meeting.

The DOT 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 of this notice no later than one week prior to each meeting.

The FAA is not accepting oral presentations at the meetings due to time constraints. Members of the public may present written statements to ARAC by providing a copy to the Designated Federal Officer via the email listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than one week before each meeting. Advance submissions that become part of the committee deliberations will become part of the official record of the meeting.

Issued in Washington, DC, on May 24, 2024.

Brandon Roberts,

Executive Director, Office of Rulemaking.

[FR Doc. 2024–11877 Filed 5–29–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Advanced Aviation Advisory Committee (AAAC); Notice of Public Meetings; Cancellation

AGENCY: Federal Aviation Administration, Department of Transportation.

ACTION: Cancellation notice of Advanced Aviation Advisory Committee (AAAC) meetings.

SUMMARY: The Federal Aviation Administration published a notice in the **Federal Register** concerning a public meeting of the Advanced Aviation Advisory Committee (AAAC). The public meetings scheduled for June 11, 2024, and October 9, 2024, have been cancelled and will not be rescheduled. The notice is in the **Federal Register** on Friday May 24, 2024, in FR Document Number 2024–11440 on pages 45933–45934 (2 pages).

FOR FURTHER INFORMATION CONTACT: Gary Kolb, Advanced Aviation Advisory Committee Manager, Federal Aviation Administration, U.S. Department of Transportation, at *gary.kolb@faa.gov* or 202–267–4441.

Issued in Washington, DC.

Sherita L. Jones,

Acting Chief of Staff, UAS Integration Office, Federal Aviation Administration.

[FR Doc. 2024–11872 Filed 5–29–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2024–0043]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by July 29, 2024.

ADDRESSES: You may submit comments identified by DOT Docket ID Number FHWA–2024–0043 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: Ms. Tashia J. Clemons, Office of Infrastructure, 202–493–0551, *tashia.clemons@dot.gov,* Federal Highway Administration, 1200 New Jersey Ave. SE, Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Risk-Based Asset Management Plans.

Background: Under 23 U.S.C. 119(e) and implementing regulations at 23 CFR part 515, State Departments of Transportation (DOT) are required to develop Risked-Based Asset Management Plans (AMP) for the National Highway System (NHS) to improve or preserve the condition of the assets on and the performance of the NHS. Each State DOT must also annually demonstrate to FHWA that it has implemented an AMP that meets the requirements of 23 U.S.C. 119(e) and 23 CFR part 515 (23 CFR 515.13(b)(2)), and each State DOT must submit its processes for the development of its AMP to FHWA for certification and recertification every four years following the year of initial certification (23 U.S.C. 119(e)(6)). Section 11105(3) of the Bipartisan Infrastructure Law (BIL) (Pub. L. 117–58) added the requirement in 23 U.S.C. 119(e)(4)(D) that risk management and lifecycle cost analyses in AMPs discuss extreme weather and resilience.

Respondents: There are 52 State Departments of Transportation (State DOT) that are required to submit information (State DOTs).[1] Of these, 17

[1] The District of Columbia and Puerto Rico are considered States for the purposes of the Federal-aid highway program. *See* 23 U.S.C. 101(a)(28).

State DOTs already conduct extreme weather and resilience analyses.

Frequency: Annually (to demonstrate implementation of an AMP) and every 4 years (when submitting processes for the development of an AMP for recertification).

Estimated Average Burden per Response: Per State DOT, the estimated annual burden is 884 hours for the general AMP preparation, plus an additional 1,560 burden hours per State DOT that does not already perform extreme weather and resilience analyses.

Estimated Total Annual Burden Hours: Total estimated average annual burden is 100,568 hours.

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 May 24, 2024.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2024–11843 Filed 5–29–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0148]

Commercial Driver's License: Application for Exemption; National School Transportation Association

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of application for renewal of exemption; request for comments.

SUMMARY: FMCSA announces that it has received an application from the National School Transportation Association (NSTA) to renew its exemption that permits all commercial driver's license (CDL) applicants seeking a school bus endorsement to forgo the engine compartment portion of the pre-trip vehicle inspection skills testing requirement, known informally as the ''under-the-hood'' testing requirement. Drivers issued CDLs pursuant to the requested exemption are restricted to intrastate operation of school buses only. The current exemption is effective from November 28, 2022, through November 28, 2024, and NSTA has requested a three-year extension of the exemption. FMCSA requests public comment on NSTA's request for exemption.

DATES: Comments must be received on or before July 1, 2024.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2022–0148 using any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* See the Public Participation and Request for Comments section below for further information.
- *Mail:* Docket Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Each submission must include the Agency name and the docket number for this notice (FMCSA–2022–0148). Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: If you do not have access to the internet, you may view the docket by visiting Docket Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice DOT/ALL–14 FDMS, which can be reviewed at *https://www.transportation.gov/privacy.* The comments are posted without edit and are searchable by the name of the submitter.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; 202–366–2722; *richard.clemente@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2022–0148), indicate the specific section of this document to which the comment applies, and provide a reason for your suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number ''FMCSA–2022–0148'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on the ''Comment'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly

designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at *brian.g.dahlin@dot.gov.* At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analyses. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision(s) from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reason for the denial (49 CFR 381.315(c)(2)). The exemption may be renewed (49 CFR 381.300(b)).

III. Background

Current Regulatory Requirements

FMCSA's CDL regulations in 49 CFR 383.113(a) require that applicants for a CDL possess basic pre-trip vehicle inspection skills for the vehicle class that they operate or expect to operate. Applicants must be able to identify each safety-related part on the test vehicle and explain what needs to be inspected to ensure a safe operating condition of each part.

On January 3, 2022, in response to a request from NSTA, FMCSA issued a three-month waiver from 49 CFR 383.113(a)(1)(i), which requires CDL applicants to demonstrate familiarity with the engine compartment, the so-called ''under-the-hood'' requirement. The waiver responded to the unique circumstances resulting from the school bus driver shortage, which was exacerbated by the COVID–19 pandemic. FMCSA issued two subsequent three-month waivers, on March 28, 2022, and June 30, 2022.

FMCSA published notice of NSTA's application for a longer-term exemption from the ''under-the-hood'' skills testing requirement on August 11, 2022 (87 FR 49646). The Agency analyzed the application and public comments and determined that granting it was likely to achieve a level of safety equivalent to or greater than the level of safety that would be achieved in the absence of the exemption. On October 27, 2022, FMCSA granted a two-year ''under-the-hood'' exemption which will expire on November 27, 2024 (87 FR 65114). The exemption applies to CDL applicants seeking the school bus (S) and passenger (P) endorsements and the intrastate only (K) restriction. Consequently, drivers issued a CDL pursuant to the exemption are restricted to the intrastate operation of school buses only.

IV. Applicant's Request

NSTA applied for renewal of the exemption on February 28, 2024. NSTA is a membership organization for school bus contract-operators engaged primarily in transporting students to and from school and school-related activities. Its members range from small family businesses serving one school district, to large corporations operating tens of thousands of buses across multiple states all with a stated commitment to the safe, efficient, and economical transportation of students. According to NSTA, private school bus contractors account for 38 percent of the nation's pupil transportation services and employ more than 250,000 individuals as bus drivers, mechanics, maintenance workers, dispatch workers, and office workers. School transportation represents the largest form of mass transportation in the United States, and daily almost 26 million K–12 students are transported by an estimated 480,000 yellow school buses.

NSTA requests renewal of the exemption for a three-year period because NSTA claims it has aided in the successful recruitment of school bus drivers who otherwise may not have obtained a CDL. According to NSTA, the industry's CDL training resources are limited, and the exemption helps ensure that the limited resources are used to train school bus drivers, rather than operators of other kinds of CMVs. NSTA indicates that the current exemption has had a demonstrably positive impact on student transportation thus far, and notably with no negative impact on safety.

V. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on NSTA's application for the renewal of the exemption from the requirement in 49 CFR 383.133(a)(1)(i) that requires CDL applicants seeking a school bus endorsement, to perform the engine compartment portion of the pre-trip vehicle inspection skills testing requirement. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry Minor,

Associate Administrator for Policy.

[FR Doc. 2024–11869 Filed 5–29–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2024–0063]

Commercial Driver's License: Covenant Transport Inc. and Landair Transport Inc. jointly d/b/a Covenant Logistics; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of correction.

SUMMARY: FMCSA corrects the notice published in the **Federal Register** on May 23, 2024, requesting comments on the application for exemption submitted

by Covenant Transport Inc. and Landair Transport Inc., jointly doing business as Covenant Logistics. The notice contained two errors regarding the approximate number of drivers hired and number of drivers covered by the proposed exemption, which the Agency now corrects.

FOR FURTHER INFORMATION CONTACT: Ms. Pearlie Robinson, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards, FMCSA; (202) 366–4225; or *pearlie.robinson@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION: The original notice of application and request for comments, published on May 23, 2024, at 89 FR 45732, contains on page 45733 the following two sentences ''On an annual basis, it hires approximately 1,200 new drivers each year through driver training schools. Covenant Logistics estimates that approximately 2,000 drivers annually would operate CMVs under the requested exemption.'' FMCSA is correcting these sentences to read: ''On an annual basis, it hires approximately 2,400 new drivers each year through driver training schools. Covenant Logistics estimates that approximately 4,000 drivers annually would operate CMVs under the requested exemption.''

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024–11868 Filed 5–29–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2021–0052]

Hours of Service (HOS) of Drivers; American Pyrotechnics Association (APA); Request To Include Additional Member Companies to Current APA HOS Exemptions

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of application for exemptions; request for comments.

SUMMARY: FMCSA announces that it has received an application from the American Pyrotechnics Association (APA) requesting extension of its current exemptions from the Agency's hours-of-service (HOS) regulations for 12 additional member companies. The request would allow drivers employed by the 12 member carriers to exclude off-duty and sleeper-berth time of any length from the calculation of the 14-hour limit. It would also to allow these drivers to use paper records of duty status (RODS) in lieu of an electronic logging device (ELD) during the designated Independence Day periods.

DATES: Comments must be received on or before July 1, 2024.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Number FMCSA–2021–0052 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* See the Public Participation and Request for Comments section below for further information.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Each submission must include the Agency name and the docket number (FMCSA–2021–0052) for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: If you do not have access to the internet, you may view the docket by visiting Docket Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice DOT/ALL–14 FDMS, which can be reviewed at *https://www.transportation.gov/privacy.* The comments are posted without edit and are searchable by the name of the submitter.

FOR FURTHER INFORMATION CONTACT: Ms. Pearlie Robinson, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards, FMCSA; 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–4225; *pearlie.robinson@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2022–0122), indicate the specific section of this document to which the comment applies, and provide a reason for your suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number ''FMCSA–2022–0148'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on the ''Comment'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the notice, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as ''PROPIN'' to indicate it contains

proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the notice. Submissions containing CBI should be sent to Brian Dahlin, Chief, Regulatory Evaluation Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 or via email at *brian.g.dahlin@dot.gov.* At this time, you need not send a duplicate hardcopy of your electronic CBI submissions to FMCSA headquarters. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this notice.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including the applicant's safety analyses. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely maintain a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305(a)). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)). If granted, the notice will identify the regulatory provision(s) from which the applicant will be exempt, the effective period, and all terms and conditions of the exemption (49 CFR 381.315(c)(1)). If the exemption is denied, the notice will explain the reasons for the denial (49 CFR 381.315(c)(2)).

III. Applicant's Request

The APA is a trade association representing the domestic fireworks industry. In 2022, FMCSA granted the APA exemptions from the requirements of 49 CFR 395.3(a)(2) and 395.8(a)(1)(i) for 32 of its member companies through the annual Independence Day periods ending on July 8, 2024 [87 FR 79935, December 28, 2022]. One of the 32 APA member companies, Dominion Fireworks Inc., DOT # 540485, no longer requires the exemptions, leaving the total number of companies currently covered by the exemptions at 31. APA has requested exemptions for 12 additional member companies, which would increase the total to 43 if the exemption request is granted. The 12 additional companies consist of three new member companies that have not operated under the exemptions, and nine member companies that previously held such exemptions. If granted, the exemptions would expire on July 8, 2024. The 12 additional companies, like the 31 current companies, would be subject to all of the terms and conditions of the exemptions set forth in the December 28, 2022, decision (87 FR 79935, 79937). The 12 companies combined are listed in the appendix table of this notice, including the three new companies, which are identified by asterisks.

APA member companies have held waivers or exemptions during Independence Day periods each year since 2005. Copies of the initial request for an exemption, subsequent renewal requests, and all public comments received may be reviewed at *www.regulations.gov* under docket numbers FMCSA–2005–21104, FMCSA–2007–28043, FMCSA–2018–0140, and FMCSA–2021–0052.

A copy of the APA's application for exemptions is available for review in the docket for this notice.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on APA's application for exemptions from 49 CFR 395.3(a)(2) and 395.8(a)(1)(i). All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the Addresses section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

Appendix to Notice of Application To Include Additional Member to Current APA Exemptions From the 14-Hour and ELD HOS Rules for Independence Day Period, June 28 Through July 8, 2024, for 12 Motor Carriers

	Motor carrier	Street address	City, state, zip code	DOT No.
1	*Extreme Logistics	26926 Hardy Run	Boerne, TX 78015	1971328
2	Hamburg Fireworks Display, Inc	2240 Horns Mill Road SE	Lancaster, OH 43130	395079
3	*Herbie's Famous Fireworks, Inc	1406 Cherokee Falls Rd	Blacksburg, SC 29702	0112743
4	J&J Computing dba Fireworks Extravaganza.	174 Route 17 North	Rochelle Park, NJ 07662	2064141
5	J&M Displays, Inc	18064 170th Ave	Yarmouth, IA 52660	377461
6	Magic in the Sky, LLC	27002 Campbellton Road	San Antonio, TX 78264	2134163
7	Miand Inc. dba Planet Productions (Mad Bomber).	P.O. Box 294, 3999 Hupp Road R31	Kingsbury, IN 46345	777176
8	Rainbow Fireworks, Inc	76 Plum Ave	Inman, KS 67546	1139643
9	RKM Fireworks Company	27383 May St	Edwardsburg, MI 49112	1273436
10	*Special FX Wizard, Inc	Box 266	Mastick Beach, NY 11951	3442905
11	Starfire Corporation	682 Cole Road	Carrolltown, PA 15722	554645
12	Zambelli Fireworks MFG, Co., Inc	120 Marshall Drive	Warrendale, PA 15086	033167

[FR Doc. 2024–11867 Filed 5–29–24; 8:45 am]

BILLING CODE 4910–EX–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, 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 July 1, 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: Power of Attorney and Declaration of Representative.

OMB Number: 1545–0150.

Form Number: 2848 and 2848 (SP).

Abstract: Form 2848 or Form 2848 (SP) is issued to authorize someone to act for the taxpayer in tax matters. It grants all powers that the taxpayer has except signing a return and cashing refund checks. The information on the form is used to identify representatives and to ensure that confidential information is not divulged to unauthorized persons.

Current Actions: There are no changes being made to the forms at this time, however the estimated number of responses were reduced based on the current filing data.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, business or other for-profit organizations, not-for-profit institutions, and farms.

Form 2848

Estimated Number of Respondents: 378,087.

Estimated Time per Respondent: 1.99 hours.

Estimated Total Annual Burden Hours: 752,393 hours.

Form 2848 (SP)

Estimated Number of Respondents: 80,000.

Estimated Time per Respondent: 2.26 hours.

Estimated Total Annual Burden Hours: 180,800 hours.

2. Title: Sale of Residence from Qualified Personal Residence Trust.

OMB Number: 1545–1485.

Form Project Number: TD 8743.

Abstract: Internal Revenue Code section 2702(a)(3) provides special favorable valuation rules for valuing the gift of a personal residence trust. Regulation section 25.2702–5(a)(2) provides that if the trust fails to comply with the requirements contained in the regulations, the trust will be treated as complying if a statement is attached to the gift tax return reporting the gift stating that a proceeding has been commenced to reform the instrument to comply with the requirements of the regulations.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and households.

Estimated Number of Responses: 300.

Estimated Time per Respondent: 2 Hrs., 5 Min.

Estimated Total Annual Burden Hours: 625.

3. Title: Pre-Approved Plans Program.

OMB Number: 1545–1674.

Revenue Procedure: 2023–37

Abstract: Revenue Procedure 2023–37, and its successors, set forth the procedures of the IRS for issuing opinion letters confirming that the form of a provider's plan satisfies the qualification requirements under the Internal Revenue Code. The OMB approval for 1545–1674 is only covering the third-party disclosures and recordkeeping requirements.

Current Actions: There are no changes being made to the revenue procedure or burden at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not-for-profit institutions, farms, and state, local, or tribal governments.

Revenue Procedure 2023–07, Section 9.02(8) and 9.06(6)

Estimated Number of Respondents: 350,356.

Estimated Time per Response: 1 hour.

Estimated Annual Burden Hours: 350,356 hours.

Revenue Procedure 2023–07, Sections 6.04, 13.01 and 23

Estimated Number of Respondents: 1,556.

Estimated Time per Response: 160 hours.

Estimated Annual Burden Hours: 248,960 hours.

4. Title: Election Out of GST Deemed Allocations.

OMB Number: 1545–1892.

Regulation Project Number: TD 9208.

Abstract: This information is required by the IRS for taxpayers who elect to have the automatic allocation rules not apply to the current transfer and/or to future transfers to the trust or to terminate such election. This information is also required by the IRS for taxpayers who elect to treat trusts described in section 2632(c)(3)(B)(i) through (vi)as GST trusts or to terminate such election. This information will be used to identify the trusts to which the election or termination of election will apply.

Current Actions: There are no changes being made to the regulations at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 25,000.

Estimated Time per Respondent: 30 minutes.

Estimated Total Annual Burden Hours: 12,500.

5. Title: Continuation Sheet for Item # 16 (Additional Information)—OF–306, Declaration for Federal Employment.

OMB Number: 1545–1921.

Regulation Project Number: Form 12114.

Abstract: This form is used by recruitment personnel of the Covington Host Site. This form is provided to applicants when completing OF 306, Declaration for Federal Employment. It is used as a continuation sheet to clearly define additional information that is requested in item 15 of the OF 306. Due to lack of space on the OF 306 this form can be used in lieu of an additional sheet of paper.

Current Actions: There are no changes to the burden previously approved by OMB. This submission is for renewal purposes.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 24,813.

Estimated Time per Respondent: 15 min.

Estimated Total Annual Burden Hours: 6,203.

6. Title: Preparer Hardship Waiver Request and Preparer Explanation for Not Filing Electronically.

OMB Number: 1545–2200.

Form Number(s): 8944 and 8948.

Abstract: A tax preparer uses Form 8944 to request a waiver from the requirement to file tax returns on magnetic media when the filing of tax returns on magnetic media would cause a hardship. A specified tax return preparer uses Form 8948 to explain which exception applies when a covered return is prepared and filed on paper.

Current Actions: There are no changes being made to the forms or burden at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Form 8944

Estimated Number of Respondents: 90,000.

Estimated Number of Responses: 90,000.

Estimated Time per Response: 1 hour.

Estimated Annual Burden Hours: 719,100 hours.

Form 8948

Estimated Number of Respondents: 180,000.

Estimated Number of Responses: 740,500.

Estimated Time per Response: 160 hours.

Estimated Annual Burden Hours: 1,473,595 hours.

7. Title: Longevity Annuity Contracts.

OMB Number: 1545–2234.

Form Number: Form 1098–Q and TD 9673.

Abstract: This collection covers final regulations relating to the use of longevity annuity contracts in tax qualified defined contribution plans under section 401(a) of the Internal Revenue Code (Code), section 403(b) plans, individual retirement annuities and accounts (IRAs) under section 408, and eligible governmental plans under section 457(b).

Form 1098–Q is used to comply with the reporting requirements under TD 9673. Any person who issues a contract intended to be a QLAC that is purchased or held under any plan, annuity, or account described in section 401(a), 403(a), 403(b), 408 (other than a Roth IRA) or eligible governmental plan under section 457(b), must file Form 1098–Q.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals, not-for-profit institutions, individuals, or households.

Estimated Number of Respondents: 150.

Estimated Time per Respondent: 8 mins.

Estimated Total Annual Burden Hours: 28,529.

8. Title: Certified Professional Employer Organization (CPEO) Forms.

OMB Number: 1545–2266.

Form Name: Identity Verification Application, Responsible Individual Personal Attestation (RIPA), Certified Professional Employer Organization Application, Form 14751, and Form 8973.

Regulation Project Number: TD 9860.

Abstract: Section 206 of the Achieving a Better Life Experience (ABLE) Act passed Dec. 19, 2014) created the Certified Professional Employer Organization (CPEO) designation. The application, attestation and supporting information is used by the IRS to qualify professional employer organizations to become and remain a Certified Professional Employer Organization, which entitles them to certain tax benefits. This certification is renewed annually and the CPEO will submit annual and quarterly financial statements in addition to supporting documentation. Responsible individuals will submit annual attestation forms and fingerprint cards. The Identity Verification Application, Responsible Individual Personal Attestation (RIPA), Certified Professional Employer Organization Application, Form 14751, Certified Professional Employer Organization Surety Bond, Form 8973, Certified Professional Employer Organization/Customer Reporting Agreement, and TD 9860, Certified Professional Employer Organizations, will only be used by program applicants and related responsible individuals.

Current Actions: There are changes to the existing collection. Form 14737 and Form 14737–A have been replaced by the CPEO online system.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations & Individuals.

Identity Verification Application

Estimated Number of Respondents: 565.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 5,141.

Responsible Individual Personal Attestation (RIPA)

Estimated Number of Respondents: 565.

Estimated Time per Respondent: 40 hours.

Estimated Total Annual Burden Hours: 22,600.

Certified Professional Employer Organization Application

Estimated Number of Respondents: 120.

Estimated Time per Respondent: 77 hours, 45 minutes.

Estimated Total Annual Burden Hours: 9,330.

Form 14751

Estimated Number of Respondents: 170.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 340.

Form 8973

Estimated Number of Respondents: 41,350.

Estimated Time per Respondent: 1.5 hours.

Estimated Total Annual Burden Hours: 62,025.

Authority: 44 U.S.C. 3501 et seq.

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2024–11860 Filed 5–29–24; 8:45 am]

BILLING CODE 4830–01–P

U.S.-CHINA ECONOMIC AND SECURITY REVIEW COMMISSION

Notice of Open Public Hearing

AGENCY: U.S.-China Economic and Security Review Commission.

ACTION: Notice of open public hearing.

SUMMARY: Notice is hereby given of the following hearing of the U.S.-China Economic and Security Review Commission. The Commission is mandated by Congress to investigate, assess, and report to Congress annually on ''the national security implications of the economic relationship between the United States and the People's Republic of China.'' Pursuant to this mandate, the Commission will hold a public hearing

in Washington, DC on June 13, 2024 on ''China's Stockpiling and Mobilization Measures for Competition and Conflict.''

DATES: The hearing is scheduled for Thursday, June 13, 2024 at 9:30 a.m.

ADDRESSES: Members of the public will be able to attend in person at a location TBD or view a live webcast via the Commission's website at *www.uscc.gov. Visit the Commission's website for updates to the hearing location or possible changes to the hearing schedule. Reservations are not required to view the hearing online or in person.*

FOR FURTHER INFORMATION CONTACT: Any member of the public seeking further information concerning the hearing should contact Jameson Cunningham, 444 North Capitol Street NW, Suite 602, Washington, DC 20001; telephone: 202–624–1496, or via email at *jcunningham@uscc.gov. Reservations are not required to attend the hearing.*

ADA Accessibility: For questions about the accessibility of the event or to request an accommodation, please contact Jameson Cunningham via email at *jcunningham@uscc.gov.* Requests for an accommodation should be made as soon as possible, and at least five business days prior to the event.

SUPPLEMENTARY INFORMATION:

Background: This is the sixth public hearing the Commission will hold during its 2024 reporting cycle. The hearing will evaluate the Chinese Party-state's efforts to prepare society for a period of enhanced competition, crisis, or conflict. First, the hearing will examine Chinese leaders' rhetoric and efforts to instill a siege mentality in the Chinese public. Next, the hearing will examine China's efforts to materially and financially prepare its economy for a crisis or conflict scenario through efforts to boost domestic production capacity, sanction-proof its economy, and attain self-sufficiency in key sectors. Finally, the hearing will assess the China's national defense mobilization system and ability to leverage civilian resources during a crisis.

The hearing will be co-chaired by Commissioners Carte P. Goodwin and Cliff Sims. Any interested party may file a written statement by June 13, 2024 by transmitting it to the contact above. A portion of the hearing will include a question and answer period between the Commissioners and the witnesses.

Authority: Congress created the U.S.-China Economic and Security Review Commission in 2000 in the National Defense Authorization Act (Pub. L. 106–398), as amended by Division P of the Consolidated Appropriations Resolution, 2003 (Pub. L. 108–7), as amended by Public Law 109–108 (November 22, 2005), as amended by Public Law 113–291 (December 19, 2014).

Dated: May 24, 2024.

Christopher Fioravante,

Director of Operations and Administration, U.S.-China Economic and Security Review Commission.

[FR Doc. 2024–11841 Filed 5–29–24; 8:45 am]

BILLING CODE 1137–00–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0881]

Agency Information Collection Activity Under OMB Review: Lay/Witness Statement

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: 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. 2900–0881.''

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Nancy Kessinger, 202–632–8924, *nancy.kessinger@va.gov.*

VA PRA information: Maribel Aponte, 202–461–8900, *vacopaperworkreduact@va.gov*

SUPPLEMENTARY INFORMATION:

Title: Lay/Witness Statement (VA Form 21–10210).

OMB Control Number: 2900–0881.

https://www.reginfo.gov/public/do/PRASearch.

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 21–10210 is used by the claimant to gather lay or witness statements that support an existing claim for benefits/services. Without this information, VA may not be able to efficiently and successfully process claims that may require additional statements associated with a claim for benefits/services. No changes have been made to this form. The respondent burden has decreased due to the estimated number of receivables averaged over the past year.

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 20298, Thursday, March 21, 2024.

Affected Public: Individuals or Households.

Estimated Annual Burden: 10,767 hours.

Estimated Average Burden per Respondent: 10 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 64,603 per year.

Authority: 38 U.S.C. 501, 5103, and 5101(a), 38 CFR 3.159 and 3.303, 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–11844 Filed 5–29–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0075]

Agency Information Collection Activity Under OMB Review: Statement in Support of Claim

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: 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. 2900–0075.''

FOR FURTHER INFORMATION CONTACT: VA PRA information: Maribel Aponte, 202–461–8900, *vacopaperworkreduact@va.gov.*

SUPPLEMENTARY INFORMATION:

Title: Statement in Support of Claim (VA Form 21–4138).

OMB Control Number: 2900–0075 *https://www.reginfo.gov/public/do/PRASearch.*

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 21–4138 is used to provide self-certified statements in support of various types of claims processed by VA. Statements submitted by or on behalf of a claimant should contain certification by the respondent that the information provided is true and correct. This form facilitates claims processing by providing a uniform format for the certification statement. No changes have been made to this form. The respondent burden has increased due to the estimated number of receivables averaged over the past year.

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 20299, March 21, 2024.

Affected Public: Individuals or Households.

Estimated Annual Burden: 317,265 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 1,269,058 per year.

Authority: 44 U.S.C. 3501 *et seq.,* 38 U.S.C. 501, 38 CFR 3.150.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–11840 Filed 5–29–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0760]

Agency Information Collection Activity: Paralympics & Olympics Monthly Training Allowance Application and Certification

AGENCY: Veterans Health Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Health Administration (VHA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Comments must be received on or before July 29, 2024.

ADDRESSES: Comments must be submitted through *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT:

Program-Specific information: Veta Brooks-Berryman, 202–480–4633, *Veta.Brooks1@va.gov*.

VA PRA information: Maribel Aponte, 202–461–8900, *vacopaperworkreduact@va.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (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 or the use of other forms of information technology.

Title: Paralympics & Olympics Monthly Training Allowance Application and Certification (VA Forms 0918a & 0918b).

OMB Control Number: 2900–0760. *https://www.reginfo.gov/public/do/PRASearch* (Once at this link, you can enter the OMB Control Number to find the historical versions of this Information Collection).

Type of Review: Revision of a currently approved collection.

Abstract: Section 703 of the Veterans' Benefits Improvement Act of 2008, Public Law 110–389, authorizes the Department of Veterans Affairs (VA) to administer a monthly assistance allowance to a veteran with a service-connected or non-service-connected disability if the veteran is competing for a slot on or selected for the United States Paralympics and Olympics team or is residing at a United States Paralympics or Olympics training center. The Office of National Veterans Sports Programs and Special Events will use VA Forms 0918a and 0918b to collect information to certify eligibility for the monthly assistance allowance, verify the veteran's mailing address, confirm that he or she has been accepted by the Paralympics or Olympics to compete in a specific Paralympic or Olympic sport, and to determine their marital status and number of dependents for the purpose of assessing payment amounts.

Affected Public: Individuals and households.

Estimated Annual Burden: 43 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: Once annually.

Estimated Number of Respondents: 170.

Authority: 44 U.S.C. 3501 *et seq.*

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–11861 Filed 5–29–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0404]

Agency Information Collection Activity under OMB Review: Veteran's Application for Increased Compensation Based on Unemployability

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: 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. 2900–0404.''

FOR FURTHER INFORMATION CONTACT: VA PRA information: Maribel Aponte, 202–461–8900, *vacopaperworkreduact@va.gov*

SUPPLEMENTARY INFORMATION:

Title: Veteran's Application for Increased Compensation Based on Unemployability (VA Form 21–8940).

OMB Control Number: 2900–0404 *https://www.reginfo.gov/public/do/PRASearch*

Type of Review: Revision of a currently approved collection.

Abstract: VA Form 21–8940 is used by veterans to apply for increased VA disability compensation based on the inability to secure or follow a substantially gainful occupation due to service-connected disabilities. Without this information, entitlement to individual unemployability benefits could not be determined. No changes have been made to this form. The respondent burden has increased due to the estimated number of receivables averaged over the past year.

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 20299, March 21, 2024.

Affected Public: Individuals or Households.

Estimated Annual Burden: 50,558 hours.

Estimated Average Burden per Respondent: 45 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 67,411 per year.

Authority: 44 U.S.C. 3501 *et seq.,* 38 U.S.C. 1163, 38 CFR 3.340, 3.341, and 4.16.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration, Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2024–11859 Filed 5–29–24; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Intent To Exempt Copayments for the First Three Mental Health Care Outpatient Visits Annually

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: VA intends to implement a new law that prohibits the collection of copayments for the first three mental health care outpatient visits of a Veteran in a calendar year for which the Veteran would otherwise be required to pay a copayment. VA's current regulations regarding copayments do not include an exemption for this purpose, but VA will revise them soon to align with the law. In April 2024, VA was able to modify its systems and processes to comply with the law for qualifying appointments that occurred on or after June 27, 2023. By law, the exemption will expire on December 29, 2027.

DATES: Implementation will be applicable upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Tamara Wagner, Office of Finance, Revenue Operations, (104RO2), Veterans Health Administration, Department of Veterans Affairs, 128 Bingham Road, Suite 1000, Asheville, NC 28806; 970–242–0731, extension 2219. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The primary purpose of this notice is to inform the public of VA's intent to modify its systems and processes to comply with new statutory requirements while rulemaking proceeds to modify existing regulations. On December 29, 2022, the Joseph Maxwell Cleland and Robert Joseph Dole Memorial Veterans Benefits and Health Care Improvement Act of 2022 (the Act; Pub. L. 117–328, Division U), added a new section 1722C to title 38, U.S.C., that generally prohibits VA from imposing or collecting a copayment for the first three mental health care outpatient visits of a Veteran in a calendar year for which the Veteran would otherwise be required to pay a copayment to VA. The Act defines a mental health care outpatient visit to mean an outpatient visit with a qualified mental health professional for the primary purpose of seeking either mental health care, or treatment for substance abuse disorder. The copayment exemption for the first three outpatient mental health care visits includes appointments completed in VA clinics as well as those conducted by community care providers.

VA will modify its regulations regarding copayments for outpatient mental health care, set forth at 38 CFR 17.108, to reflect this authority. Mental health care outpatient visits are defined in law to mean an outpatient visit with a qualified mental health professional for the primary purpose of seeking either mental health care or treatment for substance abuse disorder.

The determination of the first three mental health visits is expected to be complex due to a variety of issues, including the need to consider whether care is service-connected or otherwise exempt, how to handle Veterans with multiple appointments in the same day, and administrative requirements (such as establishing a tool to count the number of appointments a Veteran has had in a calendar year). To ensure the most effective application of this benefit and exempt copayments as applicable under the statute, VA will determine if a visit qualifies for a copayment exemption using the following process.

First, VA will evaluate the clinic where the appointment occurred. If the clinic is a mental health, psychiatry, psychology, or substance abuse clinic, VA will exempt the copayment, if applicable, if the appointment is one of the first three qualifying visits in a calendar year. Second, if the visit was not performed in such a clinic, VA will review what provider completed the appointment to determine if the visit applies for a copayment exemption. If the provider is a psychiatrist, psychologist, licensed professional mental health counselor, marriage or family therapist, or social worker, and if the medical service provided is classified as an evaluation and management visit, mental health visit, group therapy visit, or psychiatric diagnostic assessment, VA will exempt the copayment, if applicable, provided the appointment is one of the first three qualifying visits in a calendar year. Veterans that are otherwise copayment exempt based on Priority Group or service connection should see no difference in their copayment status as the copayment would already be exempt for other reasons. If a Veteran has multiple appointments in one day, including a visit that would qualify for

this exemption as well as a visit that does not, the copayment for the visit that does not qualify for this exemption will still apply (in other words, if a Veteran has a primary care appointment and a mental health appointment that would qualify for this exemption, the primary care copayment would still apply). Further examples are provided below to help illustrate how the copayment exemption will be applied.

Example 1: A Priority Group 7 Veteran has an appointment with the general mental health clinic and is treated by a psychologist. This is the first appointment of the calendar year for this Veteran. The Veteran is not service connected for any mental health conditions. Under the new law, a copayment will not be applied to this visit.

Example 2: A Priority Group 7 Veteran has an appointment with a primary care clinic and is treated by a general medicine provider. The Veteran discusses symptoms of depression and anxiety during the primary care visit. This visit is for a non-service-connected condition that would be subject to a copayment. This visit is not subject to the copayment exemption under the new law as the provider type and clinic location are not considered outpatient mental health care.

Example 3: A Priority Group 7 Veteran has an appointment with the general mental health clinic and is seen by a general medicine provider. This is the first visit of the year for the Veteran and is for a non-service-connected condition that would be subject to a copayment. Under the new law, a copayment will not be applied to this visit as the visit occurred in a mental health clinic and meets the definition of outpatient mental health care.

Example 4: A Priority Group 7 Veteran has an appointment with the general mental health clinic with a psychologist for a psychological assessment using psychometric instruments for the purpose of neuropsychological testing. The Veteran has been followed by this provider for many months; however, this is the first visit for the Veteran in the calendar year and is for a non-service-connected condition. This service would normally be assessed a specialty copayment. Under the new law, this copayment would be waived as it is the first mental health visit in a calendar year.

Example 5: A Priority Group 8 Veteran has three appointments at a VA medical center (VAMC) on the same day. The first visit is in the primary care clinic with the Veteran's primary care provider. The second appointment is a specialty appointment with Cardiology following a prior referral by the primary care provider. The third appointment is with the substance abuse clinic and is with a licensed clinical social worker and is the first visit in the calendar year. All the care is considered non-service connected. As this Veteran had multiple appointments on the same day, a copayment decision is made for each service to determine which should apply. The basic copayment would normally apply for the first primary care visit. The specialty copayment would apply for the cardiology visit, which would take precedence over the basic copayment (thereby nullifying that obligation). The copayment for the substance abuse visit would be exempt on the same basis. This Veteran would be assessed one copayment for the day at the specialty copayment level for the cardiology visit, and the substance abuse visit would not count as one of the three mental health outpatient visits during the calendar year.

Example 6: A Priority Group 8 Veteran has two appointments at a VAMC on the same day. The first visit is in the primary care clinic with the Veteran's primary care provider. The second appointment is a specialty appointment with the mental health clinic, is with a licensed clinical social worker, and is the first visit in the calendar year. All the care is considered non-service connected. As this Veteran had multiple appointments on the same day, a copayment decision is made for each service to determine which should apply. The basic copayment would normally apply for the first primary care visit. The specialty copayment would apply for the mental health visit, which would take precedence over the basic copayment; however, because the copayment for the specialty care mental health visit would be exempt based on this law, the Veteran would be assessed one copayment for the day at the primary care copayment level for the primary care visit. The mental health visit would count as one of the three mental health outpatient visits exempted from a copayment during the calendar year.

Example 7: A Priority Group 8 Veteran has two appointments at a VAMC on the same day. The first visit is in the primary care clinic with the Veteran's primary care provider. The second appointment is a specialty appointment with the mental health clinic, is with a licensed clinical social worker, and is the fifth visit in the calendar year. All the care is considered non-service connected. As this Veteran had multiple appointments on the same day, a copayment decision is made for each service to determine which should apply. The basic copayment would normally apply for the first primary care visit. The specialty copayment would apply for the mental health visit, which would take precedence over the basic copayment; because the copayment for the specialty care mental health visit would not be exempt based on this law (as it not one of the first three visits), the Veteran would be assessed one copayment for the day at the specialty care copayment level for the mental health visit.

Section 1722C, by prohibiting the imposition or collection of copayments ''for the first three mental health care outpatient visits of a Veteran in a calendar year *for which the Veteran would otherwise be required to pay a copayment*'' to VA, intersects with section 1710(g), which subjects Veterans (generally in Priority Groups 7 and 8) to making copayments for the receipt of care. This intersection is discussed in the examples above. Section 1722C also intersects with section 1725A(f) (and VA's regulations at 38 CFR 17.4600), which authorizes VA to furnish walk-in care from qualifying non-Department providers. Veterans receiving walk-in or urgent care under this authority may be subject to copayments in at least some cases. While theoretically mental health care outpatient visits exempt from copayments under section 1722C could be provided pursuant to the walk-in care authority of section 1725A, VA does not believe they are provided today under VA's existing network of community providers. In the future, VA's community network could expand to include services furnished in the clinics described above (a mental health, psychiatry, psychology, or substance abuse clinic) or by the provider types and services (psychiatrist, psychologist, licensed professional mental health counselor, marriage or family therapist, or social worker, and if the medical service provided is classified as an evaluation and management visit) described above. If this occurs, VA will provide additional guidance to Veterans on how these authorities would affect their copayment liability. For now, if Veterans have questions or concerns about outpatient mental health care copayments furnished in a community walk-in care clinic or urgent care facility, we recommend they contact the Revenue Department at the local VAMC for further information.

Section 193A(b) of the Act provided that the new 38 U.S.C. 1722C shall apply with respect to mental health care outpatient visits occurring on or after the date that is 180 days after the date of the enactment of this Act. The Act

was enacted into law on December 29, 2022, and 180 days after that date was June 27, 2023. VA will apply the process described above and issue a refund to Veterans who paid a copayment for the first three mental health care outpatient visits on or after June 27, 2023, during that calendar year. This will give effect to the applicability provisions set forth in section 193A(b) of the Act.

While this process is expected to identify the vast majority of qualifying mental health care outpatient visits, Veterans who believe a copayment was applied in error may contact VA to review its determination and correct the copayment, if applicable. Information on disputing VA copayments can be found on the VA website at *www.va.gov/health-care/pay-copay-bill/dispute-charges/* or by contacting the Facility Revenue Department at the Veteran's local VAMC.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on May 6, 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.

[FR Doc. 2024–10483 Filed 5–29–24; 8:45 am]

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Part II

Environmental Protection Agency

40 CFR Part 142
Water System Restructuring Assessment Rule; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 142

[EPA–HQ–OW–2022–0678; FRL 7487–02–OW]

RIN 2040–AF96

Water System Restructuring Assessment Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA or the agency) is proposing a regulatory framework for states and public water systems (PWSs) to identify and assess restructuring alternatives to ensure that every community receives safe, affordable, and reliable drinking water. The proposed regulations would: establish a new mandatory restructuring assessment authority for states; require states with primary enforcement authority (primacy) to develop mandatory restructuring assessment programs and submit primacy revisions for EPA review and approval; establish requirements for states and PWSs that implement system-specific mandatory restructuring assessments; and establish eligibility requirements and limitations for restructuring incentives under state-approved restructuring plans. This proposed rulemaking is required under amendments to the Safe Drinking Water Act (SDWA). By taking this action, the EPA intends to strengthen the ongoing efforts of states and PWSs to protect public health.

DATES: Comments must be received on or before July 29, 2024. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before July 1, 2024.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OW–2022–0678, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov* (our preferred method). Follow the online instructions for submitting comments.
- *Email: ow-docket@epa.gov.* Include Docket ID No. EPA–HQ–OW–2022–0678 in the subject line of the message.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Office of Water Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery/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. to 4:30 p.m., Monday through Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. 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 ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Will Bowman, Drinking Water Capacity & Compliance Assistance Division, Office of Ground Water and Drinking Water (MC–4606M) Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–3782; email address: *bowman.will@epa.gov.*

SUPPLEMENTARY INFORMATION:

Preamble acronyms and abbreviations. Throughout this document the use of ''we,'' ''us,'' or ''our'' is intended to refer to EPA. We use acronyms in this preamble. For reference purposes, EPA defines the following acronyms here:

AMWA Association of Metropolitan Water Agencies
ASDWA Association of State Drinking Water Administrators
AWWA American Water Works Association
CBI Confidential Business Information
CFR Code of Federal Regulations
DWSRF Drinking Water State Revolving Fund
E.O. Executive Order
EPA United States Environmental Protection Agency
FR Federal Register
ICR Information Collection Request
NPDWR National Primary Drinking Water Regulations
NRWA National Rural Water Association
OMB Office of Management and Budget
PRA Paperwork Reduction Act
PWS Public Water System
PWSS Public Water System Supervision
RCAP Rural Community Assistance Partnership
RFA Regulatory Flexibility Act
RTCR Revised Total Coliform Rule
SBREFA Small Business Regulatory Enforcement Fairness Act
SDWA Safe Drinking Water Act
SDWIS Safe Drinking Water Information System
TMF Technical, Managerial and Financial
UMRA Unfunded Mandates Reform Act
U.S.C. United States Code
WSRAR Water System Restructuring Assessment Rule

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I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OW–2022–0678 at *https://www.regulations.gov* (our

preferred method), or the other methods identified in the **ADDRESSES** section of this document. Once submitted, comments cannot be edited or removed from the docket. 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 generally will not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). Please visit *https://www.epa.gov/dockets/commenting-epa-dockets* for additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments.

II. General Information

A. Applicability of This Action

This proposed rulemaking would apply to all states with primary enforcement responsibility, to a PWS that is the subject of a mandatory restructuring assessment where the state has mandated such assessment, and to a PWS that submits a restructuring plan to the state for purposes of enforcement relief or liability protection. Consistent with the SDWA, a PWS is subject to a mandatory assessment if the state finds that: (1) the PWS has repeatedly violated one or more National Primary Drinking Water Regulations (NPDWRs) and such violations are likely to adversely affect human health; (2) the PWS is unable or unwilling to implement restructuring activities, or already has attempted to implement such activities but has not achieved compliance; (3) restructuring of the PWS, including a form of consolidation or a transfer of ownership, is feasible; and (4) restructuring of the PWS could result in greater compliance with drinking water standards. Although the mandatory assessment requirements would not apply to a PWS that does not meet these four SDWA criteria, such PWSs may develop and submit restructuring plans eligible for restructuring incentives. This description of the applicability of this proposed regulation is not intended to be exhaustive, but rather provides a guide for readers regarding entities intended to be regulated by this action. To determine whether a particular entity or state would be regulated by this action, the reader should carefully examine the definitions of ''primary enforcement responsibility,'' ''public water system'' or ''PWS,'' ''supplier of water,'' and ''state'' found in the Code of Federal Regulations (CFR) at 40 CFR 142.2 entitled ''Definitions'' and in 40 CFR 142.3 entitled ''Scope.'' The reader also should review the paragraph entitled ''Applicability'' in the proposed 40 CFR 142.90 of this document. For any questions regarding the applicability of this action to a particular entity, the reader should consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

B. Summary of Proposed Action

The proposed Water System Restructuring Assessment Rule (WSRAR) would create a framework for states and PWSs to evaluate and implement restructuring alternatives for systems in chronic noncompliance. Assessments may identify a broad array of alternatives that may include sharing resources (*e.g.,* operators or equipment), debt restructuring, operational changes, upgrades, or replacement of components of water system infrastructure (treatment technology, transmission, distribution, or storage), interconnection with another PWS, consolidation, or transfer of ownership to achieve the capacity to provide safe drinking water. Restructuring alternatives for an assessed water system depend on system-specific physical and socio-economic factors (Green, et al. 2018). Therefore, the proposed rule would provide states the authority to mandate assessments and to approve restructuring plans eligible for incentives but would not limit the restructuring alternatives that the assessment could identify.

In some cases, consolidation or transfer of ownership could be the most feasible alternative to ensure a community receives safe drinking water in a sustainable manner, particularly if a PWS already has attempted to build technical or managerial capacity, to invest in infrastructure improvements, or to implement other restructuring actions, yet public health remains at risk due to persistent noncompliance with drinking water standards. For example, consolidation can reduce costs per household by spreading the cost of service across a larger customer base (US Water Alliance and UNC Environmental Finance Center 2019). As described in section IV of this preamble, the proposed rule distinguishes consolidation from privatization, which can occur under a transfer of PWS ownership from a public entity to a private entity. A common form of consolidation by small water utilities is referred to as regionalization, in which neighboring water utilities facing similar challenges choose to consolidate administratively or physically. The EPA recognizes that forms of consolidation or transfers of ownership, particularly those that would result in privatization, might raise community concerns. These concerns include affordable water rates, the need for transparency and community involvement in decision making, and ensuring accountability for utility management and operations (Zhang, et. al, 2022). A recently published case study on privatization provides an example that highlights these concerns. The case study found that, due to lack of consumer protections and utility mismanagement under private control, residents and community organizers demanded public ownership and management of the water system, more equitable water rates, and greater accountability and transparency in governance (Rivas and Schroering, 2021). To address these concerns, the proposed rule would establish several ''tailoring'' requirements to ensure that the assessment identifies feasible restructuring alternatives based on the physical and socio-economic characteristics of the water system, which can limit its capacity to restructure without technical and financial assistance. These characteristics include not only those cited in the SDWA (population served, water system type), but also the following: source water type; the technical, managerial, and financial (TMF) capacity of the water system; whether the community it serves is disadvantaged or underserved; as well as other characteristics. In addition, the proposed rule would require the mandatory assessment to describe how restructuring would ensure that the service community would sustainably receive safe, affordable drinking water. To ensure that the local community can raise concerns, ask questions, and provide input to the state and to the water utility, the proposed rule also would require the state to hold a public meeting before approving either a mandatory assessment or a restructuring plan that would result in consolidation or transfer of ownership. Finally, the proposed rule would require the state to make electronic and physical copies of state-approved assessment reports or restructuring plans available to the public. In addition to the assessment

report, the EPA strongly encourages states to make publicly available a written summary of its responses to comments received during the public meeting. Section III.C of this preamble describes guiding principles of water system restructuring to help states, drinking water utilities, and local communities navigate the challenges of identifying feasible alternatives to ensure safe drinking water.

The SDWA also establishes enforcement relief and liability protection incentives for state-approved restructuring plans. The enforcement relief incentive would prohibit enforcement action for up to two years for specific violations identified in the plan. The liability protection incentive would protect a compliant water system from liability for violations at an assessed water system until it has acquired an assessed water system through transfer of ownership or has completed physical or administrative consolidation with the assessed water system. The SDWA limits these incentives to plans for managerial or physical consolidation, transfer of ownership, or contracts for managing or administering the water system to resolve violations. As described in sections IV.E and IV.F of this preamble, the proposed rule also would establish additional eligibility requirements and limitations for both incentives, which would apply only to violations that the PWS identified in a state-approved plan.

Finally, the proposed rule would revise existing primacy regulations to require states to develop programs with the authority to mandate restructuring assessments and to review and approve restructuring plans. To obtain this authority, states would submit primacy revision applications for the EPA's approval. To assist the agency with oversight of state mandatory assessment programs, the revised primacy regulations would establish new reporting and recordkeeping requirements for states.

C. Agency Authority for This Action

The EPA proposes this regulation as mandated by SDWA section 1414(h)(6), 42 U.S.C. 300g–3(h)(6) and pursuant to SDWA sections 1413, 42 U.S.C. 300(g)–2 and 1450(a), 42 U.S.C. 300j–9.

D. Incremental Costs and Benefits of This Action

The proposed rule, if finalized, would impose direct costs on states that are required under the SDWA to establish mandatory assessment programs, and, when a state mandates an assessment, would impose indirect costs on both states and assessed PWSs to ensure that the proposed assessment requirements are satisfied. The EPA estimated that the annualized direct costs to states of implementing the requirements of this proposed WSRAR, if finalized, would be within $0.8 million to $1.0 million at a 2 percent discount rate. The estimated benefits of this proposed rulemaking would be reduced risks to public health at assessed water systems that return to compliance through restructuring, and reduced enforcement costs for states.

E. Stakeholder Engagement

In 2019, the EPA met with the Association of State Drinking Water Administrators (ASDWA) on the restructuring-related amendments to SDWA sections 1413 and 1414(h). The purpose of the consultations was to determine how the EPA should communicate with states regarding each set of amendments and their implications for states, especially the mandatory primacy revisions. Following these initial conversations, in August 2019, the EPA participated in a national webinar on water system consolidation hosted by ASDWA. During the webinar, the EPA presented a detailed summary of the America's Water Infrastructure Act (AWIA) amendments to SDWA sections 1413 and 1414(h), described several policy issues that the agency might consider as part of WSRAR development, and explained the likely effects of the amendments on state programs.

Consistent with Paperwork Reduction Act (PRA) requirements, following the national webinar, from September through November 2019, the EPA conducted telephone interviews with drinking water program staff and managers in the States of California, Connecticut, Indiana, Nebraska, Nevada, Pennsylvania, Virginia, and Washington. The EPA selected these eight states as representative of state Public Water System Supervision (PWSS) programs based on total population served, sizes of PWS inventory, geographic region, and features of their capacity development programs as documented in the EPA's 2017 compendium of state partnership programs (EPA 2017). The interviews allowed the EPA to develop a clearer understanding of states' perspectives on how these new SDWA primacy requirements and the proposed mandatory assessment authority could affect their PWSS programs. In addition, the interviews helped the EPA understand how these states currently conduct four types of water system assessments: sanitary surveys; Revised Total Coliform Rule (RTCR) Level 1 and 2 assessments; technical, managerial, and financial (TMF) capacity assessments; and feasibility studies. Collectively, these four types of assessment, which include the identification of system vulnerabilities, evaluations of water system performance, or financial capacity assessments, are closely related to the proposed elements of mandatory restructuring assessments under the WSRAR. As a result of the state interviews, the EPA obtained, for each of the assessment types, state costs of establishing an assessment program, including training staff, developing training materials for water systems, preparing databases, and conducting assessment activities. The interviews also yielded data from each state that the EPA used to calculate the cost estimates for the proposed WSRAR discussed in section VI of this preamble.

In 2019 and 2020, the EPA conducted webinars and held informational meetings with national associations that represent large and small drinking water utilities, or that provide direct technical assistance to PWSs, to discuss water system partnerships, including forms of consolidation, transfers of ownership, and other types of restructuring. These organizations included: The Rural Community Assistance Partnership (RCAP), the Rural Community Assistance Corporation (RCAC), the Association of Metropolitan Water Agencies (AMWA), the National Rural Water Association (NRWA), and the American Water Works Association (AWWA). During these meetings, the EPA provided stakeholders with an overview of the AWIA amendments to SDWA sections 1413 and 1414(h), and described potential provisions of interest, including those that require the EPA to establish implementing regulations in the WSRAR. For large water utilities, the discussion centered on the statutory requirements for liability protection as an incentive to consolidate with assessed water systems. Small water utilities focused on the SDWA tailoring provision that requires assessment of restructuring options to be based on the characteristics of each water system, and on enforcement relief as a restructuring incentive. The EPA outlined these SDWA requirements to ensure that stakeholders were aware of how these provisions might affect them. During these discussions, utility stakeholders also identified restructuring barriers and incentives and provided case studies for the EPA to consider when developing the proposed WSRAR. This feedback informed our rulemaking process. The

EPA is requesting public comment on the resulting tailoring and liability provisions.

In October 2022, the EPA conducted an informational meeting with the Natural Resources Defense Council (NRDC) and community-based organizations from Michigan and California. The meeting provided the agency an opportunity to listen to concerns about: the importance of community involvement in restructuring decisions; community impacts when restructuring alternatives are evaluated and implemented; and the potential impacts of consolidation or transfer of ownership on community access to safe, affordable drinking water. Of particular concern were the potential impacts of water system privatization that could result in unaffordable water rate increases or water shut offs, particularly in disadvantaged or underserved communities. This feedback also informed the agency's rulemaking process.

III. Background

A. Purpose of the Proposed Rule

Congress has long been concerned about PWSs that struggle to comply with drinking water standards, particularly small PWSs.[1] In 1996, Congress added section 1414(h) to the SDWA. This provision allows a water system to receive enforcement relief if a state approves a restructuring plan for consolidation or ownership transfer. In 2018, Congress added section 1414(h)(3) to authorize a state or the EPA to require a PWS in chronic noncompliance (among other factors) to perform an assessment of restructuring alternatives that are expected to help the PWS achieve compliance. Congress also added section 1414(h)(5) to provide liability protection for a ''non-responsible'' PWS that consolidates with, or acquires, an assessed water system. In section 1414(h)(6), Congress mandated that the EPA promulgate regulations to implement these new SDWA 1414(h) provisions. This rule would, consistent with SDWA mandates in sections 1413 and 1414(h), enable states and PWSs to identify and to implement feasible water system restructuring alternatives, including consolidation or transfer of ownership, that support compliance with drinking water standards and help ensure communities receive safe, affordable drinking water. Under the proposed rulemaking, a PWS could be subject to a mandatory restructuring assessment if the state were to find that: (1) the PWS has repeatedly violated one or more NPDWRs and such violations are likely to adversely affect human health; (2) the PWS is unable or unwilling to take feasible and affordable restructuring actions, or already has attempted such actions without achieving compliance with NPDWRs; (3) restructuring, including a form of consolidation or a transfer of ownership, is feasible; and (4) restructuring of the PWS could result in greater compliance with drinking water standards. A PWS that meets these four criteria has consistently failed to demonstrate it has the capacity to comply with drinking water standards that are established to protect public health. As a result, the proposed WSRAR, if finalized, would establish a regulatory framework and requirements for states and PWSs to conduct water system-specific assessments to identify feasible restructuring options for such PWSs, and to implement SDWA incentives for PWSs to develop and implement restructuring plans that can increase sustainable access to safe, affordable drinking water. These incentives include enforcement relief for a persistently noncompliant water system that restructures, and liability protection for a non-responsible water system from any violations committed by an assessed water system. By establishing enforcement relief and liability protection incentives, the SDWA encourages an assessed water system to consider forms of consolidation or transfer of ownership as permanent, long-term solutions to noncompliance. Therefore, if consolidation or transformation of ownership were determined to be infeasible, the proposed rule would require the mandatory assessment to include an explanation of how consolidation or transfer of ownership is infeasible for the assessed PWS.

B. Scope of the Proposed Rule

There are three regulatory components of the proposed rule: (1) requirements for state primacy revisions to establish a mandatory assessment program with the authority to mandate assessments and to approve assessors; (2) requirements for mandatory assessments to evaluate restructuring alternatives based on water system characteristics, content requirements for assessment reports, and an assessment schedule that includes holding a public meeting prior to state approval of an assessment that identifies ownership transfer or consolidation as a feasible restructuring option; and, (3) requirements for restructuring plans, including content requirements to determine eligibility for enforcement relief or liability protection, and public meeting requirements. These regulatory components are based on the America's Water Infrastructure Act of 2018 (AWIA) amendments to SDWA sections 1413 (Primary Enforcement Responsibility) and 1414(h) (Consolidation Incentive). Through this action, the EPA proposes implementing regulations for both the section 1413 amendments that modify 40 CFR part 142 subpart B and the section 1414(h) amendments under new 40 CFR part 142 subpart J. The proposed WSRAR would give states the authority, as part of their approved SDWA primacy programs, to mandate restructuring assessments and to approve restructuring plans eligible for enforcement relief or liability protection. The implementing framework for the three regulatory components, and the guiding principles of water system restructuring, are summarized in the following section.

1. State Primacy Revisions

SDWA section 1413 describes requirements for states with primary enforcement responsibility (primacy). The proposed revisions would require states to establish procedures to identify and notify PWSs that meet the statutory preconditions for a mandatory assessment; review and approve eligible assessors; review and approve mandatory assessments; review restructuring plans to determine water system eligibility for enforcement relief or liability protection; and enforce mandatory assessment requirements. The WSRAR would establish implementing regulations for these new primacy requirements under revised 40 CFR 142.10 and 142.11. To support the EPA's oversight of state mandatory assessment programs, the proposed WSRAR would establish new reporting and recordkeeping requirements, codified under revised 40 CFR 142.14 and 142.15.

2. Mandatory Restructuring Assessments

The primary objective of a mandatory restructuring assessment under SDWA section 1414(h) is to identify feasible restructuring activities expected to help the assessed water system comply with NPDWRs. Consistent with the SDWA, the proposed rule requires a state to find that a PWS meets the following conditions before mandating an assessment: the PWS has repeatedly violated NPDWRs; the PWS is unwilling or unable to implement feasible and affordable restructuring activities to comply, or already has attempted to take

[1] See *e.g.,* House Report 104–632 (104th Cong. 2d Sess.) at 9–10 for discussion of small system noncompliance in report accompanying the 1996 SDWA amendments.

such actions but not achieved compliance; that restructuring at the PWS is feasible; and that restructuring could result in greater compliance. Then the EPA, a state, the assessed water system or a state-approved third party could perform the mandatory assessment. Given the knowledge, expertise, and resources required, the EPA expects that states, or third-party assessors on behalf of states, would perform most mandatory assessments.

A mandatory restructuring assessment process would include:

a. Notifying the public water system that it is the subject of a mandatory restructuring assessment;

b. Performing an evaluation to identify feasible restructuring alternatives for a water system based on its geographical, managerial, financial, socio-economic, and physical characteristics;

c. Preparing an assessment report that: identifies the unresolved violations at the assessed PWS and their underlying causes; identifies at least one feasible alternative to return the PWS to compliance while ensuring its long-term TMF capacity based on its socio-economic, physical and other characteristics; describes how feasible alternatives were identified, including an explanation if consolidation or ownership transfer are infeasible, based on documented procedures, data and data sources; and, describes how any alternative would ensure that the community achieves access to safe, affordable drinking water;

d. Holding a public meeting with community leaders, *e.g.,* mayors, town council members, community activists, and residents served by the PWS, to share the assessment results if the report identified a form of consolidation or transfer of ownership as a feasible alternative, and to provide an opportunity for community input and dialogue with the state and the assessed PWS;

e. Making physical and electronic copies of the assessment report publicly available; and,

f. Consulting with the assessed PWS and community leaders during the assessment and any next steps, which might include applying for Federal or state funding to voluntarily carry out restructuring activities that the PWS and community decide to implement.

3. Restructuring Plans and Eligibility Requirements for Incentives

SDWA section 1414(h) establishes enforcement relief and liability protection incentives for struggling water systems to restructure. Under SDWA section 1414(h)(2), if a state approves a restructuring plan for administrative or managerial consolidation, physical consolidation, or transfer of ownership, then for a period of no more than two years from the date of state approval, the PWS that submitted the plan would be eligible for enforcement relief (as discussed further in section IV of this preamble). During this enforcement relief period, the state could not take further enforcement action for a specific violation identified in the approved plan, although the PWS that received enforcement relief would remain subject to existing enforcement orders to ensure it takes short-term corrective actions to protect public health.

Under SDWA section 1414(h)(5), a non-responsible PWS that either has assumed ownership of, or has completed administrative or physical consolidation with, an assessed PWS would not be liable for the specific violations identified in the plan. However, the non-responsible PWS must use any liquid assets of the assessed PWS to pay any outstanding fines or penalties for those violations. The proposed rule clarifies that a non-responsible PWS would not be liable for violations not identified in the approved plan, such as those that occur during restructuring, until the non-responsible system became the owner of the restructured water system. As described in more detail in section IV of this preamble, under the proposed rule a state may determine eligibility for either enforcement relief or liability protection, or for both incentives under the same restructuring plan. The proposed WSRAR also would establish implementing regulations for this statutory provision, with clarifications regarding eligibility requirements, as described in section IV of this preamble.

C. Guiding Principles for Water System Restructuring

The proposed WSRAR, if finalized, would establish implementing regulations for statutory provisions that give states the authority to mandate restructuring assessments and to approve restructuring plans that are eligible for enforcement relief or liability protection. These new authorities complement other Federal and state programs and policies that are collectively intended to increase sustainable access to safe and affordable drinking water supplies in all communities served by PWSs. To achieve these goals, in addition to regulatory requirements, the EPA proposes three guiding principles of restructuring to help ensure that mandatory assessments and restructuring plans are the result of collaborative efforts between states, local authorities, water utilities and community leaders (US Water Alliance 2022; 2019a, 2019b). These guiding principles are applicable not only to assessed water systems, but also to compliant water systems that are considering restructuring to ensure a sustainable capacity to provide access to safe, affordable drinking water.

1. Evaluate Restructuring Alternatives Based on the Needs of the Community

States should consider restructuring alternatives that take into consideration community culture, needs and interests to ensure that the planned restructuring leads to access to safe, affordable drinking water for all consumers served by the PWS. This principle is consistent with the EPA's Water Technical Assistance (WaterTA) initiative, which focuses directly on the status and needs of recipients and on developing locally driven approaches to identifying and implementing public health solutions to ensure equitable access to water infrastructure funding (EPA Office of Water 2023). For example, when a large water utility consolidates with a smaller utility that serves a disadvantaged community, the restructuring could result in less affordable drinking water. As a result, the proposed WSRAR would require any identified restructuring alternative, including consolidation, to describe how it will ensure that the community served by the assessed PWS will achieve access to safe, affordable drinking water. Feasible alternatives for PWSs struggling with long-term compliance challenges should reflect the socio-economic conditions of the communities they serve, including disadvantaged or underserved status, or other barriers to water equity such as historical disinvestment in water infrastructure. Therefore, when identifying solutions for a restructuring water system, the assessor must consider not only geographical and technical factors, but also water affordability and socio-economic conditions of the community. States should proactively engage with local governments and community leaders that would be affected by restructuring to fully understand the range of technical, managerial, financial, and socio-economic factors that create long-term compliance challenges. Public water systems that might have attempted to restructure but remain persistently noncompliant have demonstrated they do not have the sustainable capacity to provide safe, affordable drinking water. To address the significant public health risks to the

communities they serve, community leaders and drinking water utilities should work closely with states to evaluate all forms of restructuring, including whether a form of consolidation or transfer of ownership is the right solution.

2. Engage Affected Communities Directly in Restructuring Decision Making

States and water utilities should directly engage with community leaders when making restructuring decisions. This approach is essential to ensure successful collaboration between state and local authorities, community leaders, and drinking water utilities. Direct engagement is particularly important if the water system is considering consolidation or transfer of ownership, which can raise community concerns about the affordability of safe drinking water and which involve complicated technical and financial terms and concepts. States should work with utilities, trained facilitators, and technical assistance providers to clearly communicate the costs and benefits of restructuring alternatives to community leaders and consumers and should ensure frequent opportunities for public input. In addition, the management structure determines the authority to establish water rates and rate structures, to apply for state and Federal funding, and to operate the water system. Therefore, states should provide comprehensive information that describes alternative management structures and water system ownership types to the affected communities. Providing information to support community involvement in decision making includes, for example, access to state data, and to mapping and planning tools. The EPA can assist in this process by providing guidance and tools to support community-level engagements in workshops, public meetings, and information sharing, including the agency's partnerships implementation tools and resources. More information about these implementation tools and resources is available at the agency's website for water system partnerships.[2]

3. Ensure the Community Has Capacity To Make Affordable Investments in Safe Drinking Water

Under SDWA section 1414(h), a water system may be a candidate for a mandatory assessment even if it has attempted to obtain technical or financial assistance through the Drinking Water State Revolving Fund (DWSRF). Under the proposed WSRAR, states and drinking water utilities would benefit from the availability of an unprecedented level of Federal investment in grant programs that focus on small, disadvantaged, and underserved communities. These programs can help PWSs achieve and maintain the long-term capacity to provide safe drinking water through the implementation of a wide range of eligible restructuring activities, including consolidation or transfer of ownership. The 2021 Infrastructure Investment and Jobs Act, also known as the Bipartisan Infrastructure Law (BIL), is set to provide $16.6 billion in additional investment in the DWSRF over the next three years. A key priority of the BIL is to increase investment in disadvantaged communities, including those with environmental justice concerns. Nearly half (49 percent) of this investment is designated for disadvantaged communities either as loan forgiveness or as grants to water systems that meet a state's disadvantaged community criteria as described in SDWA section 1452(d). These resources may be used to: identify restructuring alternatives that address the underlying causes of noncompliance; provide technical support for communities applying for funding; design and implement restructuring plans; and build and maintain water systems with the long-term capacity to provide affordable access to safe drinking water. The EPA will continue to work with states to implement program administration flexibilities under the DWSRF that are designed to help disadvantaged communities overcome barriers in applying for and receiving DWSRF funds. In addition, the EPA's Small, Underserved and Disadvantaged Community (SUDC) grant program can help communities establish and maintain access to safe, affordable drinking water by funding eligible restructuring activities. These activities include physical infrastructure improvements related to treatment, distribution, and storage; development of new sources; and assistance to increase technical, managerial, and financial (TMF) capacity, physical interconnection, water system consolidation or purchase of a water system. For more information on how SUDC grants may be used to support water system restructuring, please refer to the EPA's website.[3] The EPA will continue to collaborate with states, technical assistance providers and community leaders to implement the EPA's WaterTA programs to ensure that small, disadvantaged, or underserved communities can successfully identify water challenges, develop plans, apply for, and effectively utilize, BIL, SUDC and other funding to build their capacity and address compliance challenges. In addition, states, water utilities, and local communities should explore customer-assistance programs that can help ensure affordability of water rates and allow the water utility to make the infrastructure investments necessary to provide sustainable access to safe, reliable drinking water services (UNC EFC 2017, EPA 2016).

IV. Proposed Water System Restructuring Assessment Rule

The three regulatory components previously described—state primacy revisions, mandatory assessment requirements, and restructuring plan eligibility requirements and limitations for enforcement relief and liability protection—comprise the framework of the proposed rule. This section of the preamble describes the proposed rule sections that govern mandatory restructuring assessments and restructuring plans.

The agency seeks public comment on whether the rule appropriately balances meeting the statutory requirements of the SDWA while considering the impacts of the proposed requirements on our state and Tribal co-regulators, large and small water utilities, and the communities they serve. The EPA also has identified in this preamble specific topics for which the agency seeks public comment.

A. General

1. Authority

SDWA section 1413 and its implementing regulations under 40 CFR part 142 subpart B set forth the requirements for a state to obtain primacy for EPA regulations under 40 CFR parts 141 and 142, and for EPA review and approval of state applications for primacy or for revisions to primacy. Because AWIA directly amended the criteria for primacy under SDWA section 1413(a), every state with primacy for the PWSS program must submit to the EPA an application for a primacy revision that demonstrates that the state has adopted, and is prepared to implement, the requirements of the proposed WSRAR. The proposed WSRAR, if finalized, would amend 40 CFR 142.10 and 142.11 to describe the basis on which the EPA would determine whether to authorize state

[2] *https://www.epa.gov/dwcapacity/water-system-partnerships-implementation-tools-and-resources.*

[3] *https://www.epa.gov/dwcapacity/wiin-grant-small-underserved-and-disadvantaged-communities-grant-program-0.*

primacy for the WSRAR, and the content of a state application that is required for the agency's approval of a primacy revision. The proposed WSRAR also contains state recordkeeping requirements under amended 40 CFR 142.14, and state reporting requirements under amended 40 CFR 142.15. These proposed reporting and recordkeeping requirements, if finalized, would support the EPA's oversight of state implementation of the WSRAR and ensure consistent compliance with the proposed requirements.

2. Direct Implementation by the EPA

Where an EPA Region has primacy for the WSRAR, the Regional Administrator would have the authority, fully equivalent to that of a state, to mandate restructuring assessments, to perform assessments, to review and approve restructuring plans, and to determine PWS eligibility for restructuring incentives. This equivalent authority also would include EPA enforcement actions for noncompliance with the WSRAR and use of its independent enforcement authority under SDWA section 1414. Accordingly, the term ''state'' as it appears throughout this preamble, also refers to the EPA exercising its authority to implement the WSRAR. In addition, states with primacy for the WSRAR could, at their discretion, request that the EPA Region mandate an assessment of a PWS or assist the state with the implementation and enforcement of WSRAR requirements.

3. Applicability

The proposed requirements of the WSRAR would apply to all states for which the EPA has approved primacy for the WSRAR, and to PWSs for which an approved state has mandated a restructuring assessment. Additional proposed WSRAR requirements would apply to PWSs that submit plans to states seeking enforcement relief or liability protection.

B. Definitions

The EPA proposes the following terms and definitions for the WSRAR:

1. Assessed Water System

The EPA proposes this term to refer to a PWS that meets all four preconditions for a state to use its mandatory assessment authority described in SDWA section 1414(h)(3)(A), and that is the subject of a mandatory restructuring assessment as required by the state pursuant to proposed 40 CFR 142.92.

2. Enforcement Relief

The EPA proposes this term to refer to the incentive described in SDWA section 1414(h)(2). Enforcement relief would apply to an eligible PWS as specified in proposed sections 40 CFR 142.93 and 142.94. A PWS would be eligible for enforcement relief if the state approved a restructuring plan that met the proposed requirements and that would result in physical or administrative consolidation; transfer of ownership to improve water quality; or a contractual agreement to carry out the administrative or managerial functions of a water system. Enforcement relief would mean that if a state approved a restructuring plan, the state could not take enforcement action under SDWA for specific violations identified in the plan for up to two years from the date of state approval. If the eligible water system were to complete its planned restructuring earlier, the enforcement relief period would end on the date of completion.

3. Liability Protection

The EPA proposes this term to refer to the incentive described in SDWA section 1414(h)(5). This incentive applies to a non-responsible (compliant) water system that seeks liability protection when it restructures with an assessed (non-compliant) water system. Under the proposed rule, a non-responsible water system would be eligible for liability protection once restructuring has been completed under a state-approved restructuring plan for physical or administrative consolidation; transfer of ownership to improve water quality; or a contractual agreement to carry out the administrative or managerial functions of a water system. Liability protection would mean that, after using available assets of the assessed water system to pay any liabilities for specific violations identified in the approved plan, the non-responsible water system would have no remaining liability under SDWA for those specific violations. Liability protection would continue for SDWA violations at the assessed system that occur during restructuring, but that protection would end after the state determined that the non-responsible system had become the owner of the newly restructured water system.

4. Mandatory Restructuring Assessment

The EPA proposes this term to refer to a mandatory evaluation of restructuring alternatives at an assessed water system as described in SDWA section 1414(h)(3) and that is performed consistent with the requirements of proposed 40 CFR 142.92. For rule implementation purposes, the term ''restructuring'' means any planned change in water system operations, management, or infrastructure.

5. Non-Responsible System

The EPA proposes this term to refer to a compliant PWS that restructures with an assessed water system under a state-approved plan that is based on a completed mandatory restructuring assessment. The non-responsible system is the PWS that intends to benefit from liability protection because it did not commit the violations identified in the approved restructuring plan. Under the proposed rule, if the state determined that all requirements for liability protection in proposed 40 CFR 142.95 had been met, then the non-responsible system would not be liable for assessed water system violations identified in the plan, but it would be required to use any acquired liquid assets of the assessed water system to compensate the state for any fines or penalties associated with the identified violations. Under the proposed rule, a non-responsible system would continue to receive liability protection for violations at the assessed system that occurred during restructuring but would become liable for violations after it became the owner of the newly restructured water system.

6. Restructuring Plan

The EPA proposes this term to refer to the four restructuring plan types cited in SDWA section 1414(h)(1): physical consolidation of a water system with one or more other water systems; the consolidation of significant management or administrative functions of a water system with one or more other water systems; the transfer of ownership of a water system to another water system for purposes of improving drinking water quality; and a contractual agreement for significant management or administrative functions of a water system. Although other restructuring plan types are possible, they are outside the scope of this proposed rulemaking. A PWS that voluntarily develops and submits a plan to potentially benefit from the SDWA incentives should only incur burden when there is an incentive to do so. Unlike a mandatory restructuring assessment, a restructuring plan would be optional for a water system to submit. Consistent with SDWA, under the proposed 40 CFR 142.93, a submitted restructuring plan must include a schedule for restructuring activities and measures of progress. In addition, to be eligible for enforcement relief or liability

protection, the restructuring plan must identify the specific violations to which the restructuring incentives would apply.

C. Mandatory Restructuring Assessments

The proposed WSRAR, if finalized, would establish requirements for the EPA, the state, or a state-approved assessor to implement a mandatory restructuring assessment according to an established schedule, and to produce an assessment report that satisfies the proposed content and tailoring requirements of the WSRAR. The specific elements of the proposed mandatory assessment requirements are outlined in the following sections.

1. When a State May Mandate an Assessment

SDWA section 1414(h)(3)(A) describes four preconditions that a state would be required to find are applicable to a PWS before it could mandate a restructuring assessment. The proposed WSRAR restates these four preconditions to provide additional clarifications. A state with primacy for the proposed WSRAR may mandate a restructuring assessment if it finds that: (1) the PWS has repeatedly violated one or more NPDWRs and such violations are likely to adversely affect human health; (2) the PWS is unable or unwilling to implement restructuring activities, or already has attempted to implement such activities but has not achieved compliance; (3) restructuring of the water system, including a form of consolidation or a transfer of ownership, is feasible; and (4) restructuring of the water system could result in greater compliance with drinking water standards. Consistent with the SDWA, under the proposed rule each state has the discretion to determine whether a PWS meets all four preconditions and, if so, whether to mandate a restructuring assessment as a result. When exercising its mandatory assessment authority, a state would be required to provide written notification to the assessed system. This ''state notification date'' would determine the milestones and dates in the required assessment schedule.

Recurring monitoring violations might conceal repeated health-based violations at PWSs. Although recurring monitoring violations are not a regulatory precondition for a mandatory assessment, states should ensure there are no underlying health-based violations by investigating possible causes of the monitoring violations.

2. State Notification

If a state finds that a public water system meets the four preconditions and mandates a restructuring assessment, the state would be required to notify the assessed system in writing.

3. Minimum Assessment Tailoring Criteria

SDWA section 1414(h)(3)(A) requires a mandatory assessment to identify restructuring options that are expected to help the water system achieve compliance and that are feasible for the water system to implement. A wide range of water system restructuring alternatives are possible. These alternatives range from temporary, informal agreements between neighboring water systems to permanent, formal types of restructuring, such as physical consolidation. The EPA expects that an assessor would evaluate and compare restructuring alternatives from within this range, such as changes in rate structure and associated impacts, installation of treatment technology, operator training, or access to alternative water supplies. SDWA section 1414(h)(3)(B) states that the requirements of a mandatory restructuring assessment must be tailored to the size, type, and other characteristics of the assessed water system. Therefore, consistent with these two SDWA provisions, and with the proposed principles of restructuring, the proposed rule requires the assessor to ''tailor'' the feasibility of restructuring options based on the following geographical, socio-economic, and physical criteria. The information would ensure that a feasible restructuring alternative is technically, managerially, and financially feasible in the long term for the assessed PWS to implement.

a. System Size

The population served by the assessed water system. This criterion is required by the SDWA.

b. System Type

The classification of the assessed system as a community water system or a noncommunity water system. This criterion is required by the SDWA.

c. Source

The extent to which the assessed system uses ground water, surface water, or both ground and surface water as a drinking water supply, and the extent to which the drinking water supply is purchased from another supplier of water.

d. TMF Capacity

The technical, financial, and managerial capacity of the assessed system, using the state definition of each term as part of its capacity development strategy under SDWA section 1420(c).

e. Disadvantaged or Underserved Community Status

A determination whether the service area of an assessed water system meets the state definition of a disadvantaged community pursuant to the requirements of SDWA section 1452(d) or SDWA section 1459A(c)(2), or whether a community is underserved pursuant to SDWA section 1459A(a)(2). Disadvantaged or underserved status is a critical socio-economic factor that determines feasibility of the restructuring options both in terms of the affordability of the restructuring and the impacts of the restructuring on the community served by the assessed water system.

f. Geographic Factors

The extent to which proximity to neighboring water systems, changes in elevation, or other geographic factors affect the available restructuring alternatives.

g. Hydrogeologic or Geologic Factors

The potential or known interactions between surface activities, such as agriculture, and the ground water or surface water sources of water used by the assessed system. This criterion includes naturally occurring levels of contaminants in the geologic formation surrounding a ground water source.

h. State or Local Statutory or Regulatory Requirements

State or local laws or regulations can determine the permissible legal authorities and types of restructuring at assessed water systems.

Request for public comment: The EPA requests public comment on all aspects of the proposed rulemaking, but in particular on the proposed minimum Federal tailoring criteria, including other water system characteristics or socio-economic factors that could affect restructuring alternatives.

4. Minimum Assessment Report Content Requirements

Under the proposed WSRAR, a mandatory restructuring assessment would identify feasible restructuring alternatives that must be documented in a report that meets five minimum content requirements. These requirements would establish a minimum standard that requires a focus

on identifying underlying causes of non-compliance, protecting public health from ongoing violations, and a long-term plan to develop a sustainable capacity to provide safe, affordable drinking water. The content requirements also include a description of the potential community impacts of restructuring alternatives.

First, to address immediate health risks, the proposed rule would require the assessment report to describe all unresolved violations, their underlying causes, their enforcement status, and how restructuring would return the system to compliance as soon as practicable. Underlying causes can be technical, such as inadequate treatment technologies, or financial or managerial issues such as those related to being a disadvantaged or underserved community.

Second, to achieve a sustainable capacity to provide safe drinking water, the proposed rule would require the assessment report to identify at least one feasible restructuring alternative for the assessed water system that will return the PWS to compliance as soon as possible, while also improving its technical, managerial, and financial (TMF) capacity. For purposes of implementing these proposed requirements, the term ''TMF capacity'' generally means the capability of a public water system to achieve and maintain compliance with NPDWRs, including ensuring sufficient resources for sustainable fiscal planning and management. Technical capacity improvements may include greater access to higher quality source water; sharing, upgrading, or building new infrastructure; or implementing more effective treatment technologies. Managerial capacity improvements may include increasing expertise in water system planning and operations, or enhancing systems' financial, accounting, and asset management practices. Financial capacity improvements may include reducing costs, achieving greater economies of scale through shared services, or increasing a system's sustainable access to funding through new partnerships (EPA Office of Water 2017).

Third, the assessment report would be required to describe how the assessor has used the tailoring criteria to take a holistic approach to identifying feasible and affordable alternatives based on a broad range of technical, managerial, financial, and socio-economic factors. The report also must describe how the proposed alternatives ensure that the communities served by the assessed water system sustainably achieve or maintain access to safe, affordable drinking water. As part of its primacy revision for the rule, a state may propose using affordability criteria in addition to those already identified by the state as required under SDWA section 1452(d)(3). This requirement helps to ensure that the assessment considers the long-term affordability impacts of restructuring alternatives, particularly at water systems that serve disadvantaged or underserved communities.

Fourth, because SDWA section 1414(h) establishes incentives for consolidation or transfer of ownership at struggling water systems, the proposed rule would require the mandatory assessment report to provide an explanation if these alternatives are considered infeasible.

Finally, to help the state or EPA ensure the assessment is valid, the proposed rule would require that the assessment report include a description of the data, data sources, information, procedures, and techniques used to identify the feasible restructuring alternatives for the assessed water system. This documentation requirement helps ensure that the state or EPA could independently determine the quality of the evidence used as the basis for an evaluation of alternatives.

5. Burden of Assessments

SDWA section 1414(h)(3)(D) describes a sense of Congress that a mandatory restructuring assessment should not be ''overly burdensome'' on the assessed system. Under the proposed WSRAR, the mandatory assessment would involve collecting data; identifying and evaluating feasible alternatives using the tailoring criteria; and preparing an assessment report. Although the EPA expects that the assessment burden would vary by individual water system, the WSRAR's minimum content and tailoring requirements have been designed to minimize the burden. In addition, as described in the economic impact analysis of the proposed WSRAR, due to the technical expertise necessary to meet the WSRAR's proposed requirements and the proposed principles of restructuring, the EPA anticipates that states would perform nearly all mandatory restructuring assessments (EPA Office of Water 2022). Therefore, a mandatory assessment conducted according to the proposed requirements would not be overly burdensome on the assessed system.

6. Eligible Assessors

Consistent with the meaning and intent of the statute, the EPA's proposed rule restates SDWA section 1414(h)(3)(C) while providing additional clarifications. The assessor would be responsible for ensuring that the assessment report aligns with the proposed restructuring principles, meets all content requirements, is submitted on time, and that the restructuring alternatives identified during the assessment are feasible in the long term based on the tailoring requirements. A state or a third-party assessor may perform the assessment. A third-party assessor could be a technical assistance provider or another individual whom the state deems to be qualified to perform the mandatory assessment on behalf of either the water system or the state. A third-party assessor that performed an assessment on behalf of the state would be acting as ''the state'' for purposes of performing the evaluation of alternatives and preparing the assessment report. Alternatively, the assessed water system could conduct a self-assessment if approved by the state. To ensure that an assessor is qualified, as part of its primacy revision each state would be required to establish and implement procedures and qualifications for reviewing and approving eligible assessors.

7. Assessment Schedule

The following proposed assessment schedule requirements apply to a state, to a PWS performing a self-assessment, and to a third-party assessor retained by the assessed water system. These requirements would begin as of the date the state notifies the water system in writing. Within 30 days of the state notification date, the water system could request in writing that the state approve either a self-assessment or a third-party assessor retained by the water system. The state would have 30 days from receipt of the system's request to approve or reject the request. If the state rejected the request, or if the system did not request a self-assessment within 30 days, the state could decide to perform the assessment instead. In such cases, the system also would be required to provide relevant information requested by the state, such as an asset inventory, accounting records to demonstrate financial capacity, or monitoring results, to help the state perform the assessment.

If the state approved the request for a self-assessment or third-party assessor, the assessment report would be due on the submittal date established by the state. The EPA expects that the submittal date would be based on the anticipated complexity of the mandatory assessment. During the assessment, either the assessed system or the state could propose a different

submittal date. In such cases, the state ultimately would decide, based on information or other documentation that the state deemed acceptable, whether to change the submittal date. When submitting the assessment report to the state, the assessed water system or an approved third-party assessor would be required to include a certification statement. The certification statement would attest that: the assessor has the authority to verify the assessment results; the report content is true, accurate, and complete; and the assessor understands the penalties for submitting false information to the state.

8. Public Meeting

If the mandatory restructuring assessment identified a form of consolidation or transfer of ownership as a feasible alternative for the immediate and long-term needs of the community, the state would be required to notify the community that it will hold a public meeting. The state would hold this meeting as soon as practicable after receiving the assessment report from the assessed water system. If the state performed the assessment, it would be required to hold the meeting before approving the mandatory assessment report.

Consistent with the principles of restructuring, the required public meeting would allow community-based organizations and residents served by the system to be directly involved in decision-making to ensure that the proposed consolidation or transfer of ownership would meet immediate and long-term community needs. The state and the water utility would provide specific details from the assessment report to the local community, including the anticipated costs and benefits, to ensure transparency into how the assessment was based on a holistic approach to identify consolidation or transfer of ownership as a sustainable, feasible and affordable alternative. To ensure meaningful opportunity for community participation, the public meeting would be required to comply with the EPA's notice, location, and time requirements under 40 CFR 25.6, as well as any state-specific-regulations for public meetings. The EPA expects that the state would consider community feedback received during the public meeting, and the potential impacts of restructuring on the community, before it determines whether to approve the report. The EPA also strongly encourages states to make publicly available a written summary of its responses to comments received during the public meeting. The public meeting requirements are intended to provide transparency into, and accountability for, the mandatory assessment decision-making process.

9. State Determination

Following the public meeting, the state would determine whether the report complied with tailoring and content requirements. Once the state determined that the submitted assessment met all requirements and was developed consistent with the proposed restructuring principles, it would approve the assessment, and notify the assessed water system in writing. If the state determined that the submitted assessment report did not meet all proposed requirements, it could choose to consult with the assessed system to determine a schedule and a method for completing a revised assessment report.

10. Public Availability of Approved Assessment Report

Within 30 days of approval, the state would be required to make electronic copies of the report publicly available on the state website, and physical copies available in one or more public libraries within, or as near as possible to, the communities served by the assessed water system. Requiring both electronic and physical copies would help ensure that that the approved assessment is widely available to the local community, including to individuals without internet service. The EPA expects that states will take additional steps to ensure that approved assessment reports are publicly available in an alternative format, and that translation services are provided, in communities where English is not the primary language.

11. State Consultation With the Assessed Water System and the Local Community

In addition to making the approved report publicly available, the state would be required to meet with the assessed water system to discuss the restructuring alternatives. The state consultation is intended to ensure that the assessed water system understands proposed alternatives and their potential benefits, as well as available sources of state and Federal funding for restructuring. Additionally, consistent with the principles of restructuring, the EPA strongly encourages states to either create a Citizen's Advisory Committee (CAC) or to identify an existing organization, such as the local water utility board, a town committee, or a local environmental justice group, that would serve as a community point-of-contact to perform three essential roles during the assessment. First, it would collaborate with the state and assessed PWS to ensure a shared understanding of the purpose, schedule, and objectives of the assessment. Second, it would consult with the state and assessed PWS as restructuring alternatives are identified, to help ensure that the tailoring requirements are met. Third, it would assist the state and assessed water system in the development of a restructuring plan, after the assessment is complete.

Request for public comment: The EPA requests public comment on all aspects of the proposed rulemaking, but in particular on the proposed schedule for mandatory assessments, including the reasonableness of the proposed time frames. The agency is aware of stakeholder concerns that when communities are excluded from restructuring decisions, the goal of access to safe, affordable drinking water may not be achieved. Given these concerns, a key goal of the WSRAR is to ensure that communities are directly involved in mandatory restructuring assessments. At the same time, the EPA assumes that, due to the technical and financial resources necessary to implement the proposed requirements, states will perform nearly all mandatory restructuring assessments. As a result, another key goal of the WSRAR is to ensure that state implementation burden is minimized while meeting the requirements of SDWA section 1414(h). Therefore, the EPA requests specific comment on how best to strengthen community involvement in mandatory restructuring assessments in the final rule, while also considering the potential implementation burden of such requirements on states. The EPA considers direct community involvement to include both regular collaboration between a local community organization, the state, and the restructuring PWS, and periodic engagement with the broader community at key junctures of the assessment. Regular collaboration is important to building trust with the local community while also ensuring that restructuring decisions are locally driven, and based on community culture, needs and interests. To ensure regular collaboration with the local community, the EPA could require states to ensure a community point-of-contact for each mandatory assessment, either by creating a CAC or by identifying an existing organization for this purpose. As previously described, an existing organization would be defined broadly and could include a local water utility board, a town

committee, or a local environmental justice group.

Periodic engagement with the broader community also is important because although not every member of the affected community is able to collaborate regularly with the state and assessed PWS, all members of the community should be fully informed about the purpose, objectives, and schedule of the assessment, and about the potential impacts of restructuring on each household's ability to maintain or achieve access to safe, affordable drinking water. To ensure periodic engagement with the broader community, the EPA would require a state to describe in its mandatory primacy revisions how it would implement the WSRAR principles of restructuring at three key stages of the mandatory restructuring assessment: when the assessment is mandated, to provide information to the community about the purpose, objectives and schedule; when restructuring alternatives are identified, to explain what kinds of changes the state and water utility are considering; and, when the assessment is complete, to explain what kind of restructuring the state has approved, when it will be completed, and how community access to safe, affordable drinking water will be maintained or achieved.

In addition, the EPA seeks public comment on how best to ensure transparency into restructuring decisions, and accountability for the impacts of restructuring, in communities where English is not the primary language.

D. Restructuring Plans

1. Plan Types Eligible for Restructuring Incentives

SDWA section 1414(h)(1) identifies four types of restructuring plans that are eligible for enforcement relief under SDWA section 1414(h)(2) or for liability protection under section 1414(h)(5): physical consolidation between water systems; management or administrative consolidation; transfer of ownership to improve drinking water quality; and a contractual agreement for significant management or administrative functions of a water system to correct violations identified in the plan. In addition, SDWA section 1414 (h)(1) requires a restructuring plan to identify the violations at the restructuring water system(s) and include an implementation schedule and measures of restructuring progress. Consistent with the meaning and intent of the SDWA, the proposed WSRAR reaffirms and clarifies these SDWA section 1414(h)(1) requirements while providing additional clarifications.

In preparing this proposed rulemaking, the EPA conducted a literature review that identified several published reports and case studies on public water system restructuring (RCAP 2020; Water Research Foundation 2020; UNC Environmental Finance Center 2019b; Water Research Foundation 2018; RCAC 2016a; RCAC 2016b; AWWA 2012; AWWARF 2008). These reports and studies collectively refer to a typology of restructuring that generally defines physical consolidation as two or more water systems joining physically and managerially; administrative consolidation as the merger of decision-making and management authority of two or more water systems under one governance structure; and transfer of ownership as one water system acquiring the assets and liabilities of another water system. The reports and studies also showed that plans for physical consolidation, administrative consolidation, or transfers of ownership can vary based on several factors. These factors include extent of physical interconnection; type of governance (decision-making) structure; full or partial ownership transfer; ownership type; whether a new legal entity is created; and state laws governing restructuring (AWWARF 2008). Because of this variability, the EPA proposes to define each of the four eligible plan types in general terms, instead of through formal regulation, to assist states as they implement the rule. Further, a restructuring plan that is eligible for incentives may combine aspects of more than one type, *e.g.,* a plan for transfer of ownership also could involve administrative consolidation while the systems remain physically independent.

The first eligible type would be a plan for administrative or managerial consolidation.[4] Under the proposed rule, the term ''administrative consolidation'' generally would mean combining the decision-making authority for the administrative and managerial functions of two or more water systems under a single governance structure. These functions would include, for example, asset management, capital improvement planning, operator training, sampling, reporting, recordkeeping, accounting, establishing water rates, billing, and purchases of equipment. In practice, governance under administrative consolidation varies based on the legal powers and responsibilities permitted in each state and can take different forms, including joint or balanced mergers, joint powers authorities, regional utilities, and water and sewer authorities, among others (UNC Environmental Finance Center 2019a; Water Research Foundation 2018). Although administratively consolidated water systems would operate under a single governance structure, each could maintain physically independent supplies, treatment facilities, and distribution systems. Each water system also could remain independently owned and retain some degree of decision-making authority.

The second eligible type would be a plan for full physical consolidation. The EPA's proposed rule would distinguish physical consolidation from physical interconnection because a consecutive water system can be physically interconnected to purchase water while remaining administratively and managerially independent.[5] Therefore, although a mandatory restructuring assessment might identify physical interconnection as a feasible restructuring alternative, a plan for physical interconnection by itself would not be eligible for liability protection or enforcement relief. In this case, the proposed rule would require a plan for physical consolidation to include the administrative consolidation of two or more physically interconnected water systems.

The third eligible type would be a plan for the transfer of ownership to improve drinking water quality. In a transfer of ownership, a merged water system no longer exists as an independent entity because another water system has acquired its assets and liabilities. In practice, a transfer of ownership is often, but not necessarily, combined with administrative consolidation (Water Research Foundation 2020; UNC Environmental Finance Center 2019a; RCAC 2016a). Transfers of ownership generally involve:

- Direct acquisition, in which one water system directly acquires another water system in its entirety;
- Joint merger, in which two existing water systems combine to create a new, jointly owned and jointly managed water system or water system facility; or,
- Balanced merger, in which one water system acquires another water system but the acquired water system

[4] In this preamble, the EPA uses the terms ''administrative consolidation'' and ''managerial consolidation'' synonymously.

[5] As used here, ''consecutive water system'' has the same meaning as ''consecutive system'' as defined at 40 CFR 141.2.

retains some decision-making authority after the merger.

The fourth eligible plan type would be a contract for administrative or managerial functions of a PWS to correct the violations identified in the restructuring plan. Under this plan type, a technical assistance provider would contract with a water system to perform some or all administrative functions of the water system, while the water system owner would retain ownership of the PWS's assets and liabilities (AWWARF 2008). A technical assistance provider could be a non-governmental organization, a private company, or another water system. Like the other plan types, to be eligible the restructuring plan would be required to identify the violations to be resolved and to include an implementation schedule with measures of progress. Unlike plans for permanent forms of restructuring such as consolidation or transfer of ownership, however, the schedule and duration of this plan type would be limited to the contract terms.

Consistent with SDWA, this proposed WSRAR, if finalized, would not mandate any type of restructuring plan, including plans for consolidation, transfer of ownership, or contracts for administrative or managerial functions.

2. State Determination of Plan Eligibility for Restructuring Incentives

The proposed WSRAR, if finalized, would require each state to determine plan eligibility for restructuring incentives in two steps. First, the state must determine within 60 days whether a submitted plan is an eligible type and notify the submitting water system(s) in writing. Second, after this initial determination the state would determine within 12 months whether the submitted plan is eligible for enforcement relief, or, it would determine within 18 months whether the plan is eligible for liability protection. Because under the proposed rule the eligibility requirements for liability protection incorporate the requirements for enforcement relief, a plan for liability protection may include enforcement relief for the assessed PWS. If a state determined that a plan was an eligible type that did not satisfy the minimum requirements, the state could consult with the submitting system(s) to decide when and how to submit a revised plan.

3. Plan Revisions

The EPA recognizes that due to such challenges as unforeseen project delays or increases in project costs, either the planned restructuring or the implementation schedule could become infeasible. As a result, either revisions to an existing restructuring plan, or a new plan entirely, could be necessary to protect public health. To account for such cases, the EPA proposes to allow a restructuring water system to submit a new or revised plan to the state for approval. As with the original submitted restructuring plan, the state would be required to evaluate the new or revised plan against the same minimum eligibility requirements and any applicable requirements for enforcement relief or for liability protection as established under the proposed WSRAR.

Request for public comment: The EPA requests public comment on all aspects of the proposed rulemaking, but in particular on plan type eligibility and reasonableness of the proposed time frames.

E. Enforcement Relief Under Approved Restructuring Plans

1. Minimum Plan Eligibility Requirements for Enforcement Relief

Under the proposed WSRAR, if finalized, the state first would determine whether the submitted restructuring plan is eligible. Then the state would determine whether the plan satisfies the minimum requirements for enforcement relief. Unlike the SDWA eligibility requirements for liability protection, a plan could be eligible for enforcement relief even if it were not based on a mandatory restructuring assessment. As a result, under the proposed rule, the first minimum requirement is to identify each violation that the restructuring plan is intended to resolve. Second, because the identified violations indicate a public health risk, the restructuring plan would be required to describe how the proposed restructuring activities would return the system to compliance as soon as practicable by addressing the underlying causes of noncompliance. Third, as stated in SDWA section 1414(h)(1), the restructuring plan would be required to include an implementation schedule and measures of progress. The schedule and measures would allow the state to monitor restructuring progress to determine that the plan is on schedule and that the proposed restructuring activities remain feasible. Fourth, the plan would be required to describe how restructuring would improve the technical, managerial, and financial capacity of the restructuring system. This requirement is intended to ensure that an approved restructuring plan focuses not only on corrective actions for the violations identified in the plan, but also on strengthening water system capacity to sustainably maintain compliance over time. Fifth, the plan would be required to ensure that all consumers served by the restructuring water system continuously achieve access to safe, affordable drinking water. This requirement is intended both to prevent communities from losing access to safe drinking water because of restructuring, and to ensure consumers who live in disadvantaged or underserved communities receive sustainable, safe, and affordable drinking water. Finally, the restructuring plan would be required to include a request for enforcement relief for the noncompliant water system(s) subject to the plan.

The restructuring plan would be required to incorporate state-approved quantitative and qualitative types of information that describe how restructuring would protect public health in the short term while also improving the long-term TMF capacity of the restructuring PWS. States would have the discretion to determine whether the submitted documentation or data are acceptable for this purpose. Although the proposed rule does not prescribe specific forms of acceptable data or documentation, examples could include engineering plans, feasibility studies, performance specifications for treatment technologies, proposed changes to water system operations, state-approved water system operator certification, or sample results from alternative water supplies.

2. Conditional Eligibility Requirements for Enforcement Relief

In addition to the minimum eligibility requirements for enforcement relief, the proposed WSRAR, if finalized, would require the submitted restructuring plan to meet additional requirements under three sets of conditions. First, a restructuring plan that involves a transfer of ownership to improve drinking water quality would be required to describe the date on which ownership is expected to change and to identify the new water system owner. These conditional requirements would ensure that the state could determine when the new owner becomes legally liable for compliance at the restructured water system. Second, conditional requirements would apply if the restructuring plan were to establish a new or revised governance structure. Water system governance structures can vary based on state law and on the approach to administrative or physical consolidation. In some cases, a merged public water system no longer participates in the decision making for the newly consolidated water utility. As

a result, plans that featured a new or revised governance structure would be required to describe how the proposed structure would help achieve public health objectives. These additional requirements would allow the state to ensure that the proposed governance structure is consistent with state and local laws, supports resolving the underlying causes of the violations, and is likely to strengthen the capacity of the water system to provide sustainable access to affordable safe drinking water. Third, conditional requirements would apply if the submitted plan proposed to establish a temporary alternative source or supply of water. These additional requirements would apply under a wide range of site-specific conditions that include: the provision of bottled water or of water filters that are certified to remove contaminants to safe levels; purchased water from a wholesaler; or a temporary physical interconnection to a nearby water system.[6] The EPA anticipates that temporary alternative sources or supplies would be utilized under restructuring plans that take several years to implement, such as plans for physical consolidation. Under the proposed WSRAR, if finalized, such restructuring plans would be required to include an implementation schedule and measures of progress that are specific to the provision of a temporary alternative source or supply of water. In addition, the plan would need to incorporate data and other forms of documentation that the state finds acceptable to demonstrate how the alternative source or supply will comply with Federal and state health-based drinking water standards or other requirements. Finally, such plans would be required to identify when the temporary supply or source will no longer be needed. Before approving a plan that includes a temporary alternative source or supply of water, states also should consider the simultaneous compliance implications of this restructuring activity. Taking this step would help ensure that restructuring activities intended to improve compliance with one NPDWR would not potentially result in noncompliance with another.

[6] Organizations accredited by the American National standards Institute (ANSI) certify units using ANSI/NSF standards. Each ANSI/NSF standard requires verification of contaminant reduction performance claims, an evaluation of the unit, including its materials and structural integrity, and a review of the product labels and sales literature. ANSI/NSF standards are issued in two different sets, one for health concerns (such as removal of specific contaminants) and one for aesthetic concerns (such as improving taste or appearance of water).

The EPA expects that the time frame for developing and submitting a restructuring plan would vary widely based on several factors, including the specific characteristics of the restructuring water system, the number and type of restructuring activities planned, the nature and extent of the violations to be corrected, and applicable state or local laws and regulations. As a result, states are in the best position to determine, on a case-by-case basis, whether the proposed measures of progress and the implementation schedule are acceptable for each restructuring plan.

Request for comment: Similar to a mandatory restructuring assessment, implementation of the temporary provision of alternative water sources or supplies involves site-specific considerations for each public water system. The EPA plans to provide implementation training materials or case studies to describe examples of the temporary provision of an alternative source water or supply of water in a variety of site-specific scenarios. These materials would be designed to help states implement these proposed WSRAR requirements. Alternatively, the EPA could include in the rule language specific examples of the temporary provision of alternative water supplies; however, this approach could unnecessarily limit the applicability of the requirement. The EPA requests comment on whether adding such rule language would be appropriate for states and PWSs to understand these requirements.

3. Eligible Violation Types

Consistent with SDWA section 1414(h)(2), under the proposed WSRAR a PWS would be eligible for enforcement relief from specific violations under SDWA that were identified in the submitted restructuring plan, subject to state approval. The restructuring plan should identify each violation by its identification number, type, and the date of notification.

4. Public Meeting

As soon as practicable after determining a submitted plan is eligible for enforcement or liability protection, a state would be required to notify the service community and to conduct a public meeting. Like the requirements for a mandatory restructuring assessment, the purpose of the public meeting would be to ensure that the impacted communities are aware of how the draft restructuring plan, subject to public input and available before and during the meeting, would be implemented to ensure their sustainable access to safe, affordable drinking water. For example, a restructuring plan could include potential changes in water rates or rate structures, or terms of service. The public meeting would need to comply with the EPA's requirements in 40 CFR 25.6, as well as any state-specific-regulations. The EPA expects that state would incorporate community feedback received during the public meeting when determining whether the proposed restructuring plan is feasible in terms of the immediate and long-term needs of the community, particularly for plans that would result in consolidation or transfer of ownership.

5. State Determination Date

No later than 12 months from the date it determines that a restructuring plan is an eligible type, the state would be required to determine whether a plan meets all minimum and applicable conditional eligibility requirements. If the plan meets all rule requirements, and the public meeting has been held, the plan would be considered approved, and the state would be required to notify the supplier of water in writing.[7] If the plan did not meet all requirements, the state could consult with the water system that submitted the plan regarding a time frame for submitting a corrected plan.

6. Plan Availability

Within 30 days of approving a restructuring plan, the state would be required to make electronic copies of the plan publicly available on the state website, and physical copies available in one or more public libraries within, or as near as possible to, the communities served by the assessed water system. Requiring both electronic and physical copies ensures that that the approved assessment is widely available to the local community, including to individuals without internet service. The EPA also expects that states will take additional steps to ensure that approved restructuring plans are publicly available in an alternative format, and that translation services are provided, in communities where English is not the primary language.

7. Extent of Enforcement Relief

On the date the state determines that the submitted plan met all requirements, the plan would be approved and an enforcement relief period of up to two years would begin. During this enforcement relief period,

[7] As used here, ''supplier of water'' has the same meaning as defined at 40 CFR 142.2, *i.e.,* any person who owns or operates a public water system.

the state could neither initiate, nor continue to take, enforcement action for any of the specific violations of the SDWA that are identified in the plan. Consistent with SDWA section 1414(h)(2), the enforcement relief period could end earlier if the state determines that all restructuring activities in the approved plan were completed sooner than two years. Additionally, the proposed WSRAR clarifies that during the enforcement relief period the EPA could exercise its SDWA section 1431 imminent and substantial endangerment authority to protect public health.

8. Limitations

The proposed rulemaking contains limitations on enforcement relief. These limitations clarify that enforcement relief would apply only to violations identified in a restructuring plan. In addition, under the proposed rule a water system eligible for enforcement relief would be required to:

a. Implement any corrective actions that are required under existing enforcement orders or agreements that were established prior to the state's approval of the restructuring plan. This limitation ensures that steps are taken to protect public health by resolving existing noncompliance as soon as practicable. Although the corrective actions under existing enforcement orders must be taken, the EPA recommends that states consider ways to align such orders with proposed restructuring plans. For example, the implementation schedule for corrective actions under an existing enforcement order could be incorporated within a state-approved restructuring plan as part of the SDWA-required measures and schedule of restructuring activities.

b. Comply with any applicable requirements of the SDWA or its implementing regulations, including EPA directives stemming from the use of its SDWA section 1431 authority. These requirements including monitoring, reporting sample results, and notifying and informing consumers regarding their drinking water quality.

c. Comply with any enforcement actions for new violations that occur after the date on which the state approves the plan. Only violations identified in the approved restructuring plan would be eligible for statutory enforcement relief. Therefore, new violations at the restructuring water system would be ineligible.

9. Termination of Enforcement Relief Under Approved Plans

The EPA considers the proposed measures and schedule required for each approved restructuring plan to be critical elements of state oversight of water system restructuring. The EPA expects that during the enforcement relief period, each state would use the required measures and schedules to conduct oversight and to consult with the restructuring water system as needed. As a result of its oversight, a state might determine that a noncompliant water system is unwilling or unable to restructure according to the approved plan. In such cases, if the state determines that enforcement relief is no longer applicable to the water system, the state would be required to inform the supplier of water in writing as soon as practicable.

Request for comment: The EPA requests comment on all aspects of the proposed rulemaking, but in particular on the proposed minimum and conditional requirements for enforcement relief, and the reasonableness of the proposed time frames for state determination of plan eligibility for enforcement relief. In addition, the EPA seeks public comment on how best to ensure transparency into restructuring plans, and accountability for the impacts of restructuring, in communities where English is not the primary language.

10. Enforcement Relief Under Revised Plans

The EPA recognizes that restructuring activities, the project schedule, or both could become infeasible due to unanticipated project delays or increases in project costs. The EPA also recognizes that a water system that would benefit from enforcement relief is likely to incur additional violations as it restructures. Because SDWA section 1414(h)(2) establishes a two-year time frame for enforcement relief under an approved restructuring plan, pursuant to the proposed 40 CFR 142.94(h), the EPA proposes that a water system would not be eligible for additional Federal enforcement relief under an approved revised restructuring plan. Under a revised plan, states could instead provide state-level enforcement relief granted through system-specific enforcement agreements. Such enforcement agreements could identify additional compliance options for a noncompliant water system, thereby providing additional relief for the duration of the restructuring beyond the initial two years.

Request for comment: Although SDWA section 1414(h)(1) establishes a two-year limit on enforcement relief for each approved plan, the SDWA does not establish a limit on the number of restructuring plans that a state may approve for an individual PWS. As a result, the EPA requests comment on the assumptions underlying the proposed limits on enforcement relief under revised plans as described in this preamble.

F. Protection of Non-Responsible Water Systems Under Approved Restructuring Plans

1. Minimum Requirements for Liability Protection

The proposed eligibility requirements for liability protection build on the eligibility requirements for enforcement relief. Under the proposed rule the state would be required to determine whether the plan is an eligible type and meets the minimum and conditional requirements for enforcement relief. After this initial determination, the state would then determine whether the plan also satisfied the proposed requirements for liability protection.

Consistent with the language and intent of the statute, the proposed WSRAR restates the SDWA section 1414(h)(5) requirements for liability protection while providing additional clarifications. The proposed WSRAR, if finalized, would ensure that only a non-responsible system is potentially eligible for liability protection. To meet the proposed eligibility requirements, the non-responsible water system would be required to submit to the state a restructuring plan that:

a. Is based on a mandatory restructuring assessment that the state has approved. To meet this requirement, the EPA expects that the submitted plan would describe how the non-responsible water system plans to implement the feasible restructuring alternatives identified in the approved mandatory assessment report.

b. Identifies the non-responsible water system(s) and assessed water system(s) that are subject to the restructuring plan, to allow the state to determine the extent of any liability protection.

c. Identifies and describes, using data and other forms of documentation that the state finds acceptable for purposes of calculating liability, any potential and existing liability for violations that are identified in the restructuring plan. SDWA section 1414(h) does not describe or define potential or existing liability. The EPA proposes that states and suppliers of water would consider an ''existing liability'' to be a known obligation or responsibility for penalties and damages that the state has assessed for a violation identified in the plan. The submitted plan could identify these existing liabilities as the amounts of penalties or fines that would be cited in formal state notices of violation or

enforcement orders. In addition, states and suppliers of water would consider a ''potential liability'' to be an expected obligation or responsibility for health-based violations that are likely to reoccur at the assessed system until the identified underlying causes of noncompliance are resolved through restructuring. Identification of potential liabilities could include references to state regulations that specify the amounts of penalties or fines associated with the violation types that the assessed water system has repeatedly incurred and that prompted the state to mandate the restructuring assessment.

d. Identifies and describes, using data and other forms of documentation acceptable to the state, the available funds or other liquid assets of the assessed water system as of the date of plan submittal. The EPA expects that as part of its submitted restructuring plan a non-responsible water system would conduct an asset inventory of the assessed system. The asset inventory could identify and document recoverable assets that could be used to pay the liability for the identified violations.

e. Requests liability protection of the non-responsible system for the violations identified in the submitted plan.

2. Eligible Violation Types

Consistent with SDWA section 1414(h)(5), a non-responsible water system would be eligible for liability protection from specific violations under the SDWA if the violations were identified in the submitted restructuring plan, subject to state approval. The restructuring plan should identify each violation by its identification number, type, and the date of notification.

3. Exclusions

The EPA proposes that either an assessed water system, or a water system that otherwise meets the four statutory preconditions for a mandatory restructuring assessment, would be ineligible for liability protection. Under the SDWA, such water systems have repeatedly violated health-based standards and therefore cannot be considered ''non-responsible'' water systems.

4. Public Meeting

As under the proposed enforcement relief requirements, before approving a restructuring plan that is eligible for liability protection, the state would be required to notify the community that would be affected by the restructuring plan and to hold a public meeting. The primary purposes of the meeting are to provide the community served by the restructuring water system(s) a meaningful opportunity to understand how the restructuring would ensure their continuous access to safe, affordable drinking water, and how the restructuring plan would be implemented, including potential changes in water rates or rate structures, or terms of service. The state would be required to hold the meeting as soon as possible after it determines that a plan is an eligible type. The public meeting would need to comply with the EPA's notice, location, and time requirements for public meetings under 40 CFR 25.6, as well as any state-specific-regulations. The EPA also expects that the state would consider the outcomes of the public meeting when determining whether the proposed restructuring plan is feasible for both the immediate and long-term needs of the community, particularly for plans that would result in consolidation or transfer of ownership.

5. State Determination Date

The EPA proposes to require the state to determine that the plan meets the rule eligibility requirements for liability protection, and to notify the non-responsible water system, no more than 18 months from the date on which the state determines plan type eligibility. The proposed time frame would include the time necessary for the state to review and verify the required documentation of existing and potential liabilities and assets before making its determination. If the state determined that the submitted plan met all requirements, the submitted plan would be approved. As under the proposed requirements for enforcement relief, if the submitted plan did not meet all requirements, the state could consult with the non-responsible water system regarding a time frame for submitting a corrected plan.

6. Extent of Liability Protection

Unlike the enforcement relief incentive, a non-responsible water system would not be eligible as of the date of state approval of a plan that meets eligibility requirements. Instead, as required by SDWA section 1414(h)(5), under the proposed rule all restructuring must be completed before the non-responsible system is eligible for liability protection. As a result, the EPA expects that restructuring would begin as soon as practicable after the state determined that the plan met eligibility requirements. During restructuring, the state should consult with the non-responsible water system and apply the required measures and schedules of the restructuring plan to track progress. Once the state determined that all restructuring activities in the plan were complete, the state would be required to notify the non-responsible system in writing within 30 days.

Under the proposed rule, the state's notification must explain that, as of the date of state notification, the non-responsible water system is eligible for liability protection. To determine the extent of liability protection, the state would be required to calculate the difference between the total value of all liabilities and assets of the assessed (noncompliant) water system. To enable the state to perform this calculation, the submitted plan would be required to identify all assets and liabilities of the assessed water system. Although the non-responsible system would not be liable for penalties or fines that exceed the value of the identified liquid assets, the non-responsible water system would be required to transfer to the state any identified liquid assets or funds of the assessed system up to the amount necessary to pay the outstanding penalties or fines. The state's notification also would be required to explain that the non-responsible water system must consult with the state to determine when and how it would transfer the funds or other identified assets of the assessed system(s) to the state. Based on stakeholder consultation, the EPA acknowledges that an assessed system could have no liquid financial assets that could be used to pay liabilities. In such cases, to obtain liability protection, the non-responsible water system would be required to submit data or other forms of documentation acceptable to the state that demonstrate that the assessed system had no liquid financial assets.

In addition, although the eligibility requirements for each SDWA restructuring incentive are separate, a state may approve a restructuring plan that provides both enforcement relief for a noncompliant system and liability protection for a compliant system. For example, under an approved plan for transfer of ownership, enforcement relief would begin on the date the state approves the plan and end up to two years later. If the transfer of ownership were completed in fewer than two years, the enforcement relief would end on the date of completion. Under the same restructuring plan, liability protection for the non-responsible system would begin on the date that the transfer of ownership is completed. Within 30 days of this date, the non-responsible water system would consult with the state to determine if there were any acquired

assets that could be used to pay for fines or penalties owed by the noncompliant system. The non-responsible PWS would not be liable for any remaining amount.

7. Plan Availability

As with the proposed requirements for enforcement relief, within 30 days of approving a restructuring plan eligible for liability protection, the state would be required to make the approved plan publicly available. The state would need to provide electronic copies on the state website, and physical copies in one or more public libraries within, or as near as possible to, the communities served by the assessed water system. Requiring both electronic and physical copies would ensure that that the approved assessment is widely available to the local community, including to individuals without internet service. The EPA also expects that states will take additional steps to ensure that approved restructuring plans are publicly available in an alternative format, and that translation services are provided in communities where English is not the primary language.

8. Limitations

The EPA's proposal would not establish any liability protection that exceeds the extent of protection that the state calculates as required under the rule. The non-responsible water system also would be required to comply with all other applicable requirements of SDWA and its implementing regulations.

9. Determination of Change in the Supplier of Water

Under proposed 40 CFR 142.94(b)(1), if the non-responsible water system intended to take ownership of the restructured water system, then the restructuring plan would be required to identify the planned date of the change in ownership. This date should appear in the schedule of restructuring activities as would be required of any eligible plan. As part of its determination that all restructuring activities were completed, the state would be required to identify the date on which the non-responsible water system took ownership of the restructured water system, and to provide notice. Until this notification date, the non-responsible water system would not be liable for any violations that occurred during restructuring.

10. Liability Protection Under Revised Plans

As with plans seeking enforcement relief, the EPA recognizes that there could be circumstances under which an approved restructuring plan should be revised. The proposed WSRAR, if finalized, would allow a non-responsible water system to remain eligible for liability protection under a revised restructuring plan under three conditions. First, the non-responsible water system would need to provide a justification to the state, using data and other forms of documentation that the state found acceptable, that a revised plan is necessary to ensure that the restructuring objectives are achieved as soon as practicable. Second, the state would need to confirm that any violations identified in the revised restructuring plan did not occur at the non-responsible system. Third, the state would need to approve the revised restructuring plan consistent with the proposed rule's plan requirements for liability protection. As a result, the state would have 18 months from submittal of the revised plan to determine whether it met the eligibility requirements.

Request for comment: The EPA requests public comment on all aspects of the proposed rule, but in particular on the following aspects of this section of the proposed WSRAR: the liability protections proposed in this rulemaking, including the meaning of the terms ''potential liability'' and ''existing liability''; approaches to the identification of existing and potential liabilities and assets; the calculation of liability protection for the non-responsible system; minimum requirements for liability protection; and the reasonableness of the proposed time frames for state determination of plan eligibility for liability protection. The EPA also requests comment on how best to engage communities with environmental justice concerns as part of the proposed public meeting requirements for restructuring plans. In addition, the EPA seeks public comment on how best to ensure transparency into restructuring plans, and accountability for the impacts of restructuring, in communities where English is not the primary language.

G. Financial Assistance for Restructuring Activities

As provided under SDWA section 1414(h)(4), a PWS that has completed a mandatory restructuring assessment would be eligible for a DWSRF loan to support restructuring. The EPA believes that the language of SDWA section 1414(h)(4) is consistent with statutory language regarding DWSRF loan eligibility under SDWA section 1452(a)(3). As a result, under existing regulations states and assessed water systems should consider a completed mandatory restructuring assessment to be a means of identifying restructuring activities that are eligible for DWSRF loans. As a result, the agency does not propose to amend existing DWSRF regulations in 40 CFR part 35 to implement this provision under the WSRAR.

H. Violations

Under the proposed rule, a reporting violation would occur if the assessed water system, or an approved third party on behalf of the assessed water system:

1. Failed to submit the assessment report as mandated by the state;

2. Submitted an assessment report to the state after the submittal date that the supplier of water and the state had established through previous consultation;

3. Submitted an assessment report to the state that does not address all minimum elements; or

4. Submitted an assessment that does not include the required certification statement.

I. Effective Date

Pursuant to the Administrative Procedure Act (APA) at 5 U.S.C. 553(d), the EPA is proposing that the WSRAR would be effective 60 days from the date of publication in the **Federal Register**. Primacy agencies would be required to update their programs to incorporate the new primacy requirements within two years from the date of promulgation, with an optional two-year extension as provided under 40 CFR 142.12(b).

V. State Implementation

As of the date of this proposed rulemaking, the EPA has approved PWSS primacy for 49 states, Puerto Rico, American Samoa, Commonwealth of the Northern Mariana Islands, Virgin Islands, Guam, and the Navajo Nation. Primacy for the PWSS program is established under SDWA section 1413. The EPA may approve primacy for the PWSS program for states, territories, and federally recognized Tribes. To obtain initial primacy from the EPA, a state must meet the EPA's regulatory requirements under 40 CFR 142.10, including that it: has adopted drinking water regulations that are no less stringent than the NPDWRs established under SDWA section 1412; has adopted and is implementing adequate procedures for enforcement of the regulations; and, is keeping records and making reports as required by SDWA section 1413.

Under 40 CFR 142.11, a state's primacy application must contain several elements including:

- The text of the state's PWSS statutes and administrative regulations.
- Documentation of the primacy agency's procedures for enforcement of its drinking water regulations including a description of the state's procedures to maintain its PWS inventory and conduct sanitary surveys, identification of certified laboratories, a brief description of the state's program to ensure that new or substantially modified PWSs will be capable of complying with the state's drinking water regulations, copies of state statutory and regulatory provisions authorizing adoption and enforcement of state primary drinking water regulations.
- A brief description of state procedures for administrative or judicial action against noncompliant PWSs.
- A statement that the state will satisfy reporting and recordkeeping requirements.
- Text of the state's statutory and regulatory provisions concerning variances and exemptions (if allowed by the state).
- A description of the state's plan for ensuring safe drinking water under emergency conditions.
- Copies of state statutory and regulatory provisions authorizing the state executive branch to impose administrative penalties.
- An Attorney General's statement certifying that the laws and regulations were duly adopted and are enforceable.

The 2018 AWIA amended SDWA section 1413 to require, as a condition of primacy, the adoption and implementation of procedures for requiring public water systems to assess options or consolidation or transfer of ownership or other actions in accordance with regulations issued by the EPA under SDWA section 1414(h)(6). As a result, the proposed WSRAR would revise the implementing regulations under 40 CFR part 142 subpart B to include a description of the state's procedures for an assessment to be completed with respect to options for consolidation, transfer of ownership, or other restructuring actions in accordance with WSRAR requirements.

The proposed primacy requirements are intended to ensure that states would adequately describe how they would implement mandatory assessment programs and determine eligibility for enforcement relief or liability protection. The requirements would apply both to a state seeking an initial determination of primacy under 40 CFR 142.11 and to existing primacy agencies that seek a revision under 40 CFR 142.12. The EPA may not grant interim primacy for WSRAR under 40 CFR 142.12(e) because the proposed rule is not a NPDWR.

A. Revisions to Primacy Requirements

As described in proposed requirements under 40 CFR 142.10(i), the EPA would approve a state primacy application for the WSRAR if the agency were able to determine that, consistent with state legal authority, the state had adopted and is implementing procedures for conducting or approving mandatory restructuring assessments, and review of restructuring plans, as would be required under 40 CFR part 142 subpart J. To obtain primacy for the WSRAR, an applicant would be required to show that is has adopted and is implementing procedures to, among other activities: find that a PWS has satisfied the SDWA preconditions for a mandatory restructuring assessment; review and approve eligible assessors; ensure assessed water system compliance with the requirements for conducting a mandatory assessment, including public meetings; and, review restructuring plans to determine water system eligibility for enforcement relief or liability protection and the extent of liability protection, as applicable, based on rule requirements.

Pursuant to the proposed requirements under 40 CFR 142.11(a)(8), a state primacy application would be required to demonstrate to the EPA that it has adequate authority to satisfy all the proposed new WSRAR primacy requirements under 40 CFR 142.10(i), and the proposed new WSRAR reporting and recordkeeping requirements for mandatory assessments and approved restructuring plans under 40 CFR 142.14 and 142.15. The submitted application would serve as the basis for the EPA's initial primacy determinations for the WSRAR.

Pursuant to 40 CFR 142.12(c), an entity that already has primacy would be required to submit to the EPA a primacy revision application that includes: the documentation required by proposed new WSRAR primacy requirements under sections 142.10(i) and 142.11(a)(8); any primacy elements that would not change under a proposed program revision; and, a certification statement from the state's Attorney General or independent counsel, or the attorney representing the Indian Tribe, that its laws and regulations to carry out the requested program revisions were duly adopted and are enforceable.

B. State Reporting and Recordkeeping Requirements

The proposed WSRAR, if finalized, also would establish new reporting and recordkeeping requirements that are intended to ensure that mandatory assessments satisfy scheduling, content, and tailoring requirements, and that states determine water system eligibility for statutory incentives consistent with WSRAR requirements for restructuring plans.

1. Reporting Requirements

Existing regulations in 40 CFR 142.15 establish reporting requirements for states with primary enforcement responsibility. The proposed WSRAR would establish new requirements under 142.15(c)(8) for states to report to the EPA annually, using a format and on a schedule that the agency will have established, the name and identification number of each PWS for each of the following notifications or determinations, as applicable:

a. Candidates for a mandatory restructuring assessment. This proposed reporting element would refer to each PWS that the state has determined to be a candidate for a mandatory assessment, having met the four statutory preconditions in the proposed WSRAR, including the date of determination;

b. Mandatory assessment notifications. This proposed reporting element would refer to each identified PWS that the state has notified as the subject of a mandatory assessment, including the date of notification;

c. Mandatory assessments completed. This proposed reporting element would refer to each PWS that the state has notified as the subject of a mandatory restructuring assessment and has completed the assessment as required, including the date of completion;

d. Violations of mandatory assessment requirements. This proposed reporting element would refer to each PWS that the state has determined to be in violation of the WSRAR mandatory restructuring assessment requirements, by violation type and violation date; or

e. Eligibility for restructuring incentives. This proposed reporting element would refer to each PWS that the state has determined to be eligible for either enforcement relief or liability protection based on an approved restructuring plan, including the type of eligibility and the date of plan approval.

2. Recordkeeping Requirements

Existing regulations in 40 CFR 142.14 establish recordkeeping requirements for states with primary enforcement responsibility. To enable the EPA to

fulfill its oversight responsibilities, the proposed WSRAR also would establish recordkeeping requirements for primacy states under new 40 CFR 142.14(h). The proposed rule would require states to retain records of approved mandatory assessment reports for five years from the date of approval. In addition, the EPA also proposes to require that each state retain records of restructuring plans submitted by PWSs seeking enforcement relief or liability protection, and to provide a copy of such plans to the EPA upon request, from the date of plan approval until one year from the date on which the state determines that all restructuring activities in the approved plan are complete. In such cases, the EPA also proposes that states be required to retain an approved mandatory assessment report if: the approved assessment report served as the basis for a restructuring plan that met regulatory requirements for enforcement relief, or for any restructuring plan that met regulatory requirements for liability protection. In such cases, states would be required to retain a copy of an assessment report until one year following the completion of restructuring under an approved restructuring plan.

VI. Economic Impact Analysis

The following section summarizes the EPA's analysis to estimate the economic impact of the proposed WSRAR on states with primacy, including the Navajo Nation and U.S. territories, and EPA Regions, to develop and maintain mandatory assessment programs. Because the EPA is required to propose the WSRAR pursuant to 42 U.S.C. 300g–3(h)(6), and the scope of the proposed WSRAR is defined by 42 U.S.C. 300g–3(h), the agency did not consider regulatory alternatives. In addition, because the proposed WSRAR does not mandate restructuring plans, the EPA also did not estimate the costs to PWSs of developing restructuring plans, or the costs to states of reviewing restructuring plans to make eligibility determinations. The full economic impact analysis (EIA) *Analysis of the Economic Impacts of the Proposed Water System Restructuring Assessment Rule* is available in the docket for this action. See the **ADDRESSES** section of this document for instructions on accessing the docket.

A. Annualized and Present Value Cost Estimates

SDWA section 1413 requires states to develop mandatory assessment programs as a condition of primacy. In addition, consistent with SDWA section 1414(h)each state would have discretion to decide whether a PWS meets the statutory preconditions and whether to mandate a restructuring assessment. As a result, states would incur direct costs of the mandatory primacy revision under the proposed WSRAR, even if they elected not to use their mandatory assessment authority. To estimate the indirect costs of the proposed rule requirements on states and PWSs where a state chooses to exercise its mandatory assessment authority, the EPA also conducted a supplementary analysis, which is provided in Appendix A of the EIA for the proposed rule.

The direct costs of the proposed rule requirements would comprise both program development costs and program administration costs. States would incur program development costs to establish state programs to implement the proposed WSRAR. These costs would include reading and understanding the WSRAR, developing policies and procedures, preparing a primacy revision package, updating data systems, preliminary data analysis, outreach to PWS, and the education and training of staff. States would incur program administration costs to maintain established mandatory assessment programs. These costs would include maintaining program staffing and funding, collecting, and reviewing data to identify PWSs that meet the assessment preconditions, and reporting and recordkeeping.

Because the proposed rule would impose direct costs only on states, the EIA focused primarily on the program development and program administration costs of the mandatory primacy revision. Additionally, the EPA expects that to protect public health, states with primacy for the WSRAR would exercise their mandatory assessment authority. As a result, the EPA also conducted a supplementary analysis of the indirect costs of the proposed rule requirements on states and PWSs. The indirect cost estimates were based on different approaches to estimating the number of mandatory restructuring assessments that would be conducted over a 25-year period after promulgation of the rule. The indirect costs of the proposed WSRAR would include performing mandatory restructuring assessments; reviewing assessment reports to ensure they satisfy the content and tailoring requirements; and enforcement of assessment reporting violations. Details of the supplementary analysis are available in Appendix A of the EIA for the proposed WSRAR.

For each direct cost, the EPA developed high and low estimates. The EPA derived the high estimates from a cost model that assumed no prior experience conducting water system assessments. The EPA derived the low estimates based on available information about each primacy agency's baseline capacity to implement the WSRAR. The primary source of data for these estimates was interviews conducted with staff and managers from eight state PWSS programs. The EPA used data from these interviews to estimate the level-of-effort (LOE, in hours) to develop, administer and implement a mandatory assessment program. Following the interviews, states provided assessment forms, report examples, procedural documents, and spreadsheets showing the LOE for various assessments. The EPA used this information to better characterize the LOE estimates provided during the interviews. The EPA supplemented the interview information with details available on primacy agency websites, as well as documents provided by interview states that included assessment forms, report examples, state procedures and spreadsheets. The agency also used published EPA and state reports on state programs and state resource needs.

1. Program Development Burden Estimation

Based on these assumptions and data sources, the EPA estimated the costs of program development using two approaches. Under the first approach, the EPA assumed a constant uniform distribution between the high and low burden estimate. This approach permitted the EPA to estimate a theoretical upper bound program development burden of the proposed rule. The EPA refers to estimates based on this approach as ''full program development'' burden. The ''full program development'' burden is designed to show that, even under the constraint that prior experience conducting similar activities would not lower the burden of developing a mandatory assessment program, the estimated costs of the proposed WSRAR would not exceed any statutory or executive order thresholds (see section VII of this preamble).

Under the second approach, while the EPA assumed that all states need experience and technical expertise to implement mandatory assessment programs, each will start from a different baseline. Using the interview data, publicly available information on state websites, and published reports, the EPA established three categories of state baseline capacity, based on the assumed experience of each state in establishing and implementing

programs to conduct assessment activities like those that would be conducted under the proposed rule. Similar activities include Level 2 assessments under the Revised Total Coliform Rule (RTCR), sanitary surveys, TMF capacity assessments, and feasibility studies. The EPA assigned all states to one of the three baseline categories, from those with the lowest baseline capacity that conduct mostly technical capacity assessments (*i.e.,* sanitary surveys), to those with the greatest baseline capacity that already evaluate the feasibility of restructuring options. Under the ''differential program development'' approach, the EPA assumed that for the most experienced states program development costs would be 50 percent less than the full cost estimate, while for the least experienced states these costs would be equivalent to the ''full program development'' model values. For states that conduct assessment activities that include in-depth evaluation of technical and managerial capacity or routine site visits focused on TMF capacity, program development costs would be 25 percent less than the full cost estimate.

Of the two approaches, the EPA assumes the differential program development estimates, shown in Table VI–1 of this preamble, more accurately represent the cost of the EPA's proposal if finalized. Estimates in Table VI–1 of this preamble represent aggregate average development costs for primacy agencies during the three years after promulgation of the final rule, because the EPA assumes the LOE will vary by state based on factors other than program experience, such as program efficiencies in implementing procedures or policies, etc. As a result, some primacy agencies costs would exceed the highest estimate while others would be below the lowest estimate.

TABLE VI–1—ESTIMATED BURDEN AND COST FOR PROGRAM DEVELOPMENT ACTIVITIES

[Differential Program Development Cost Approach, Cost in 2023 Dollars]

Cost component	Average hours per primacy agency	Multiplier	Total hours [a]
Read and Understand the Rule	38	56 primacy agencies [c]	2,100
Regulation Adoption, Development of Primacy Agency Program/Primacy Revision Package [b].	623	56 primacy agencies [c]	34,905
Update Data System	76	56 primacy agencies [c]	4,229
Preliminary Data Analysis	32	56 primacy agencies [c]	1,790
PWS Outreach and Education	212	56 primacy agencies [c]	11,863
Staff Training	272	56 primacy agencies [c]	15,215
Total Hours			70,102
Labor Rate			$70.63
Estimated Total Cost			$4,951,212

[a] Totals may not add due to rounding.

[b] Although the cost of revising primacy packages does not apply to EPA Regions with primacy, the costs were included in the model because the costs could not be split out from the other regulation adoption costs.

[c] Entities with primacy include EPA (which has primacy for Wyoming and American Indian systems), 49 states (all except Wyoming), Puerto Rico, American Samoa, Commonwealth of the Northern Mariana Islands, Virgin Islands, Guam, and Navajo Nation.

2. Program Administration Costs

After adopting a new rule, states incur direct costs on an ongoing basis to administer the rule. For the proposed WSRAR, each state would incur direct program administration costs related to updating mandatory assessment guidance, forms, resources, and materials; training inexperienced staff; collecting and reviewing data to identify candidates for a mandatory assessment; and maintaining required records. Unlike the program development cost estimates, the EPA assumed that program administration costs would not vary based on past program experience conducting similar activities. Based on the results of state interviews, the EPA assumed that to identify candidates for mandatory assessments, states would collect and review data annually using one-third the amount of time required to conduct the preliminary data analysis. Like the program development cost estimates, the EPA also assumed that some primacy agencies would incur a higher level of effort (LOE) and some primacy agencies would incur a lower LOE to maintain their programs based on factors other than experience, such as program efficiencies in implementing procedures or policies. Therefore, the EPA calculated the average per primacy agency of the high and low estimates to develop the estimate for each program administration activity as shown in Table VI–2.

TABLE VI–2—ESTIMATED AVERAGE BURDEN AND COST FOR PROGRAM ADMINISTRATION

[Cost in 2023 Dollars]

Cost component	Average hours per primacy agency	Multiplier	Total hours [a]
Maintain Program	189	56 primacy agencies [b]	10,584
Collect and Review Data	13	56 primacy agencies [b]	728
Total Hours			11,312
Labor Rate			$70.63
Estimated Total Cost			$798,950

[a] Totals may not add due to rounding.

[b] Entities with primacy include EPA (which has primacy for Wyoming and American Indian systems), 49 states (all except Wyoming), Puerto Rico, American Samoa, Commonwealth of the Northern Mariana Islands, Virgin Islands, Guam, and Navajo Nation.

3. Total Direct Costs

As a result of its analysis, the EPA estimated that the annualized total direct (development and administrative) costs to states of implementing the requirements of this proposed WSRAR, if finalized, would lie within a 95 percent confidence interval of $0.8 to $1.0 million at the 2 percent discount rate. As shown in Table VI–3 of this preamble, in either the differential or full implementation burden scenarios, the estimated annualized total direct cost over a 25-year period is not more than $1 million. For more information about how the EPA estimated the annualized direct costs, please refer to section VI of the EIA.

TABLE VI–3—ANNUALIZED DIRECT COSTS TO PRIMACY AGENCIES OF THE PROPOSED WSRAR USING A 2% DISCOUNT RATE

[Millions of 2023 Dollars]

Cost component	Differential program development burden [b]	Full program development burden [c]
Read/Understand Rule:		
Est. 95% CI	*	*
	* – *	* – *
Other Program Development:		
Est. 95% CI	$0.2	$0.3
	$0.2–$0.2	$0.3–$0.3
Direct On-Going Program Administration:		
95% CI	$0.6	$0.6
	$0.6–$0.7	$0.6–$0.7
Total Direct Costs [a].		
Est. 95% CI	$0.9	$0.9
	$0.8–$0.9	$0.9–$1.0

* Costs are positive but less than $50,000, so would round to $0.0 in millions of dollars.
[a] Totals may not add due to rounding.
[b] Assumes that some primacy agencies will incur lower program development costs than others.
[c] Assumes all primacy agencies will incur the full program development costs.

B. Accounting for Uncertainty in the Cost Estimates

When preparing the EIA, the EPA also accounted for uncertainty in estimating the differences in the states' baseline capacity to conduct mandatory restructuring assessments, and in the estimated level of effort needed to complete program development and administrative tasks. The uncertainty in the estimates stems from the limited amount of data that could be used to estimate direct costs for all state programs and is inherent to the data sources available to populate the cost model. Therefore, the EPA used a three-pronged approach to address uncertainty in its estimate of the total (direct and indirect) cost of the proposed rule, including estimating the cost under four different cost scenarios based on two sets of assumptions about the number of assessments that primacy agencies could mandate and the cost of program development. Each scenario reflects a combination of one of two alternative assumptions about the number of assessments primacy agencies will mandate and one of two approaches for estimating primacy agencies' program development costs.

Scenario 1a assumes primacy agencies will mandate a low number of assessments and have a differential program development burden. Scenario 2a assumes primacy agencies will mandate a low number of assessments and have a full program development burden. Scenario 1b assumes primacy agencies will mandate a high number of assessments and have a differential program development burden. Scenario 2b assumes primacy agencies will mandate a high number of assessments and a have a full program development burden. Table VI–4 summarizes the four scenarios for which the EPA evaluated total costs of the proposed rule.

TABLE VI–4—RESULTS OF SCENARIO ANALYSIS

[Cost in 2023 Dollars]

Program development costs	Number of assessments mandated by primacy agencies	
	Low estimate based on violation duration approach: 352 Initial Assessments; 2,015 Assessments over 2028–2048	High estimate based on violation frequency approach: 575 Initial Assessments; 4,457 Assessments over 2028–2048.
Primacy Agencies in Categories B and C Face Differential Program Development Burden.	Scenario 1a (Low cost): ..... Low number of assessments, differential Program Development burden. Annualized cost: $1.6 million ..... Maximum annual cost in a single year: $2.4 million	Scenario 1b (Moderate-high cost): High number of assessments, differential Program Development burden. Annualized cost: $2.3 million. Maximum annual cost: $4.1 million.
All Primacy Agencies Face Full Program Development Burden as in Category A.	Scenario 2a (Moderate-low cost): ..... Low number of assessments, full Program Development burden. Annualized cost: $1.7 million ..... Maximum annual cost: $2.4 million	Scenario 2b (High cost): High number of assessments, full Program Development burden. Annualized cost: $2.4 million. Maximum annual cost: $4.1 million.

Present value of costs and annualized costs calculated using a 2 percent discount rate.

C. Non-Quantified Benefits of the Proposed WSRAR

Consistent with the provisions of SDWA section 1414(h), states have the discretion to mandate restructuring assessments that require assessed PWSs to undertake the restructuring alternatives identified in mandatory restructuring assessments, including forms of consolidation or transfer of ownership. To quantify the potential costs of these activities, the EPA estimated the number of restructuring assessments that states would mandate under different scenarios. For the potential benefits of the proposed WSRAR, the EPA conducted qualitative analysis that included the types of benefits likely to result from implementation of the proposed rule, as there is no reasonable basis for quantifying the effects of future restructuring activities on compliance rates. The EPA could not quantitatively estimate how the proposed WSRAR would affect water system capacity to comply with health-based standards, or what reductions in morbidity or mortality could result from water systems that return to compliance. The primary nonquantifiable benefit of mandatory restructuring assessments under the proposed WSRAR would be returning assessed PWSs to compliance. The EPA also estimates that the proposed WSRAR would generate two potential long-term benefits. First, the enforcement relief and liability protection incentives increase the likelihood that assessed public water systems will restructure and return to compliance with health-based standards. As a result, public health risks would be reduced in communities where the assessed water system restructures. Second, states that utilize the mandatory assessment authority will be able reduce the administrative costs of enforcement against water systems that otherwise would remain persistently noncompliant.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review, as Amended by Executive Order 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 14094, and was therefore not subject to a requirement for Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rulemaking have been submitted for approval to the OMB under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2736.01. You can find a copy of the ICR in the docket for this rulemaking, and it is briefly summarized here.

Because the AWIA directly revised primacy requirements under SDWA section 1413, all primacy agencies must submit to the EPA a primacy revision application for the proposed WSRAR. Primacy agencies include each of the 49 states (all U.S. states except Wyoming), Puerto Rico, American Samoa, Commonwealth of the Northern Mariana Islands, Guam, Virgin Islands, and Navajo Nation, for a total of 56 primacy agencies. The ICR for the proposed WSRAR describes costs and burden for all 56 primacy agencies to conduct the following activities: adopt the proposed WSRAR by developing primacy agency programs and submitting primacy revision packages to the EPA for review and approval; update data systems; analyze data on water systems that are potential candidates for a mandatory restructuring assessment; develop PWS outreach and education materials about the WSRAR; and train staff for adoption and implementation of the WSRAR (USEPA 2024b).

The burden estimate is derived from the economic impact analysis of the proposed WSRAR (USEPA 2024a). The EPA estimated the potential cost of the proposed WSRAR under alternative scenarios to account for uncertainty regarding how primacy agencies will develop their programs and implement the WSRAR. For the proposed ICR, the EPA used the estimated burden hours and costs from the highest cost scenario. Under this scenario, the EPA assumed the full program development cost for every primacy agency, regardless of existing program capacity to implement the proposed WSRAR requirements. This approach established an upper bound on the estimated burden and cost of the proposed WSRAR.

The ICR for the proposed WSRAR presents the total time, effort, and financial resources required of primacy agencies to generate, maintain, retain, disclose, and/or provide information to the EPA during the first three years following WSRAR promulgation. Existing regulations under 40 CFR 142.12(b), promulgated pursuant to 42 U.S.C. 300g–2(b)(1), allow primacy agencies up to two years to request approval of primacy revisions to adopt regulations that are no less stringent than those that the EPA promulgates, with an extension of up to two years if the EPA Administrator determines the extension is necessary and justified. Once approved, primacy agencies may exercise this authority to require a PWS to assess options for system restructuring, including forms of consolidation or the transfer of ownership to improve drinking water quality. The proposed WSRAR imposes no direct reporting requirements on PWSs.

The EPA will use the information collected during the first three years after promulgation of the WSRAR to review each submitting primacy agency's application and to determine whether the submitting primacy agency has met the proposed revised requirements under 40 CFR 142.10 and 142.11.

Respondents/affected entities: Primacy agencies.

Respondent's obligation to respond: Mandatory pursuant to 42 U.S.C. 300g–2(a)(6) and the agency's authority in the implementing regulations for revisions to state programs under 40 CFR 142.12.

Estimated number of respondents: 56.

Frequency of response: Once for each respondent to read and understand the rule; develop a program; submit a primacy application to the EPA; update data systems; conduct preliminary data analysis; educate PWSs in rule requirements; and conduct staff training.

Total estimated burden: 29,088 hours per year across all 56 primacy agencies. Burden is defined at 5 CFR 1320.3(b).

Total estimated costs: $1,889,497 per year across all 56 primacy agencies, including $0 in annualized capital or operation and maintenance costs. 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 OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. Submit your comments on the agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. The EPA will respond to any ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *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. OMB must receive comments no later than July 29, 2024.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The proposed WSRAR mandate applies only to state or Tribal government agencies with primary enforcement responsibility (primacy). The EPA expects states that elect to exercise their mandatory assessment authority will conduct nearly all mandatory restructuring assessments. Finally, this action does not require small entities to implement any restructuring activities identified in a mandatory assessment (USEPA 2024a). Small entities may voluntarily submit restructuring plans that must meet the eligibility requirements established by SDWA and any additional requirements of the proposed WSRAR.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The proposed WSRAR requirements to establish a mandatory assessment program and to submit a primacy revision to the EPA apply only to state or Tribal government agencies with primary enforcement authority under 42 U.S.C. 300(g)–2 and not to small governments as defined by UMRA.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The proposed WSRAR, if finalized, mandates primacy agencies to adopt and develop mandatory assessment programs, including new recordkeeping requirements, and to submit primacy applications to the EPA for review. The *Analysis of the Economic Impacts of the Proposed Water System Restructuring Assessment WSRAR,* which can be found in the docket, estimated the annualized direct cost for state, local, and tribal governments in the aggregate to be $0.8 to $1.0 million annualized at a 2 percent discount rate. In addition, because the proposed WSRAR also does not impose any requirements on small governments, it has no impact on small government revenues. As a result, the proposed WSRAR does not have substantial compliance costs and Executive Order 13132 does not apply to this action. Pursuant to SDWA 1413(a)(6), the proposed WSRAR would establish implementing regulations for states to adopt mandatory assessment programs and establish reporting and recordkeeping requirements but would not preempt state or local law. Therefore, the preemption threshold under Executive Order 13132 also does not apply to this action.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175. The proposed WSRAR does not uniquely affect the communities of Tribal governments, nor does it impose substantial direct compliance costs on those communities. The direct compliance costs of the primacy requirements of the proposed WSRAR would apply uniformly to primacy agencies. Thus, Executive Order 13175 does not apply to this action. Consistent with the EPA's *Policy on Consultation and Coordination with Indian Tribes,* the EPA consulted with Tribal officials during the development of this action from October 4 through November 15, 2019, including two national webinars conducted for all federally recognized Tribes. The EPA conducted the first webinar on October 16 and the second webinar on October 30, for a total of 47 participants. The EPA provided an overview of the AWIA restructuring-related amendments to the SDWA and sought Tribal input on the potential effects of the amendments on Tribal governments and Tribal PWSs.

During the webinars, the EPA requested input from Tribal governments on three aspects of WSRAR development: first, factors that EPA should consider for mandatory assessments of Tribal PWSs; second, whether and how the amended SDWA provisions to obtain enforcement relief from primacy agencies might affect the number of restructuring plans submitted by Tribal PWSs; and third, whether and how the amended SDWA provisions to obtain liability protection for compliant (non-responsible) water systems that are consolidating with, or acquiring, assessed PWSs might affect the number of restructuring plans submitted by Tribal PWSs. In addition, on October 9, 2019, the EPA participated in informational meetings upon request with the Region 1 Tribal Operations Committee (RTOC) and National Tribal Water Council (NTWC) to discuss the AWIA amendments to SDWA. During these informational meetings, the EPA encouraged broad participation in both national webinars to ensure that the agency could explain the policy implications of the SDWA-required provisions of the WSRAR to Tribal PWSs and could hear Tribal perspectives before drafting this proposal. Tribes did not provide written comments or further requests for consultation or outreach by the end of the consultation period. This discussion under Executive Order 13175 serves as a summary of EPA's Tribal consultation efforts for this proposed rulemaking.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. Therefore, this action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health, EPA's Policy on Children's Health also does not apply.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that the human health or environmental conditions that exist prior to this action may result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns. The EPA has identified several recent studies that support this Executive Order review which indicate disparities in access to safe drinking water based on racial or socioeconomic status in the United States (Zhang, et al. 2022; Martinez-Morata et al. 2022;

Rockowitz et al. 2018; London, et. al. 2018; Mack and Wrase 2017; Gasteyer, et al. 2016).

The EPA believes that it is not practicable to assess whether this action is likely to change existing disproportionate and adverse effects on communities with environmental justice concerns. Consistent with SDWA 1414(h), the proposed rule requires states to establish mandatory assessment programs and provides states with the discretion to use the mandatory assessment authority for persistently noncompliant PWSs, including those that serve communities with environmental justice concerns. The rule does not require a PWS or a community to implement any restructuring actions identified in a mandatory restructuring assessment. Instead, the rule establishes eligibility criteria for SDWA incentives under which PWSs would voluntarily submit restructuring plans. As a result, it is difficult to quantify the potential impacts of this rulemaking on communities with environmental justice concerns.

The EPA proposes in this rule several requirements that are intended to ensure that mandatory assessments and restructuring plans are carried out in a transparent manner with the direct involvement of, and engagement with, impacted communities:

- States would be required to hold a public meeting before approving an assessment report or proposed restructuring plan. The public meeting would be subject to notice, location, and time requirements to ensure it is well publicized and accessible to all interested and affected parties.
- States would be required to make drafts of mandatory assessment reports available before and during public meetings, and physical and electronic copies of state-approved mandatory assessment reports and restructuring plans publicly available within 30 days of approval. This requirement increases transparency of drinking water utility decision making for potentially impacted communities.
- Assessments would be required to meet minimum tailoring requirements that expressly require the assessor to determine whether the assessed water system meets the state definition of a disadvantaged community pursuant to the requirements of SDWA section 1452(d) or to 42 U.S.C 300j–19(c)(2)(B), or whether the consumers served by assessed system are underserved pursuant to 42 U.S.C. 300j–19a. This requirement would benefit underserved or disadvantaged populations because it ensures that the assessment identifies affordable restructuring options in the communities served by the assessed water system.
- Assessments and restructuring plans would be required to describe how restructuring would ensure that the community served by the assessed water system would achieve access to safe, affordable drinking water.
- States would be required to consult with the assessed water system to discuss the results of the assessment. This consultation is intended to ensure that the assessed water system understands the restructuring options, the potential benefits of restructuring, and available funding sources.

In addition to these proposed requirements, in section IV of this preamble the agency specifically requests public comment on additional requirements to ensure that communities are directly involved and engaged in mandatory restructuring assessments.

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List of Subjects in 40 CFR Part 142

Environmental protection, Administrative practice and procedure, Chemicals, Indian lands, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Michael S. Regan,

Administrator.

For the reasons set forth in the preamble, the EPA proposes to amend 40 CFR part 142 as follows:

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

■ 1. The authority citation for part 142 is revised to read as follows:

Authority: 42 U.S.C. 300f, 42 U.S.C. 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, and 42 U.S.C. 300j–4, 300j–9, and 300j–11.

■ 2. Amend § 142.10 by adding paragraph (i) to read as follows:

§ 142.10 Requirements for a determination of primary enforcement responsibility.

* * * * *

(i) Has adopted and is implementing procedures for requiring that an assessment be completed with respect to alternatives for consolidation, transfer of ownership, or other restructuring actions in accordance with 40 CFR part 142 subpart J, including procedures to:

(1) Establish that a public water system has satisfied the statutory preconditions for a mandatory restructuring assessment pursuant to § 142.92(a) and to notify the assessed public water system pursuant to § 142.92(b);

(2) Ensure that an assessment meets the minimum assessment tailoring criteria of § 142.92(c) and the minimum report content requirements of § 142.92(d);

(3) Review and approve eligible assessors pursuant to § 142.92(e);

(4) Ensure that the assessment is conducted according to a schedule pursuant to § 142.92(f);

(5) Determine whether a restructuring plan is eligible for restructuring incentives pursuant to § 142.93;

(6) Review restructuring plans pursuant to § 142.94 to determine public water system eligibility for enforcement relief;

(7) Review restructuring plans pursuant to § 142.95 to determine non-responsible public water system eligibility for liability protection, and the extent of liability protection, as applicable;

(8) Enforce mandatory assessment requirements pursuant to § 142.97; and

(9) Implement the reporting and recordkeeping requirements related to mandatory assessments and approved restructuring plans pursuant to §§ 142.14(h) and 142.15(c)(8).

■ 3. Amend § 142.11 by adding paragraph (a)(8) to read as follows:

§ 142.11 Initial determination of primary enforcement responsibility.

(a) * * *

(8) A description of the State's procedures for requiring that an assessment be completed with respect to alternatives for consolidation, transfer of ownership, or other restructuring actions in accordance with 40 CFR part 142 subpart J, including procedures to:

(i) Establish that a public water system has satisfied the statutory preconditions for a mandatory restructuring assessment pursuant to § 142.92(a) and to notify the assessed public water system pursuant to § 142.92(b);

(ii) Ensure that an assessment meets the minimum assessment tailoring criteria of § 142.92(c) and the minimum report content requirements of § 142.92(d);

(iii) Review and approve eligible assessors pursuant to § 142.92(e);

(iv) Ensure that the assessment is conducted according to a schedule pursuant to § 142.92(f);

(v) Determine whether a restructuring plan is eligible for restructuring pursuant to § 142.93;

(vi) Review restructuring plans pursuant to § 142.94 to determine public water system eligibility for enforcement relief;

(vii) Review restructuring plans pursuant to § 142.95 to determine non-responsible water system eligibility for liability protection, and the extent of liability protection, as applicable;

(viii) Enforce mandatory assessment requirements pursuant to § 142.97; and

(ix) Implement the reporting and recordkeeping requirements related to mandatory assessments and to approved restructuring plans pursuant to §§ 142.14(h) and 142.15(c)(8).

* * * * *

■ 4. Amend § 142.14 by adding paragraph (h) to read as follows:

§ 142.14 Records kept by States.

* * * * *

(h) Pursuant to 40 CFR part 142 subpart J, each State that has primary enforcement responsibility shall retain, and provide to the Administrator upon request, records of any plans submitted by a public water system for consolidation, transfer of ownership, or other restructuring actions, and of any mandatory assessment reports approved by the State as follows:

(1) From the date of plan approval until one year following the completion of all activities in an approved restructuring plan that meets the requirements for enforcement relief pursuant to § 142.94, a copy of the approved restructuring plan and, if conducted, a copy of the approved assessment report on which the approved plan may be based.

(2) From the date of plan approval until one year following the completion of all activities in an approved restructuring plan that meets the requirements for liability protection of a non-responsible public water system pursuant to § 142.95, a copy of the approved plan and a copy of the approved assessment report on which the plan must be based.

(3) For five years from the date of approval of a mandatory restructuring assessment pursuant to § 142.92(f), a copy of the assessment report, notwithstanding the assessment retention requirements of paragraphs (h)(1) and (2) of this section.

■ 5. Amend § 142.15 by adding paragraph (c)(8) to read as follows:

§ 142.15 Reports by States.

* * * * *

(c) *–*–*

(8) *Water system restructuring assessment rule.* Each State that has primary enforcement responsibility shall report annually to the Administrator, in a format and on a schedule prescribed by the Administrator, the name and

identification number of each public water system:

(i) That has satisfied the preconditions for a mandatory restructuring assessment as required pursuant to § 142.92(a), including the date on which the State made its finding;

(ii) That the State has identified pursuant to paragraph (c)(8)(i) of this section, and has notified as the subject of a mandatory restructuring assessment pursuant to a schedule as described in § 142.92(f) including the date of notification;

(iii) That the State has notified pursuant to paragraph (c)(8)(ii) of this section, and that has completed a mandatory restructuring assessment pursuant to § 142.92 as determined by the State, including the date of determination.

(iv) That is in violation of the mandatory restructuring assessment requirements pursuant to § 142.97, by violation type and violation date; or

(v) That the State has determined to be eligible for enforcement relief pursuant to § 142.94 or liability protection pursuant to § 142.95, including the type of eligibility and the date of plan approval.

* * * * *

■ 6. Add subpart J to read as follows

Subpart J—Mandatory Restructuring Assessments and Restructuring Plans

Sec.

Subpart J—Mandatory Restructuring Assessments and Restructuring Plans

§ 142.90 General.

(a) *Authority.* A State that meets the requirements for a determination of primary enforcement responsibility, and that has obtained such responsibility from the Administrator pursuant to 42 U.S.C 300g–2 and its implementing regulations at 40 CFR part 142, subpart B, is authorized to implement this subpart.

(b) *Implementation by the EPA.* A Regional Administrator with primary enforcement responsibility may exercise all authorities extended to States in this subpart.

(c) *Applicability.* The provisions of this subpart apply to all States with primary enforcement responsibility, to all public water systems for which a mandatory restructuring assessment is required or approved by a State pursuant to § 142.92, and to suppliers of water that have submitted a restructuring plan to the State pursuant to § 142.93.

§ 142.91 Definitions.

The following definitions apply to terms used in this subpart:

Assessed water system. Refers to a public water system that satisfies the mandatory assessment preconditions under § 142.92(a) and that is the subject of a mandatory restructuring assessment required by the State under this subpart.

Enforcement relief. Refers to the ''consequences of approval'' at 42 U.S.C. 300g–3(h)(2) and means that, except for the limitations described in § 142.94, if a primacy agency approves a restructuring plan that is eligible under § 142.93 and that satisfies the applicable requirements of § 142.94, then with respect to each specific violation identified in the approved plan, as of the date of plan approval, the State shall not take enforcement action until the earlier of:

(1) Two years from the date on which the primacy agency approves the restructuring plan; or

(2) The date on which all restructuring activities identified in the schedule of the approved plan have been completed.

Liability protection. Refers to the ''reservation of funds'' at 42 U.S.C. 300g–3(h)(5)(B) and means that if a State approves a restructuring plan that is eligible under § 142.93 and that satisfies the applicable requirements of § 142.95 and determines that all of the activities in the approved plan have been completed, then the non-responsible water system shall not be liable for a specific violation identified in the approved plan, except to the extent to which funds or other assets identified in the plan are available to satisfy such liability.

Mandatory restructuring assessment. Refers to the ''mandatory assessment'' at 42 U.S.C. 300g–3(h)(3) and means an evaluation of alternatives for consolidation, transfer of ownership or other types of restructuring at the assessed water system pursuant to the applicable requirements of § 142.92.

Non-responsible water system. Refers to a public water system that is not liable under the SDWA for a specific violation identified in an approved restructuring plan that meets all requirements of § 142.95.

Restructuring plan. Refers to ''plans'' at 42 U.S.C. 300g–3(h)(1) and means a plan that is submitted to the State for purposes of enforcement relief or liability protection under this subpart, and that is intended to achieve greater compliance with national primary drinking water regulations through:

(1) Physical consolidation of the public water system with one or more other public water systems;

(2) The consolidation of significant management or administrative functions of the public water system with one or more other public water systems; the transfer of ownership of the public water system to another public water system for purposes of improving drinking water quality; or

(3) Entering into a contractual agreement for significant management or administrative functions of the public water system to correct violations identified in the plan.

§ 142.92 Mandatory restructuring assessments.

(a) *Mandatory assessment preconditions.* A State may mandate a restructuring assessment of a public water system if the State finds that:

(1) The water system has repeatedly violated one or more national primary drinking water regulations, and such repeated violations are likely to adversely affect human health;

(2) The supplier of water is unable or unwilling to take feasible and affordable actions, as determined by the State, that will result in the public water system complying with the national primary drinking water regulations, or has already undertaken such actions, including accessing technical assistance or financial assistance from the State, without achieving compliance;

(3) Physical, administrative, or managerial consolidation, transfer of ownership, or another type of restructuring is feasible for the water system; and

(4) Physical, administrative, or managerial consolidation, transfer of ownership, or another type of restructuring of the water system could result in greater compliance with national primary drinking water regulations.

(b) *State notification.* A State that mandates an assessment pursuant to this section shall notify the supplier of water in writing.

(c) *Minimum assessment tailoring criteria.* A mandatory restructuring assessment conducted pursuant to this section shall evaluate, at a minimum, the feasibility of the proposed restructuring alternatives based on the following criteria:

(1) System size based on the number of people served by the assessed water system;

(2) Whether the assessed water system is a community or noncommunity water system;

(3) The source(s) of water used by the assessed water system;

(4) The technical, managerial, and financial (TMF) capacity of the assessed water system;

(5) Whether the service area of the assessed water system is disadvantaged pursuant to the State's definition under 42 U.S.C. 300j–12(d)(3) or to 42 U.S.C 300j–19(c)(2)(B), or is underserved pursuant to 42 U.S.C. 300j–19a;

(6) Geographic factors;

(7) Hydrogeologic or geologic factors; and

(8) State or local statutory or regulatory requirements.

(d) *Minimum assessment report content requirements.* The results of the mandatory restructuring assessment must be documented in a report that, at a minimum:

(1) Identifies all unresolved violations at the assessed water system, the underlying causes of the violations, and the enforcement status of each violation;

(2) Identifies at least one feasible restructuring alternative, and describes how the alternative(s) will:

(i) Return the system to compliance as soon as practicable; and (ii) Help ensure the technical, financial, and managerial capacity of the assessed water system to provide safe drinking water;

(3) Describes how the assessor has determined the feasibility of the identified alternative(s) pursuant to paragraph (c) of this section, including how alternative(s) will ensure that a community served by the assessed water system receives safe and affordable drinking water;

(4) Explains, if a type of consolidation or a transfer of ownership is not identified as a feasible restructuring alternative, why such alternative is not feasible; and

(5) Describes the processes, procedures, data, data sources, and other information used to identify feasible restructuring alternatives for the assessed water system.

(e) *Eligible assessors.* The supplier of water at the assessed water system or a third party-approved by the State may conduct a mandatory restructuring assessment pursuant to this section; otherwise, the State may conduct the assessment.

(f) *Assessment schedule.* Mandatory restructuring assessments shall be conducted as follows:

(1) Within 30 days of the date of State notification that a mandatory restructuring assessment is required, the supplier of water may request in writing State approval of either a self-assessment or a third-party assessor on its behalf; otherwise, the State may conduct the mandatory restructuring assessment.

(2) Within 30 days of the date of request by the supplier of water pursuant to paragraph (f)(1) of this section, the State shall determine whether to approve a third-party assessor or a self-assessment and notify the supplier of water.

(i) If the State approves a self-assessment or a third-party assessor to conduct the mandatory restructuring assessment, the supplier of water must submit an assessment report on a date that is determined by the State. At any time during the implementation of the mandatory restructuring assessment, either the supplier of water or the State may consult with the other party to determine whether to revise the assessment report submittal date. The State may determine whether to revise the submittal date based on documentation or other information acceptable to the State.

(ii) If the State does not approve a third-party assessor or a self-assessment, the State may conduct the mandatory restructuring assessment and develop the assessment report. In such cases, the supplier of water shall provide as soon as practicable any information deemed necessary by the State to complete a mandatory restructuring assessment pursuant to the requirements of this section.

(3) When submitting the assessment report to the State, the supplier of water or a third-party assessor must provide a certification statement to affirm:

(i) The authority of the assessor to verify the results of the mandatory restructuring assessment;

(ii) That the information included in the assessment report is true, accurate and complete; and

(iii) That the assessor understands that there are penalties for submitting false information to the State.

(4) If the assessment report identifies a form of consolidation or transfer of ownership during the mandatory assessment, the State shall hold at least one public meeting in the community served by the assessed water system. The public meeting shall satisfy EPA public meeting requirements under 40 CFR 25.6 and any applicable provisions of State law (as determined by the State). Otherwise, as soon as practicable following the date of submission, the State shall review the assessment pursuant to paragraph (f)(5)(i) or ((ii) of this section.

(i) If the supplier of water performs the mandatory assessment, the State shall hold the public meeting as soon as practicable from the date of submission.

(ii) If the State performs the mandatory assessment, the State shall hold the public meeting before completing its assessment report.

(5) As soon as practicable following the date of a public meeting pursuant to paragraph (f)(4) of this section, the State shall review the assessment report to determine whether it satisfies the requirements of this section.

(i) If the supplier of water has prepared the assessment report and the State determines it satisfies the requirements of this section, then the assessment is approved and the State shall notify the supplier of water in writing within 7 business days of its determination. Otherwise, the State may consult with the supplier of water to determine a schedule and a method by which a revised assessment report must be completed pursuant to the requirements of this section.

(ii) If the State has prepared the assessment report, the State shall ensure that the report satisfies the requirements of this section and is otherwise complete. Upon such completion, the State shall notify the supplier of water in writing within 7 business days of its determination.

(6) Within 30 days of the State's approval of an assessment report submitted by the supplier of water or of the State's completion of an assessment report, the State shall make available to the public a copy of the approved assessment report in an electronic format on an appropriate State website and shall transmit physical copies of the restructuring plan to one or more public libraries in the closest possible proximity to the community served by the restructuring supplier of water.

(7) If the State has notified the supplier of water that the assessment report is approved or that the State assessment report is complete, the State shall consult with the supplier of water as soon as practicable to discuss the results of the mandatory restructuring assessment.

§ 142.93 Restructuring plans.

(a) *Plan types eligible for restructuring incentives.* A supplier of water may submit to the State, for purposes of enforcement relief or liability protection under this subpart, a restructuring plan that is intended to achieve greater compliance with national primary drinking water regulations through:

(1) Physical consolidation of the water system with one or more other water systems;

(2) The consolidation of significant management or administrative functions of the water system with one or more other water systems;

(3) The transfer of ownership of the water system to another water system for purposes of improving drinking water quality; or

(4) Entering into a contractual agreement for significant management or administrative functions of the system to correct violations identified in the plan.

(b) *State determination.* As soon as practicable, but no later than 60 days from the date it receives a restructuring plan, the State shall determine whether the plan is eligible pursuant to paragraph (a) of this section and shall notify the supplier of water in writing.

(i) If the State determines that the plan is eligible pursuant to paragraph (a) of this section, then pursuant to § 142.94 or § 142.95, the State shall determine whether the plan also satisfies the applicable requirements for enforcement relief or liability protection.

(ii) If the State determines that the plan is not eligible pursuant to paragraph (a) of this section, then the State may consult with the supplier of water that submitted the ineligible plan to determine a schedule and a method by which a corrected plan may be submitted.

(c) *Plan revisions.* If at any time during the implementation of an approved restructuring plan a supplier of water submits a revised plan to the State, the State may review the revised plan pursuant to the requirements of this section and the applicable requirements and limitations of §§ 142.94 and 142.95.

§ 142.94 Enforcement relief under approved restructuring plans.

(a) *Minimum plan eligibility requirements for enforcement relief.* To obtain enforcement relief under this subpart, the supplier of water must submit a restructuring plan that the State has determined is eligible for restructuring incentives pursuant to § 142.93(a) and that:

(1) Identifies each specific violation that the restructuring plan is intended to correct;

(2) Describes, using data and other forms of documentation acceptable to the State, how the activities in the restructuring plan will protect public health as soon as practicable by addressing the underlying causes of the identified violations;

(3) Proposes a schedule for implementing and completing each of the restructuring activities identified in the plan, including corrective actions to resolve identified violations and measures by which the State can assess progress for each restructuring activity;

(4) Describes, using data and other forms of documentation acceptable to the State, how the restructuring plan will improve, as applicable, the technical capacity, managerial capacity, or financial capacity of the restructuring system to achieve compliance with national primary drinking water regulations;

(5) Describes how the proposed restructuring plan will ensure that the community served by the restructured water system receives safe and affordable drinking water; and

(6) Requests enforcement relief from the violations identified in the plan for the noncompliant water system(s) subject to the plan.

(b) *Conditional plan eligibility requirements for enforcement relief.* In addition to the minimum requirements of § 142.94(a), to obtain enforcement relief under this subpart, the supplier of water must submit a restructuring plan that satisfies the following conditional requirements, as applicable:

(1) If the restructuring plan will result in a change in the supplier of water at the restructured water system, the submitted plan must identify both the date on which the change is planned to occur, and the identity of the new supplier of water at the restructured water system.;

(2) If the restructuring plan will require one or more suppliers of water to establish a new or revised governance structure, the plan must describe the new governance structure and how it will help achieve the objectives of the plan; and

(3) If the restructuring plan includes the temporary provision of an alternative source or supply of water, the plan must include an implementation schedule and measures, supported by data and other forms of documentation acceptable to the State, that describe how the water served will comply with applicable Federal or state regulations and identify when the temporary alternative source will no longer be needed.

(c) *Eligible violation types.* For purposes of enforcement relief under this subpart, specific violations of the SDWA and its implementing regulations must be identified in the restructuring plan submitted to the State.

(d) *Public meeting.* As soon as practicable after making its determination pursuant to § 142.93(b), the State shall hold at least one public meeting with the community served by a restructuring public water system regarding the proposed restructuring plan. The meeting shall be held in accordance with EPA public meeting requirements under 40 CFR 25.6 and any applicable provisions of State law (as determined by the State).

(e) *State determination date.* As soon as practicable, but no later than 12 months from the date on which it determines that a submitted restructuring plan is an eligible type pursuant to § 142.93(b), the State shall determine whether the requirements of paragraphs (a) through (d) of this section have been satisfied and shall notify the supplier of water in writing. If the State determines that the submitted plan satisfies the requirements, then the plan is approved, otherwise, the State may consult with the supplier of water that submitted the plan to determine a schedule and a method by which a corrected plan may be submitted.

(f) *Plan availability.* Within 30 days of its determination under paragraph (e) of this section, the State shall make available to the public a copy of the approved restructuring plan in an electronic format on an appropriate State website and shall transmit physical copies of the restructuring plan to one or more public libraries in the closest possible proximity to the community served by the restructuring supplier of water.

(g) *Extent of enforcement relief.* If the State approves the plan, then with respect to the specific violations identified in the approved plan, the State shall take no enforcement action until the earlier of two years from the date on which the State approves the restructuring plan or the date on which the State determines that all restructuring activities identified in the schedule of the approved plan have been completed. Notwithstanding the enforcement relief described in this paragraph, the Agency may exercise its authority at 42 U.S.C. 300i to protect the health of persons served by the water system(s) that are subject to the plan.

(h) *Limitations.* The supplier of water of the public water system subject to enforcement relief as described in paragraph (e) of this section must:

(1) Implement any corrective actions as required under existing enforcement orders or agreements;

(2) Comply with all other applicable requirements of the SDWA and its implementing regulations, including any EPA actions pursuant to 42 U.S.C. 300i; and

(3) Comply with any enforcement actions for violations that occur after the date of plan approval.

(i) *Termination of enforcement relief under approved plans.* If during the enforcement relief period the State

determines that the supplier of water at a noncompliant water system is unwilling or unable to implement the plan according to its approved measures and schedule(s), then the noncompliant water system is no longer eligible for enforcement relief under this subpart. In such cases, the State shall inform the noncompliant supplier of water in writing as soon as practicable that the water system is ineligible for enforcement relief, and that the State may take enforcement action for the identified violations.

(j) *Enforcement relief under revised plans.* A water system that is subject to enforcement relief pursuant to this subpart is ineligible under a revised restructuring plan for enforcement relief that exceeds 2 years from the date on which the State approved the original restructuring plan.

§ 142.95 Liability protection under approved restructuring plans.

(a) *Minimum plan eligibility requirements for liability protection.* To obtain liability protection under this subpart, the non-responsible water system's supplier of water must submit a restructuring plan that:

(1) Satisfies the minimum eligibility requirements for enforcement relief pursuant to § 142.94(a);

(2) Satisfies any conditional requirements pursuant to § 142.94(b), as applicable;

(3) Is based on a mandatory restructuring assessment approved or completed by the State pursuant to § 142.92;

(4) Identifies the non-responsible water system(s) and assessed water system(s) subject to the plan;

(5) Identifies and describes, using data and other forms of documentation that the State finds acceptable, any potential and existing liability for penalties and damages associated with each specific violation identified in the plan;

(6) Identifies and describes, using data and other forms of documentation that the State finds acceptable, any funds or other assets of the assessed system(s) available as of the date of submission; and

(7) Requests liability protection of the non-responsible water system for the violations identified in the plan.

(b) *Eligible violation types.* For purposes of liability protection under this subpart, specific violations of the SDWA and its implementing regulations must be identified in the restructuring plan submitted to the State.

(c) *Exclusions.* Neither a water system that is subject to a mandatory restructuring assessment under § 142.92, nor a water system that the State finds has satisfied the preconditions for a mandatory restructuring assessment under § 142.92(a), may benefit from liability protection under this subpart.

(d) *Public meeting.* After making its determination pursuant to § 142.93(b), the State shall hold at least one public meeting as soon as practicable with the community served by a restructuring public water system regarding the proposed restructuring plan. The meeting shall be held in accordance with EPA public meeting requirements under 40 CFR 25.6 and any applicable provisions of State law (as determined by the State).

(e) *State determination date.* As soon as practicable, but not later than 18 months from the date on which it determines that a submitted restructuring plan is an eligible type pursuant to § 142.93(b), the State shall determine whether the requirements of paragraphs (a) through (d) of this section have been satisfied and shall notify the supplier of water in writing. If the State determines that the submitted plan satisfies applicable requirements, then the plan is approved, otherwise, the State may consult with the supplier of water that submitted the plan to determine a schedule and a method by which a corrected plan may be submitted.

(f) *Extent of liability protection.* If the State determines, according to the measures and schedule(s) of the plan approved pursuant to paragraph (e) of this section, that all restructuring activities have been completed, then within 30 days of its determination under this paragraph the State shall notify the non-responsible supplier of water in writing that:

(1) As of the date of State notification, the non-responsible water system is not liable under the SDWA for penalties or damages associated with the violations identified in the plan that exceed the total amount of the identified funds and the value of other identified assets of the assessed system(s); and

(2) Within 30 days of the date of State notification, the non-responsible supplier of water shall consult with the State to determine a method and a schedule by which any identified funds, and the value of the identified assets of the assessed system(s), shall be transferred to the State to satisfy the liability for violations at the assessed system(s). If the non-responsible supplier of water finds that it cannot identify funds or assets to satisfy the liability of the identified violations, it shall support its finding pursuant to the requirements of § 142.95(a)(6).

(g) *Plan availability.* Within 30 days of its determination under paragraph (e) of this section, the State shall make available to the public a copy of the approved restructuring plan in an electronic format on an appropriate State website and shall transmit physical copies of the restructuring plan to one or more public libraries in the closest possible proximity to the community served by the restructuring supplier of water.

(h) *Determination of change in supplier of water.* If the non-responsible supplier of water is subject to the requirements of § 142.94(b)(1), when making its determination and notification pursuant to paragraph (f) of this section, the State shall identify the date on which the non-responsible supplier of water becomes the supplier of water at the restructured water system. Until the date of State notification, the non-responsible water system is not liable for violations at the assessed water system(s).

(i) *Limitations.* Notwithstanding the liability protection for which a non-responsible water system may be eligible under this subpart, the non-responsible water system must comply with all other applicable requirements under the SDWA and its implementing regulations.

(j) *Liability protection under revised plans.* A non-responsible supplier of water that requests liability protection under a restructuring plan that is approved by the State remains eligible for liability protection under a revised plan if:

(1) The non-responsible supplier of water has provided a justification, using data and other forms of documentation that the State finds acceptable, that a revised plan is necessary to ensure that the objectives of the restructuring plan are achieved as soon as practicable;

(2) The non-responsible water system is not the water system that incurred the violations identified in the revised restructuring plan; and

(3) The State has determined that the revised restructuring plan meets the requirements of this section and has approved the revised plan.

§ 142.96 DWSRF eligibility of restructuring activities.

Notwithstanding 42 U.S.C. 300j–12(a)(3) and its implementing regulations, a public water system undertaking consolidation, transfer of ownership for purposes of improving drinking water quality, or other restructuring activities pursuant to a mandatory assessment that meets the requirements of § 142.92 may receive a loan described in 42 U.S.C. 300j–12(a)(2)(A) to implement such consolidation, transfer of ownership, or

other restructuring activities identified in the assessment.

§ 142.97 Reporting violations.

An assessed water system is in violation of this subpart if the supplier of water that performs a self-assessment, or an approved third party performing the assessment on behalf of the supplier of water:

(a) Fails to submit an assessment report to the State as mandated under § 142.92;

(b) Submits an assessment report after the submittal date that was determined by the State as required under § 142.92(f)(2);

(c) Submits an assessment report that does not meet the minimum content requirements of § 142.92(c); or

(d) Submits an assessment report without the certification statement required under § 142.92(f)(3).

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Part III

Federal Trade Commission

16 CFR Part 318
Health Breach Notification Rule; Final Rule

FEDERAL TRADE COMMISSION

16 CFR Part 318

RIN 3084–AB56

Health Breach Notification Rule

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') is amending the Commission's Health Breach Notification Rule (the ''HBN Rule'' or the ''Rule''). The HBN Rule requires vendors of personal health records (''PHRs'') and related entities that are not covered by the Health Insurance Portability and Accountability Act (''HIPAA'') to notify individuals, the FTC, and, in some cases, the media of a breach of unsecured personally identifiable health data.

DATES: The amendments are effective July 29, 2024.

ADDRESSES: Relevant portions of the record of this proceeding, including this document, are available at *https://www.ftc.gov* and *https://www.regulations.gov.*

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SUPPLEMENTARY INFORMATION: The amendments: (1) clarify the Rule's scope, including its coverage of developers of many health applications (''apps''); (2) clarify what it means for a vendor of personal health records to draw PHR identifiable health information from multiple sources; (3) revise the definition of breach of security to clarify that a breach of security includes data security breaches and unauthorized disclosures; (4) revise the definition of PHR related entity; (5) modernize the method of notice; (6) expand the content of the notice; (7) alter the Rule's timing requirement for notifying the FTC of a breach of security; and (8) improve the Rule's readability by clarifying cross-references and adding statutory citations, consolidating notice and timing requirements, articulating the penalties for non-compliance, and incorporating a small number of non-substantive changes.

I. Background

Congress enacted the American Recovery and Reinvestment Act of 2009 (''Recovery Act'' or ''the Act''),[1] in part to advance the use of health information technology and, at the same time, strengthen privacy and security protections for health information. Recognizing that certain entities that hold or interact with consumers' personal health records were not subject to the privacy and security requirements of HIPAA,[2] Congress created requirements for such entities to notify individuals, the Commission, and, in some cases, the media of the breach of unsecured identifiable health information from those records.

Specifically, section 13407 of the Recovery Act created certain protections for ''personal health records'' or ''PHRs,'' [3] electronic records of PHR identifiable health information on an individual that can be drawn from multiple sources and that are managed, shared, and controlled by or primarily for the individual.[4] Congress recognized that vendors of personal health records and PHR related entities (*i.e.,* companies that offer products and services through PHR websites or access information in or send information to personal health records) were collecting consumers' health information but were not subject to the privacy and security requirements of HIPAA. Accordingly, the Recovery Act directed the FTC to issue a rule requiring these non-HIPAA covered entities, and their third party service providers, to provide notification of any breach of unsecured PHR identifiable health information. The Commission issued its Rule implementing these provisions in 2009.[5] FTC enforcement of the Rule began on February 22, 2010.

The Rule the Commission issued in 2009 (''2009 Rule'') requires vendors of personal health records and PHR related entities to provide: (1) notice to consumers whose unsecured PHR identifiable health information has been breached; (2) notice to the Commission; and (3) notice to prominent media outlets [6] serving a State or jurisdiction, in cases where 500 or more residents are confirmed or reasonably believed to have been affected by a breach.[7] The Rule also requires third party service providers (*i.e.,* those companies that provide services such as billing, data storage, attribution, or analytics) to vendors of personal health records and PHR related entities to provide notification to such vendors and entities following the discovery of a breach.[8]

The 2009 Rule requires notice to individuals ''without unreasonable delay and in no case later than 60 calendar days'' after discovery of a data breach.[9] If the breach affects 500 or more individuals, notice to the FTC must be provided ''as soon as possible and in no case later than ten business days'' after discovery of the breach.[10] The FTC makes available a standard form for companies to use to notify the Commission of a breach,[11] and posts a list of breaches involving 500 or more individuals on its website.[12]

The 2009 Rule applies only to breaches of ''unsecured'' health information, which the Rule defines as health information that is not secured through technologies or methodologies specified by the Department of Health and Human Services (''HHS''). The Rule does not apply to businesses or organizations covered by HIPAA.[13] HIPAA-covered entities and their ''business associates'' must instead comply with HHS's breach notification rule.[14]

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[1] Am. Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115 (2009).

[2] Health Ins. Portability and Accountability Act, Public Law 104–191, 110 Stat. 1936 (1996).

[3] 42 U.S.C. 17937.

[4] 42 U.S.C. 17921(11).

[5] 74 FR 42962 (Aug. 25, 2009) (''2009 Final Rule'').

[6] The Recovery Act does not limit this notice to particular types of media. Thus, an entity can satisfy the requirement to notify ''prominent media outlets'' by, for example, disseminating press releases to a number of media outlets, including internet media in appropriate circumstances, where most of the residents of the relevant State or jurisdiction get their news. This will be a fact-specific inquiry that will depend on what media outlets are ''prominent'' in the relevant jurisdiction. 74 FR 42974.

[7] 16 CFR 318.3, 318.5.

[8] *Id.* § 318.3(b).

[9] *Id.* § 318.4(a).

[10] *Id.* § 318.5(c).

[11] Fed. Trade Comm'n, Notice of Breach of Health Information, *https://www.ftc.gov/system/files/documents/rules/health-breach-notification-rule/health_breach_form.pdf.*

[12] Fed. Trade Comm'n, Notices Received by the FTC Pursuant to the Health Breach Notification Rule, *https://www.ftc.gov/system/files/ftc_gov/pdf/Health%20Breach%20Notices%20Received%20by%20the%20FTC.pdf* (last visited Dec. 2, 2022).

[13] Per HHS guidance, electronic health information is ''secured'' if it has been encrypted according to certain specifications set forth by HHS, or if the media on which electronic health information has been stored or recorded is destroyed according to HHS specifications. *See* 74 FR 19006; *see also* U.S. Dep't of Health & Human Servs., *Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals* (July 26, 2013), *https://www.hhs.gov/hipaa/for-professionals/breach-notification/guidance/index.html.* PHR identifiable health information would be considered ''secured'' if such information is disclosed by, for example, a vendor of personal health records, to a PHR related entity or a third party service provider, in an encrypted format meeting HHS specifications, and the PHR related entity or third party service provider stores the data in an encrypted format that meets HHS specifications and also stores the encryption and/or decryption tools on a device or at a location separate from the data.

[14] 45 CFR 164.400 through 164.414.

Since the Rule's issuance, apps and other direct-to-consumer health technologies, such as fitness trackers and wearable blood pressure monitors, have become commonplace.[15] Further, as an outgrowth of the COVID–19 pandemic, consumer use of such health-related technologies has increased significantly.[16]

In May 2020, the Commission announced its regular, ten-year review of the Rule and requested public comment about potential Rule changes.[17] The Commission requested comment on, among other things, whether changes should be made to the Rule in light of technological changes, such as the proliferation of apps and similar technologies. The Commission received 26 public comments.[18]

Many of the commenters in 2020 encouraged the Commission to clarify that the Rule applies to apps and similar technologies.[19] In fact, no commenter opposed this type of clarification regarding the Rule's coverage of health apps. Several commenters pointed out examples of health apps that have abused users' privacy, such as by disclosing sensitive health information without consent.[20] Several commenters noted the urgency of this issue, as consumers have further embraced digital health technologies during the COVID–19 pandemic.[21] Commenters argued the Commission should take additional steps to protect unsecured PHR identifiable health information that is not covered by HIPAA, both to prevent harm to consumers [22] and to level the competitive playing field among companies dealing with the same health information.[23] To that end, commenters not only urged the Commission to revise the Rule, but also to increase its enforcement efforts.[24]

A. The Commission's 2021 Policy Statement

On September 15, 2021, the Commission issued a Policy Statement providing guidance on the scope of the Rule. The Policy Statement clarified that the Rule covers most health apps and similar technologies that are not covered by HIPAA.[25] The Rule defines a ''personal health record'' as ''an electronic record of PHR identifiable health information on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or primarily for the individual.'' [26] As the Commission explained in the Policy Statement, many makers and purveyors of health apps and other connected devices are vendors of personal health records covered by the Rule because their products are electronic records of PHR identifiable health information.

The Commission explained that PHR identifiable health information includes individually identifiable health information created or received by a health care provider,[27] and that ''health care providers'' include any entities that ''furnish[ ] health care services or supplies.'' [28] Because these health app purveyors furnish health care services to their users through the mobile applications they provide, the information held in the app is PHR identifiable health information, and therefore many health app purveyors likely qualify as vendors of personal health records.[29]

The Policy Statement further explained that the statute directing the FTC to promulgate the Rule requires that a ''personal health record'' be an electronic record that can be drawn from multiple sources.[30] Accordingly, health apps and similar technologies likely qualify as personal health records covered by the Rule if they are capable of drawing information from multiple sources. The Commission further clarified that health apps and other products experience a ''breach of security'' under the Rule when they disclose users' sensitive health information without authorization; [31] a breach is ''not limited to cybersecurity intrusions or nefarious behavior.'' [32]

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[15] *See, e.g.,* Kokou Adzo, *App Development in Healthcare: 12 Exciting Facts,* TechnoChops (Jan. 3, 2023), *https://www.technochops.com/programming/4329/app-development-in-healthcare/;* Emily Olsen, *Digital health apps balloon to more than 350,000 available on the market, according to IQVIA report,* MobiHealthNews (Aug. 4, 2021), *https://www.mobihealthnews.com/news/digital-health-apps-balloon-more-350000-available-market-according-iqvia-report;* Elad Natanson, *Healthcare Apps: A Boon, Today and Tomorrow,* Forbes (July 21, 2020), *https://www.forbes.com/sites/eladnatanson/2020/07/21/healthcare-apps-a-boon-today-and-tomorrow/?sh=21df01ac1bb9.*

[16] *See id. See also* Lis Evenstad, *Covid–19 has led to a 25% increase in health app downloads, research shows, ComputerWeekly.com* (Jan. 12, 2021), *https://www.computerweekly.com/news/252494669/Covid-19-has-led-to-a-25-increase-in-health-app-downloads-research-shows* (finding that COVID–19 has led to a 25% increase in health app downloads); Jasmine Pennic, *U.S. Telemedicine App Downloads Spikes During COVID–19 Pandemic,* HIT Consultant (Sept. 8, 2020), *https://hitconsultant.net/2020/09/08/u-s-telemedicine-app-downloads-spikes-during-covid-19-pandemic/* (''US telemedicine app downloads see dramatic increases during the COVID–19 pandemic, with some seeing an 8,270% rise YoY.'').

[17] 85 FR 31085 (May 22, 2020).

[18] Comments are available at *https://www.regulations.gov/docket/FTC-2020-0045/comments.*

[19] *E.g.,* Am. Health Info. Mgmt. Ass'n (''AHIMA'') at 2; Kaiser Permanente at 3; Allscripts at 3; Am. Acad. of Ophthalmology at 2; All. for Nursing Informatics (''ANI'') at 2; Am. Med. Ass'n (''AMA'') at 4; Am. Coll. of Surgeons at 6; Physicians' Elec. Health Rec. Coal. (''PEHRC'') at 4 (''Apps that collect health information, regardless of whether or not they connect to an EHR, must be regulated by the FTC Health Breach Notification Rule to ensure the safety and security of personal health information.''); Am.'s Health Ins. Plans (''AHIP'') and Blue Cross Blue Shield Ass'n (''BCBS'') at 2; The App Ass'n's Connected Health Initiative (''CHI'') at 3.

[20] Kaiser Permanente at 7; The Light Collective at 2; Am. Acad. of Ophthalmology at 2; PEHRC at 2–3.

[21] Lisa McKeen at 2–3; Kaiser Permanente at 7–8; AMA at 3; Off. of the Att'y Gen. for the State of Cal. (''OAG–CA'') at 3–4; Healthcare Info. and Mgmt. Sys. Soc'y (''HIMSS'') and Personal Connected Health All. (''PCH Alliance'') at 4–5.

[22] Georgia Morgan; Am. Acad. of Ophthalmology at 2–3 (arguing that consumers do not know all the ways their data is being used by third parties, and the downstream consequences of data being used in this way may ultimately erode a patient's privacy and willingness to disclose information to his or her physician); Coll. of Healthcare Info. Mgmt. Exec.'s (''CHIME'') at 3 (arguing that apps' privacy practices impact the patient-provider relationship because providers do not know what technologies are sufficiently trustworthy for their patients); AMA at 2–3 (expressing concern that patients share less health data with health care providers, perhaps because of ''spillover from privacy and security breaches'').

[23] Kaiser Permanente at 2, 4; Workgroup for Elec. Data Interchange (''WEDI'') at 2; AHIP and BCBS at 3 (''[HIPAA] covered entities, such as health plans, that use or disclose protected health information should not be subject to stricter notification requirements than those imposed on vendors of personal health records or other such entities. Otherwise, the Federal government will be providing market advantages to particular industry segments with the effect of dampening competition and harming consumers.'').

[24] Kaiser Permanente at 4; Fred Trotter at 1; Casey Quinlan at 1; CARIN Alliance at 2. At the time of this document's publication, the Commission has brought two enforcement actions under the Rule; the first against digital health company GoodRx Holdings, Inc., and the second against an ovulation-tracking mobile app marketed under the name ''Premom'' and developed by Easy Healthcare, Inc. *United States* v. *GoodRx Holdings, Inc.,* No. 23–cv–460 (N.D. Cal. Feb. 17, 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/2023090-goodrx-holdings-inc; United States* v. *Easy Healthcare Corp.,* No. 1:23–cv–3107 (N.D. Ill. June 22, 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/202-3186-easy-healthcare-corporation-us-v.*

[25] Statement of the Commission on Breaches by Health Apps and Other Connected Devices, Fed. Trade Comm'n (Sept. 15, 2021), *https://www.ftc.gov/system/files/documents/public_statements/1596364/statement_of_the_commission_on_breaches_by_health_apps_and_other_connected_devices.pdf* (''Policy Statement'').

[26] 16 CFR 318.2.

[27] *Id.* § 318.2, incorporating in part the definition from section 1171(6) of the Social Security Act (42 U.S.C. 1320d(6)).

[28] *Id.* § 318.2; 42 U.S.C. 1320d(6), d(3).

[29] *See* Policy Statement at 1.

[30] The Policy Statement provided this example: ''[I]f a blood sugar monitoring app draws health information only from one source (*e.g.,* a consumer's inputted blood sugar levels), but also takes non-health information from another source (*e.g.,* dates from your phone's calendar), it is covered under the Rule.'' *Id.* at 2.

[31] 16 CFR 318.2.

[32] Policy Statement at 2. In the Statement of Basis and Purpose to the 2009 Final Rule published in the

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B. Enforcement History

In 2023, the Commission brought its first enforcement actions under the Rule against vendors of personal health records. In February 2023, the Commission brought an enforcement action alleging a violation of the Rule against GoodRx Holdings, Inc. (''GoodRx''), a digital health company that sells health-related products and services directly to consumers, including prescription medication discount products and telehealth services through its website and mobile applications.[33]

In its complaint, the Commission alleged that between 2017 and 2020, GoodRx, as a vendor of personal health records, disclosed more than 500 consumers' unsecured PHR identifiable health information to third party advertising platforms like Facebook and Google, without the authorization of those consumers. As charged in the complaint, these disclosures violated explicit privacy promises the company made to its users about its data sharing practices (including about its sharing of PHR identifiable health information). The Commission alleged GoodRx broke these promises and disclosed its users' prescription medications and personal health conditions, personal contact information, and unique advertising and persistent identifiers. The Commission charged GoodRx with violating the Rule by failing to provide the required notifications, as prescribed by the Rule, to (1) individuals whose unsecured PHR identifiable health information was acquired by an unauthorized person, (2) the Federal Trade Commission, and (3) media outlets. 16 CFR 318.3 through 318.6. The Commission entered into a settlement that imposed injunctive relief and required GoodRx to pay a $1.5 million civil penalty for its alleged violation of the Rule.[34]

Similarly, on May 17, 2023, the Commission brought its second enforcement action under the Rule against Easy Healthcare Corporation (''Easy Healthcare''), a company that publishes an ovulation and period tracking mobile application called Premom, which allows its users to input and track various types of health and other sensitive data. Similar to the conduct alleged against GoodRx, Easy Healthcare disclosed PHR identifiable health information to third party companies such as Google and AppsFlyer, contrary to its privacy promises, and did not comply with the Rule's notification requirements. The Commission entered into a settlement that imposed injunctive relief and required Easy Healthcare to pay a $100,000 civil penalty for its alleged violation of the Rule.[35]

C. Notice of Proposed Rulemaking

Having considered the public comments on the regulatory review notification and its Policy Statement, on June 9, 2023, the Commission issued a notice of proposed rulemaking (''NPRM'') [36] proposing to revise the Rule, 16 CFR part 318, in seven ways:

- First, the Commission proposed to revise several definitions in order to clarify the Rule and better explain its application to health apps and similar technologies not covered by HIPAA. Consistent with this objective, the NPRM modified the definition of ''PHR identifiable health information'' and added two new definitions (''health care provider'' and ''health care services or supplies''). These proposed changes were consistent with a number of public comments supporting the Rule's coverage of these technologies.
- Second, the Commission proposed to revise the definition of ''breach of security'' to clarify that a breach of security includes an unauthorized acquisition of PHR identifiable health information in a personal health record that occurs as a result of a data security breach or an unauthorized disclosure.
- Third, the Commission proposed to revise the definition of ''PHR related entity'' in two ways. Consistent with its proposal to clarify that the Rule applies to health apps, the Commission first proposed clarifying the definition of ''PHR related entity'' to make clear that the Rule covers entities that offer products and services through the online services, including mobile applications, of vendors of personal health records. In addition, the Commission proposed revising the definition of ''PHR related entity'' to provide that entities that access or send unsecured PHR identifiable health information to a personal health record—rather than entities that access or send *any* information to a personal health record—are PHR related entities.
- Fourth, the Commission proposed to clarify what it means for a personal health record to draw PHR identifiable health information from multiple sources.
- Fifth, in response to public comments expressing concern that mailed notice is costly and not consistent with how consumers interact with online technologies like health apps, the Commission proposed to revise the Rule to authorize electronic notice in additional circumstances. Specifically, the proposed Rule adjusted the language in the ''method of notice section'' and added a new definition of the term ''electronic mail.'' The proposed Rule also required that any notice delivered by electronic mail be ''clear and conspicuous,'' a newly defined term, which aligns closely with the definition of ''clear and conspicuous'' codified in the FTC's Financial Privacy Rule.[37]
- Sixth, the Commission proposed to expand the required content of the notice to individuals, to require that consumers whose unsecured PHR identifiable health information has been breached receive additional important information, including information regarding the potential for harm from the breach and protections that the notifying entity is making available to affected consumers. In addition, the proposed Rule included exemplar notices, which entities subject to the Rule could use to notify consumers in terms that are easy to understand.
- Seventh, in response to public comments, the Commission proposed to make a number of changes to improve the Rule's readability. Specifically, the Commission proposed to include explanatory parentheticals for internal cross-references, add statutory citations in relevant places, consolidate notice and timing requirements in single sections, respectively, of the Rule, and add a new section that plainly states the penalties for non-compliance.

The NPRM also included a section discussing several alternatives the

Federal Register (''2009 Rule Commentary''), the Commission, in addressing questions about how the extent of individual authorization should be determined, stated data sharing to enhance consumers' experience with a PHR is authorized only if such use is consistent with the entity's disclosures and individuals' reasonable expectations. For anything beyond such uses, the Commission expects vendors of personal health records and PHR related entities to limit the sharing of consumers' information, unless the consumers exercise ''meaningful choice'' in allowing sharing. The Commission believes burying disclosures in lengthy privacy policies does not satisfy the standard of ''meaningful choice.'' 74 FR 42967.

[33] *United States* v. *GoodRx Holdings, Inc.,* No. 23–cv–460 (N.D. Cal. Feb. 17, 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/2023090-goodrx-holdings-inc.*

[34] In addition, the Commission alleged GoodRx's data sharing practices were deceptive and unfair, in violation of section 5 of the FTC Act.

[35] *United States* v. *Easy Healthcare Corporation,* No. 1:23–cv–3107 (N.D. Ill. June 22, 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/202-3186-easy-healthcare-corporation-us-v.*

[36] 88 FR 37819 (''2023 NPRM'').

[37] 16 CFR 313.3(b). The FTC's Financial Privacy Rule requires financial institutions to provide particular notices and to comply with certain limitations on disclosure of nonpublic personal information. Using a comprehensive definition of ''clear and conspicuous'' based on the Financial Privacy Rule definition aims to ensure consistency across the Commission's privacy-related rules.

Commission considered but did not propose. Although the Commission did not put forth any proposed modifications on those issues, the Commission nonetheless sought public comment on them.

The Commission received approximately 120 comments in response to the NPRM from a wide spectrum of stakeholders, including consumers, consumer groups, trade associations, think tanks, policy organizations, private sector entities, and members of Congress.[38] As discussed in detail below, commenters addressed the seven topics on which the Commission proposed changes, responded to particular points on which the Commission requested comment, offered additional comment on alternatives that the Commission considered but did not propose, and provided comment on other topics. The majority of commenters expressed support for the Commission's proposed changes.

The Commission believes the amendments are consistent with the language and intent of the Recovery Act, address the concerns raised by the public comments in response to the NPRM, and will ensure the Rule remains current in the face of changing business practices and technological developments.

II. Analysis of the Final Rule

The following discussion analyzes the amendments to the Rule.

A. Clarification of Entities Covered

1. The Commission's Proposal To Clarify the Entities Covered

The Commission proposed changes to several definitions in § 318.2 to clarify the Rule's application to health apps and similar technologies not covered by HIPAA. First, the proposed Rule revised the definition of ''PHR identifiable health information'' to remove a cross-reference and instead import language from section 1171(6) of the Social Security Act, 42 U.S.C. 1320d(6), which is also referenced directly in section 13407 of the Recovery Act. The proposed Rule defined ''PHR identifiable health information'' as information (1) that is provided by or on behalf of the individual; (2) that identifies the individual or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual; (3) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and (4) is created or received by a health care provider, health plan (as defined in 42 U.S.C. 1320d(5)), employer, or health care clearinghouse (as defined in 42 U.S.C. 1320d(2)).

The Commission explained that this proposed definition covers traditional health information (such as diagnoses or medications), health information derived from consumers' interactions with apps and other online services (such as health information generated from tracking technologies employed on websites or mobile applications or from customized records of website or mobile application interactions), as well as emergent health data (such as health information inferred from non-health-related data points, such as location and recent purchases). The Commission sought comment as to whether any further amendment of the definition was needed to clarify the scope of data covered.

Second, the NPRM proposed to define the term ''health care provider'' that appears in the proposed definition of ''PHR identifiable health information'' (''is created or received by a health care provider''). The Commission proposed to define this term in a manner similar to the definition of ''health care provider'' found in 42 U.S.C. 1320d(3) (and referenced in 42 U.S.C. 1320d(6), which is directly referenced in section 13407 of the Recovery Act), to mean a provider of services (as defined in 42 U.S.C. 1395x(u)), a provider of medical or other health services (as defined in 42 U.S.C. 1395x(s)), or any other entity furnishing health care services or supplies. The Commission observed that this proposed definition, which is consistent with the statutory scheme, differs from, but does not contradict, the definitions or interpretations adopted by HHS. The Commission sought comment on defining this term more broadly than the term is used in other contexts.

Third, the NPRM proposed to define ''health care services or supplies'' (the final term in the definition of ''health care provider'') to include any online service, such as a website, mobile application, or internet-connected device that provides mechanisms to track diseases, health conditions, diagnoses or diagnostic testing, treatment, medications, vital signs, symptoms, bodily functions, fitness, fertility, sexual health, sleep, mental health, genetic information, diet, or that provides other health-related services or tools. The Commission explained that this change clarified that the Rule applies generally to online services, including websites, apps, and internet-connected devices that provide health care services or supplies, and clarified that the Rule covers online services related not only to medical issues (by including in the definition terms such as ''diseases, diagnoses, treatment, medications'') but also wellness issues (by including in the definition terms such as ''fitness, sleep, and diet'').

The Commission explained that these proposed changes to the definitions clarified that developers of health apps and similar technologies providing ''health care services or supplies'' qualify as ''health care providers,'' such that any individually identifiable health information these products collect or use would constitute ''PHR identifiable health information'' covered by the Rule. The Commission explained that these proposed changes further clarified that a mobile health application can be a ''personal health record'' covered by the Rule and the developers of such applications can be ''vendors of personal health records.''

2. Public Comments Regarding the Commission's Proposal To Clarify the Entities Covered

The Commission received numerous comments on the application of the Rule to health apps and similar technologies. A substantial number of commenters supported the Rule's application to health apps and similar technologies not covered by HIPAA as necessary in light of the explosion of health apps and the associated dangers to the privacy and security of consumers' health information.[39] Notably, support for the

[38] Comments are available at *https://www.regulations.gov/document/FTC-2023-0037-0001/comment.*

[39] *See generally,* Am. Acad. of Fam. Physicians (''AAFP''); AHIP; AHIMA; Ass'n of Health Info. Outsourcing Serv.'s (''AHIOS''); AMA; Am. Med. Informatics Ass'n (''AMIA''); ANI; Anonymous 1; Anonymous 2; Anonymous 3; Anonymous 4; Anonymous 9; Anonymous 10; Anonymous 11 ; Anonymous 14; Am. Osteopathic Ass'n (''AOA''); Ella Balasa; Beth Barnett; Lauren Batchelor; Bipartisan Pol'y Ctr. (''BPC''); Alan Brewington; Ctr. for Democracy & Tech. (''CDT''); Ctr. for Digit. Democracy (''CDD''); Confidentiality Coal.; Consumer Rep.'s; Elec. Frontier Found. (''EFF''); Elec. Priv. Info. Ctr. (''EPIC''); Dave K.; Members of the House of Representatives; MRO Corp. (''MRO''); Omada Health; Pharmed Out; Planned Parenthood Federation of Amer. (''Planned Parenthood''); CB Sanders; Robb Streicher; SYNGAP1 Foundation and SYNGAP1 Foundation 2; Devin Thompson; Janice Tufte; Michael Turner; U.S. Public Interest Research Group (''U.S. PIRG''); UL Sol.'s; Grace Vinton; WEDI; Anli Zhou. Some commenters elaborated on the nature of the risks to consumers' health data and on the importance to consumers. Two commenters, for example, described research they had performed regarding mental health and/or reproductive health apps' disclosure of consumers' health data to third parties. Mozilla at 3–4; Consumer Reports at 2. Another commenter, a public interest group and advocacy organization, attached a petition containing 9,659 signatures

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Commission's proposals came from a variety of commenters—industry associations,[40] businesses,[41] members of Congress,[42] consumer or patient advocacy groups,[43] individual consumers,[44] and anonymous sources.[45] Many commenters argued that safeguards for non-HIPAA covered health data are essential,[46] particularly because consumers generally are not aware of varying legal protections for health data.[47] Indeed, according to some commenters, requiring notification to consumers of the breach of health information not protected by HIPAA is precisely what Congress intended by authorizing the FTC to issue this Rule; the Commission's proposed changes are, therefore, consistent with the goals of the Recovery Act.[48] Some commenters argued that Federal privacy legislation is needed to protect non-HIPAA covered health data, but, in the interim, the Commission should strengthen its Rule to protect consumer health data to the extent possible.[49] Other commenters urged the Commission to take even broader measures in this Rule, such as imposing breach prevention measures,[50] banning health-based surveillance technologies or targeted advertising,[51] banning selling or sharing of health data not necessary to provide patient care or mandating data retention limits and deletion,[52] or requiring adherence to standardized terms of service with strong privacy protections.[53]

Although many commenters expressed support for the proposed changes, several business coalitions, industry associations and individual firms opposed the changes, which, they argued, are inconsistent with Congress's intent in the Recovery Act to address a narrow subset of ''personal health records'' and therefore exceed the FTC's statutory authority.[54] According to some comments, Congress should address any privacy issues that exceed the narrow scope of the Recovery Act. These commenters also contend that if the Commission believes there has been a violation of section 5, then the Commission needs to engage in an FTC Act section 18 rulemaking.[55] One commenter argued further that consumers have different privacy expectations for an electronic health record offered by their physician versus a fitness app (for example) that they download themselves, and the Commission's Rule should respect those differing expectations.[56]

Some commenters opposed to the changes also argued that the revised definitions would reduce choice and access in the marketplace,[57] stifle innovation,[58] or create disincentives for advertising[59] because (1) firms would risk initiating breaches by sharing user data with their partners and (2) in accepting data from health apps, partners such as advertising and analytics firms would risk being covered by the Rule.[60] According to some commenters, placing such strictures on the advertising and service provider ecosystem would raise prices (by, for example, undermining ad-supported services) and thereby harm competition.[61] One commenter argued that while robust protections for consumer health data are needed, the Rule should not be a vehicle for such protections, because it will result in over-notification of consumers (who have largely learned to disregard breach notices) and be a barrier to legislative change on privacy and data security issues more generally.[62] Another commenter argued against a breach notification rule altogether, asserting that the Commission should instead focus on requiring robust data security practices to prevent breaches in the first instance.[63]

Some commenters specifically addressed the proposed changes to the definitions of ''PHR identifiable health information'' and the new definitions of ''health care provider'' and ''health care services or supplies.'' First, a number of comments addressed the scope of ''PHR identifiable health information.'' Some commenters urged greater breadth, arguing, for example, that the definition of ''PHR identifiable health information'' should be expanded to include other types of data, such as data *about* an individual—not just data provided by or on behalf of an individual.[64] Other commenters urged the Commission to state expressly that its definition encompasses particular types of information, such as unique persistent identifiers[65] or information about sexual health[66] or substance use or treatment.[67] By contrast, some commenters urged the Commission to narrow the definition or otherwise clarify its limits, by, for example, exempting data relating to clinical research or trials[68] or data that has been de-identified.[69]

Relatedly, some commenters urged the Commission to create a definition of or standard for ''identifiable data,'' ''de-identification'' or ''de-identified

asking for strong rules to protect digital health privacy. US PIRG at 5–230.

[40] *E.g.,* AAFP, AHIMA, AHIOS, AMA, AMIA, AOA; Network Advert. Initiative (''NAI'').

[41] *E.g.,* Mozilla; MRO; Omada Health; UL Sol.'s.

[42] *See* Members of the House of Representatives (six members of Congress expressing support for the proposed changes).

[43] *E.g.,* CDD; CDT; EFF; U.S. PIRG.

[44] Ella Balasa; Beth Barnett; Lauren Batchelor; Alan Brewington; Sean Castillo; Dave K.; CB Sanders; Robb Streicher; Devin Thompson; Janice Tufte; Michael Turner; Grace Vinton; Anli Zhou.

[45] Anonymous 1; Anonymous 2; Anonymous 3; Anonymous 4; Anonymous 5; Anonymous 6; Anonymous 9; Anonymous 10; Anonymous 11; Anonymous 14.

[46] *See, e.g.,* AAFP at 1–2; AHIMA at 2; AHIOS at 2; Anonymous 5 at 1; AOA at 1; Am. Speech-Language-Hearing Ass'n (''ASHA'') at 1; Am. Psychiatric Ass'n (''APA'') at 1; CDT at 3–4; CHIME at 2; EFF at 1; Generation Patient at 1; HIMSS at 2; HIMSS Elec. Health Rec. Ass'n (''HIMSS EHR Ass'n'') at 1; MRO at 1–2; Omada Health at 2; PharmedOut at 1; Planned Parenthood at 2–3; Michael Turner at 1; WEDI at 1–4.

[47] AHIMA at 2; Anonymous 5 at 1; ASHA at 1; EFF at 1; WEDI at 2. One commenter, a software company that assists digital health companies with legal compliance, argued that three factors, in particular, support greater protection for digital health data: (1) consumers mistakenly believe HIPAA covers all health data; (2) there is a culture within some digital health companies that favors rapid adoption of products to secure venture capital even when compliance infrastructure is lacking; and (3) digital health products deal with sensitive data and inherently present a greater privacy risk given their heavy reliance on data and data exchange compared to traditional medicine. Tranquil Data at 1.

[48] Confidentiality Coal. at 2; Consumer Rep.'s at 4.

[49] *See, e.g.,* AAFP at 2. One commenter, an industry coalition focused on health IT and health care information exchange, emphasized a significant privacy problem adjacent to the Rule: whether HIPAA covered entities should warn patients about the privacy risks associated with health apps and what the Federal government can do to apply equal privacy protections to health data, notwithstanding HIPAA's limitations. *See* WEDI at 3. One commenter supported the proposed changes but argued the Commission should work with Congress to update antiquated terms like ''personal health record.'' HIMSS at 3.

[50] Ella Balasa at 2; PharmedOut at 1.

[51] Light Collective at 5.

[52] EFF at 2.

[53] Texas Med. Ass'n (''TMA'') at 1–2.

[54] *See, e.g.,* Ass'n of Nat'l Advertisers, Inc. (''ANA'') at 4–5; Comput. & Commc'n's Indus. Ass'n (''CCIA'') at 2–3; Chamber of Com. (''Chamber'') at 1–3; CHI at 2; Consumer Tech. Ass'n (''CTA'') at 2; Lab'y Access and Benefits Coal. (''LAB'') at 1; Priv. for Am. at 1–2; TechNet at 2.

[55] Priv. for Am. at 2–3; Chamber at 6–7; Health Innovation All. (''HIA'') at 1. *See also* Advanced Med. Tech. Ass'n (''AdvaMed'') at 1 (recommending the Commission adopt a privacy framework pursuant to the advanced notice of proposed rulemaking (R111004) regarding commercial surveillance and data security (87 FR 51273, Aug. 22, 2022)).

[56] CCIA at 4.

[57] Am. Telemedicine Ass'n (''ATA Action'') at 1.

[58] TechNet at 1–2; CTA at 5.

[59] ANA at 3.

[60] Priv. for Am. at 3.

[61] *E.g.,* ANA at 3; Priv. for Am. at 1, 3–4.

[62] World Priv F. (''WPF'') at 4.

[63] HIA at 2.

[64] Consumer Rep.'s at 3.

[65] *Id.*

[66] BPC at 1–2; Planned Parenthood at 5.

[67] Legal Action Ctr. & Opioid Pol'y Inst. at 1–2.

[68] Soc'y for Clinical Rsch. Sites (''SCRS'') at 1.

[69] Future of Priv. F. (''FPF'') at 3.

data,'' [70] such as by adopting HHS's de-identification standard,[71] or by stating that information is identifiable if it is ''reasonably linkable to an identified or identifiable individual.'' [72] Commenters argued that clarifying what constitutes ''identifiable'' data is necessary both because of the increasing ability for de-identified data to be re-identified [73] and because the market needs clarity to enable uninhibited flow of de-identified health data for research, public health, and commercial activities.[74] Indeed, according to one commenter, failure to clarify the standard could complicate or chill public health research and other innovation.[75] One commenter argued that an objective standard of ''reasonable linkability'' is better than what the commenter described as the Rule's knowledge-based standard (*i.e.,* whether the company has a reasonable basis to believe it can be used to identify an individual).[76] One commenter urged the Commission to issue a new notice of proposed rulemaking on the issue of de-identification alone.[77]

Second, many commenters specifically addressed the Commission's proposed new definition of ''health care provider.'' One commenter applauded the Commission's revised definition of ''health care provider,'' arguing that taking a crabbed view of that or related terms would lead to further fragmentation of health data, which is already fragmented by HIPAA's limited purview.[78] Another commenter noted the Commission's definition of ''health care provider'' is simply a logical outgrowth of how consumers interact with health apps: consumers look to health apps to provide health-related services—the quintessential function of a health care provider.[79]

Other commenters, however, raised concerns that the proposed definition of ''health care provider'' is confusing in its departure from HIPAA's terminology or is otherwise overbroad.[80] Some commenters argued this departure from the traditional meaning of the term is not what Congress intended.[81] A few commenters suggested reducing the confusion with the traditional term by re-naming the definition. These commenters suggested the Commission instead use one of the following terms: ''non-HIPAA-regulated health care provider,'' [82] ''PHR provider,'' [83] ''Health-related vendor,'' [84] ''HIPAA covered entity,'' [85] or ''health-related service provider.'' [86] Another commenter recommended eliminating the confusion by stating within the definition that it excludes HIPAA-covered entities and their business associates.[87] Another commenter urged the Commission to affirm that its definition would have no impact on the term ''health care provider'' as used in other regulations.[88]

Several comments also expressed concern with the final phrase of the definition of ''health care provider'' (''any other entity furnishing health care services or supplies''), as overly broad and confusing. Commenters argued its breadth (and the breadth of the accompanying definition of ''health care services or supplies'') would have perverse results, turning retailers of tennis shoes, shampoo, or vitamins into entities covered by the Rule, which is not what Congress intended.[89] Moreover, it would result not only in compliance burdens for companies (with the downstream effect of raising prices for consumers) but also in massive over-notification of consumers, who will become desensitized to the onslaught of notices.[90]

Several commenters urged the Commission to address this problem by dropping the phrase ''any other entity furnishing health care services or supplies'' entirely—or at least excising the word ''supplies''—from the definition of ''health care provider.'' [91] One commenter recommended replacing the phrase with a different phrase: ''any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.'' [92] Another commenter recommended expressly excluding retailers.[93] Commenters requested further clarification of certain terms within the definition of ''health care provider,'' including the terms ''furnishing'' [94] and ''health care.'' [95] And another commenter argued a better approach would be to jettison the definitions of ''health care provider'' and ''health care services and supplies'' entirely and instead apply the Rule to any entity that ''promotes its offering as addressing, improving, tracking or informing matters about a consumer's health.'' [96]

Third, some commenters addressed the proposed definition of ''health care services or supplies.'' [97] Several commenters requested more clarity as to what constitutes an ''online service,'' [98] as nearly all commercial activities have some online presence.[99] Several commenters recommended deleting the final phrase of the definition (''or that provides other health-related services or tools'') to limit the definition's breadth.[100] Conversely, some commenters urged the Commission to reinforce its breadth, by expressly stating that ''health care services or supplies'' include services related to ''wellness'' [101] or to specific health conditions, such as substance abuse disorder diagnosis, treatment, medication, recurrence of use (''relapse'') and recovery.[102]

3. The Commission Adopts the Proposed Changes To Clarify the Entities Covered

After considering the comments received, the Commission adopts the proposed changes to the Rule (with only non-substantive, organizational improvements noted below) to clarify that the Rule applies to mobile health applications and similar technologies. The Commission agrees with the substantial number of comments, from many different types of entities and individuals, who argued that such clarification is necessary in light of changing technology (*i.e.,* the mass adoption of health apps) and the privacy and data security risks to consumer health data collected by that technology. The Commission also agrees with

[70] SCRS at 2; Chamber at 7; EPIC at 7–9; FPF at 3–4, LAB at 2; MRO at 4; Network for Pub. Health L. and Texas A&M Univ. (''Network'') at 3.

[71] LAB at 2; Network at 3; SCRS at 2.

[72] FPF at 3.

[73] SCRS at 2.

[74] FPF at 3; Network at 3–4.

[75] Network at 3.

[76] FPF at 3.

[77] Chamber at 7.

[78] CDT at 11.

[79] Confidentiality Coal. at 3–4.

[80] AAFP at 2–3; AdvaMed at 3–4; AHIP at 2; AMA at 2–3; ATA Action at 1; CARIN Alliance at 2–3; CCIA at 3; CTA at 4, 6–9; Datavant at 2; Invitae Corp. (''Invitae'') at 4; NAI at 3–4; Software & Info. Indus. Ass'n (''SIIA'') at 1–2; TechNet at 2; TMA at 2–3; WPF at 7.

[81] ANA at 5; ATA Action at 1; Invitae at 4–5; Priv. for Am. at 4.

[82] Planned Parenthood at 6.

[83] WPF at 7.

[84] AHIP at 2.

[85] AMA at 3.

[86] AHIP at 2.

[87] Datavant at 2.

[88] AAFP at 2–3.

[89] ANA at 7–8; CCIA at 4; CHI at 3–4; CTA at 7–8; SIIA at 2.

[90] ANA at 3; SIIA at 1.

[91] AdvaMed at 4; CHI at 4; CTA at 9; TechNet at 2.

[92] AdvaMed at 4.

[93] CTA at 8–9.

[94] EPIC at 2.

[95] AdvaMed at 3 (urging the Commission to define ''health care'' and ''health care provider'' as in 45 CFR 160.103).

[96] WPF at 10.

[97] AdvaMed at 3; AAFP at 3; AHIP at 3; Priv. for Am. at 6–7.

[98] MRO at 2; WPF at 7–8.

[99] WPF at 8.

[100] NAI at 4.

[101] EPIC at 4.

[102] Legal Action Ctr. & Opioid Pol'y Inst. at 3.

commenters who argued that the proposed changes to the Rule are consistent with the Recovery Act, which was intended to bolster breach notifications for consumer health data that falls outside HIPAA. Although the Commission agrees with commenters who argue that consumer health data should enjoy substantial and unfragmented privacy protections, this Rule addresses breach notification, not omnibus privacy protections. While this rulemaking does not address omnibus privacy protections, the Commission observes that companies collecting or holding consumers' sensitive health data should engage in many of the practices commenters described, such as imposing data retention limits, enabling deletion options, and preventing breaches through robust privacy and data security practices.[103]

The Commission is not persuaded that applying the Rule to health apps and similar technologies will have deleterious consequences for individual firms or competition or result in over-notification of consumers. Importantly, the only obligation the Rule imposes is to notify the Commission, consumers, and, in some cases, the media of a breach of unsecured PHR identifiable health information. As noted in the NPRM, many State laws already impose similar, or significantly broader, data breach obligations.[104] Moreover, firms can avoid notification costs entirely by avoiding breaches—by reducing the amount of unsecured PHR identifiable health information they access and maintain (which can be achieved by securing PHR identifiable health information), by de-identifying health information, and by implementing other privacy and data security measures appropriate to the sensitivity of the data. Congress intended for consumers to learn of breaches of their unsecured PHR identifiable health information that fall outside HIPAA; the changes to the Rule help ensure consumers will receive the notification Congress intended.

The Commission carefully considered the arguments commenters raised that the definitional changes depart from the language or spirit of the Recovery Act. The Commission does not agree. The definitions hew closely to the language of the Recovery Act and to the definitions directly referenced by the Recovery Act in section 1171(6) of the Social Security Act, 42 U.S.C. 1320d(6). As many commenters noted, while health apps did not exist when Congress passed the Recovery Act, they function in a similar manner to the personal health records that existed at the time.

For these reasons, the Commission is adopting the proposed definitions, with minor clarifications. First, the Commission has retained the definition of ''PHR identifiable health information'' as set out in the NPRM, with non-substantive organizational changes noted below. In response to comments that the definition of ''PHR identifiable health information'' should be broader, the Commission notes the definition, which closely follows the statutory language, already encompasses most of the categories of data that commenters identified. For example, unique, persistent identifiers (such as unique device and mobile advertising identifiers), when combined with health information, constitute ''PHR identifiable health information,'' if these identifiers can be used to identify or re-identify an individual. Moreover, ''PHR identifiable health information'' encompasses information about sexual health and substance abuse disorders, because the information ''relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.'' The Recovery Act states PHR identifiable health information is information provided ''by or on behalf of the individual,'' so the Commission declines to change this phrase to ''about,'' as one commenter suggested.[105] The Commission notes, however, that information provided ''by or on behalf of the individual'' will encompass much information ''about'' an individual, as the consumer is the original source of most data; many inferences ''about'' the individual originate from information provided ''by or on behalf of the individual.''

The Commission does not agree with commenters who sought to narrow the definition of PHR identifiable health information out of concern for the Rule's overall breadth. The Commission notes that liability under the Rule does not arise from a single definition. While data used for public health research, for example, may, in some instances, meet the definition of ''PHR identifiable health information,'' the firm using that data is subject to the Rule only if other conditions are met (*i.e.,* the firm is an entity covered by the Rule).

The Commission declines to create a new definition of ''de-identified data'' or another similar term, because the definition of de-identification is already embedded in the second part of the definition of PHR identifiable health information (''that identifies the individual or with respect to which there is a reasonable basis to believe that the information can be used to identify the individual''). Where there is no ''reasonable basis to believe that the information can be used to identify the individual,'' the information is not identifiable; rather, it is de-identified. If data has been de-identified according to standards set forth by HHS, then there is not a ''reasonable basis to believe that the information can be used to identify the individual,'' as the definition of PHR identifiable health information requires. Because the Commission's standard is consistent with HHS's, the Commission's Rule poses no impediment to health-related research or other flows of de-identified data. The Commission does not view the existing language as a subjective standard that turns on a company's knowledge, as one commenter suggested; by requiring a ''reasonable basis to believe'' that the information is not identifiable, the Rule creates an objective standard. Whether such reasonable basis exists will depend on whether the data can reasonably be linked to an individual consumer. There is no need for a supplemental notice of proposed rulemaking on this issue, as the Commission is not changing this aspect of the Rule, which closely follows the statute.[106]

Second, the Commission is modifying the proposed definition of ''health care provider'' to ''covered health care provider'' to distinguish that term from interpretations of the term ''health care provider'' in other contexts, which may be more limited in scope. As commenters requested, the Commission affirms its definition of ''covered health care provider'' is unique to the Rule; it does not bear on the meaning of ''health care provider'' as used in other regulations enforced by other government agencies. The Commission adopts this change merely to dispel confusion in terminology; the Commission is not making any substantive change from the definition as proposed. The Commission does not need to state expressly, either in this definition or elsewhere, that the Rule's notification requirements do not apply to HIPAA-covered entities and their business associates, as § 318.1 of the

[103] In the 2009 Final Rule, the Commission similarly underscored the importance of maintaining protections for health information, stating: ''In addition, as noted in the NPRM, the Commission expects entities that collect and store unsecured PHR identifiable health information to maintain reasonable security measures, including breach detection measures, which should assist them in discovering breaches in a timely manner.'' 74 FR 42971 n.93 (2009).

[104] 88 FR 37832 n.103.

[105] Consumer Rep.'s at 4.

[106] 42 U.S.C. 17937(f)(2).

Rule already includes this proviso. The Commission declines to remove the phrase ''any other entity furnishing health care services or supplies'' from the definition of ''health care provider,'' because this phrase is nearly identical to the language that appears in 42 U.S.C. 1320d(3), which is referenced in the definition of individually identifiable health information in 42 U.S.C. 1320d(6), which is in turn referenced in the definition of PHR identifiable health information in section 13407(f)(2) of the Recovery Act, 42 U.S.C. 17937.[107] The Commission declines to define the terms ''furnish'' and ''health care'' as the Commission believes the plain meaning of the term ''furnish'' (to supply someone with something) is already clear and adding a definition of ''health care'' is unnecessary in light of the definition of ''covered health care provider'' and ''health care services and supplies.'' Differences from HHS's regulations pursuant to HIPAA are appropriate, as the Recovery Act differs from HIPAA, and the Recovery Act's mandate is specifically to cover entities *not* covered by HIPAA.

Third, the Commission is adopting the proposed definition of ''health care services or supplies,'' with one minor modification: the Commission has substituted the word ''means'' for ''includes'' to avoid implying greater breadth than the Commission intends. The Commission adopts this change merely to dispel confusion about undue breadth; the Commission does not intend any substantive change from the definition proposed. The Commission otherwise affirms the proposed definition without change. The Commission believes the term ''online service'' in the definition of ''health care services or supplies'' is sufficiently clear because of the examples of ''online services'' given within the definition itself: website, mobile application, or internet-connected device. Providing an exhaustive list of what constitutes an online service would prevent the definition from being sufficiently flexible to account for future innovation in types of online services. The Commission also retains the catch-all ''or that provides other health-related services or tools'' for the same reason: to ensure the Rule's language can accommodate future changes in technology. There is no undue breadth, because that phrase's meaning is in the context of the preceding phrase (''provides mechanisms to track diseases, health conditions, diagnoses or diagnostic testing, treatment, medications, vital signs, symptoms, bodily functions, fitness, fertility, sexual health, sleep, mental health, genetic information, diet'').

In response to some commenters' concerns that the proposed Rule's definition of ''health care provider'' and ''health care services or supplies'' would impermissibly cause the Rule to cover retailers of general-purpose items like tennis shoes, shampoo, or vitamins, the Commission disagrees this would necessarily be the case. A threshold inquiry under the Rule is whether an entity is a ''vendor of personal health records,'' which the Recovery Act defines as ''an entity . . . that offers or maintains a personal health record.'' [108] The Recovery Act usage of the term ''vendor of'' in connection with ''personal health records'' underscores that entities that are not in the business of offering or maintaining (*e.g.,* selling, marketing, providing, or promoting) a health-related product or service are not covered—in other words, they are not ''vendors'' of personal health records. Thus, to be a vendor of personal health records under the Rule, an app, website, or online service must provide an offering that relates more than tangentially to health.[109]

The Commission notes a general retailer (one that sells food products, children's toys, garden supplies, healthcare products (such as pregnancy tests), or apparel (such as maternity clothes)) offering consumers an app to purchase and access purchases of these products—by itself—would not make the retailer a vendor of personal health records. In this scenario, purchase information relating to certain items—such as a pregnancy test or maternity clothes from a retailer—may reveal information about that person's health. While this purchase information may be PHR identifiable health information, the retailer in this scenario is not a vendor of personal health records because the app is only tangentially related to health. The Commission notes, however, there may be scenarios where a general-purpose retailer described above may become a vendor of personal health records under the Rule, such as where the retailer offers an app with features or functionalities that are sold, marketed, or promoted as more than tangentially relating to health.

In addition, the Commission reiterates a personal health record must be an electronic record of PHR identifiable health information on an individual, must have the technical capacity to draw information from multiple sources, and must be managed, shared, and controlled by or primarily for the individual. The Commission also notes that purchases of items at a brick and mortar retailer where there is no app, website, or online service to access or track that purchase information electronically is not a personal health record, because there is no electronic record at issue. Contrary to the assertions of some commenters, these definitions do not result in undue breadth, because they do not function in isolation. The Commission provides the following examples to illustrate the interplay of these definitions with the definition of ''personal health record'':

- *Example 1:* Health advice app or website A, which is not covered by HIPAA, provides information to consumers about various medical conditions. Its function is purely informational; it does not provide any mechanism through which the consumer may track or record information. Health advice app or website A is not a personal health record, because it is not an electronic record of PHR identifiable health information on an individual.
- *Example 2:* Health advice app or website B, which is not covered by HIPAA, provides information to consumers about various medical conditions and provides a symptom tracker, available to consumers who log into the site with a username and password, in which consumers may input symptoms and receive potential diagnoses. Health advice app or website B is an electronic record of PHR identifiable health information on an individual, because its information is provided by the individual, it identifies the individual (via username and password), it relates to the individual's health conditions (the symptoms), and is received by a health care provider (*i.e.,* the entity providing the site itself, as that entity is furnishing the health care service of an online service that provides mechanisms to track symptoms). However, health advice app or website B is not a personal health

[107] The definition of ''covered health care provider'' in § 318.2 substitutes ''entity'' for ''person''—*i.e.,* ''any other *entity* furnishing health care services or supplies''—because the rest of the Rule speaks in terms of ''entities,'' but the definition in § 318.2 is otherwise identical to the statutory definition in 42 U.S.C. 1320d(3).

[108] 42 U.S.C. 17921(18); *see also* 42 U.S.C. 17937.

[109] At least one commenter urged a somewhat similar interpretation, contending that a relevant inquiry in determining whether a service offers a personal health record is ''the terms under which a product or service is offered to consumers. If an entity promotes its offering as addressing, improving, tracking, or informing matters about a consumer's health, then that entity's offering would be subject to the rule. Thus, any product or services that tracks or addresses physical activity, blood pressure, heart rate, digestion, strength, genetics, sleep, weight, allergies, pain, and similar characteristics would be subject to a PHR rule.'' *See* WPF at 10.

record to the extent the site does not have the technical capacity to draw information from multiple sources (*i.e.,* if the consumer is its only source of information).

- *Example 3:* Health advice website C, which is not covered by HIPAA, functions in the same way as health advice app or website B, except that it collects geolocation data via an application programming interface (''API''). For the reasons stated in Example 2, it is an electronic record of PHR identifiable health information on an individual. It also has the technical capacity to draw information from multiple sources (consumer inputs and collection of geolocation data through the API. It is managed primarily for the individual (*i.e.,* to provide the individual health advice). Therefore, health advice app or website C is a personal health record.
- *Example 4:* Health advice app or website D, which is not covered by HIPAA, functions in the same way as health advice app or website B, except that it also draws information from a data broker and connects that information to some of its individual users to provide them with more accurate diagnostic suggestions. For the reasons stated in Example 2, it is an electronic record of PHR identifiable health information on an individual. It also has the technical capacity to draw information from multiple sources (the consumer and the data broker) and is managed by or primarily for the individual. Therefore, health advice app or website D is a personal health record.

Whether a health app or other electronic record constitutes a personal health record (and is therefore subject to the Rule) is a fact-intensive inquiry whose outcome depends not only on the nature of the information contained in that record, but also on numerous other factors, such as its ''technical capacity,'' its source(s) of information, and its relationship to the individual.

Finally, the Commission notes a non-substantive, organizational change relating to the definition of ''PHR identifiable health information.'' In the 2023 NPRM, the Commission proposed revising ''PHR identifiable health information'' by importing language from section 1171(6) of the Social Security Act, 42 U.S.C. 1320d(6), which is referenced directly in section 13407 of the Recovery Act. To hew more closely to the organization of the Recovery Act, and to preserve the word ''includes'' in the phrase ''includes information that is provided by or on behalf of the individual,'' the Commission revised slightly the order of the elements in the definition of ''PHR identifiable health information.''

B. Clarification of What It Means for a Personal Health Record To Draw Information From Multiple Sources

1. The Commission's Proposal Regarding What It Means for a Personal Health Record To Draw Information From Multiple Sources

The Commission proposed amending the definition of the term ''personal health record'' to clarify what it means for a personal health record to draw information from multiple sources. Under the 2009 Rule, a personal health record is defined as an electronic record of PHR identifiable health information that can be drawn from multiple sources and that is managed, shared, and controlled by or primarily for the individual. Under the Commission's proposed definition, a ''personal health record'' would be defined as an electronic record of PHR identifiable health information on an individual that has the technical capacity to draw information from multiple sources and that is managed, shared, and controlled by or primarily for the individual.

Changing the phrase ''that can be drawn from multiple sources'' to ''has the technical capacity to draw information from multiple sources'' serves several purposes. First, it clarifies a product is a personal health record if it can draw information from multiple sources, even if the consumer elects to limit information to a single source only, in a particular instance. For example, a depression management app that accepts consumer inputs of mental health states and has the technical capacity to sync with a wearable sleep monitor is a personal health record, even if some customers choose not to sync a sleep monitor with the app. Thus, whether an app qualifies as a personal health record would not depend on the prevalence of consumers' use of a particular app feature, like sleep monitor-syncing. Instead, the analysis of the Rule's application would be straightforward: either the app has the technical means (*e.g.,* the application programming interface or API) to draw information from multiple sources, or it does not. Next, adding the phrase ''technical capacity to draw information'' clarifies a product is a personal health record if it can draw any information from multiple sources, even if it only draws health information from one source. This change further clarifies the Commission's interpretation of the Recovery Act, as explained in the Policy Statement.[110]

The Commission sought public comment as to whether this revised language sufficiently clarifies the Rule's application to developers and purveyors of products that have the technical capacity to draw information from more than one source. The Commission invited comment on its interpretation that an app is a personal health record because it has the technical capacity to draw information from multiple sources, even if particular users of the app choose not to enable the syncing features. The Commission also requested comment about whether an app (or other product) should be considered a personal health record even if it only draws health information from one place (in addition to non-health information drawn elsewhere); or only draws identifiable health information from one place (in addition to non-identifiable health information drawn elsewhere). The Commission further requested comment about whether the Commission's bright-line rule (apps with the ''technical capacity to draw information'' are covered) should be adjusted to take into account consumer use, such as where no consumers (or only a de minimis number) use a feature, and about the likelihood of such scenarios. For example, the Commission offered an example of an app that might have the technical capacity to draw information from multiple sources, but its API is entirely or mostly unused, either because it remains a Beta feature, has not been publicized, or is not popular.

2. Public Comments Regarding What It Means for a Personal Health Record To Draw Information From Multiple Sources

Many commenters supported the Commission's proposal amending the definition of a ''personal health record.'' [111] Commenters noted, for instance, this change would help to ensure that many services that collect PHR identifiable health information are covered by the Commission's Rule,[112] and would help to promote greater privacy and security for health information,[113] while still ''hewing to

[110] Policy Statement at 2.

[111] Ella Balasa at 1; TMA at 4 (arguing that ''PHRs include applications with the technical capacity to draw information from multiple sources, regardless of the patient's preference to activate the technical capability.''); Consumer Rep.'s at 6; AAFP at 3; AHIMA at 4–5; AMA at 4; CHIME at 4; CDT at 13; AOA at 3.

[112] AHIMA at 4–5.

[113] AAFP at 3.

the limitations of the statute.'' [114] Some commenters noted without this change, developers of personal health records (such as app developers) might have incentives to design their products in ways that would intentionally skirt the Rule's requirements (such as by restricting a consumer's ability to import data from other sources).[115] Others noted the importance of the Rule covering apps with the technical capacity to draw information from multiple sources even where such capacity is not used by the consumer.[116]

Other commenters opposed this proposal.[117] Some argued the proposed clarification regarding what drawing information from multiple sources means runs counter to Congress's statutory intent,[118] because virtually every app has some sort of integration (*e.g.,* for analytics) through which it draws information other than from the consumer.[119] One commenter asserted the change would broaden the scope of the Rule to the point that it would sweep in online services that should not be thought of as a personal health record (such as email apps),[120] or otherwise create confusing standards for app developers or reduce innovation.[121] In addition, commenters expressed concern this change would sweep in apps or online services that have the technical capacity to draw from multiple sources during the development or testing phase of the product, or would sweep in products with unused, unavailable, or unpublicized APIs or integrations that count as a source.[122] One commenter expressed concern about lack of clarity, such as in scenarios where a user is required to pay for an upgrade to access a feature or integration that draws information from another source.[123] Some commenters also expressed concern that apps and online services that are subject to HIPAA (*i.e.,* HIPAA-covered entities or business associates) should be carved out of the definition of a personal health record.[124] Other commenters expressed broader concern with the definition of ''personal health record,'' urging the Commission to, for example, abandon the purportedly outdated term in favor of a more modern one.[125] For instance, some commenters urged that the Commission abandon or tweak the requirement that the personal health record be ''managed, shared, and controlled by or primarily for the individual.'' [126]

Another commenter expressed concern the proposed change could sweep in services that draw any information from multiple sources, regardless of whether that information is identifiable health information.[127]

3. The Commission Adopts the Proposed Changes Clarifying What It Means for a Personal Health Record To Draw Information From Multiple Sources

After considering the comments received, the Commission adopts the proposed amendment without change. This amendment will help clarify the types of entities covered by the Rule. The definition does not create undue breadth or deviate from Congressional intent; rather, the changes are consistent with the language of the Recovery Act, and only serve to give meaning to the phrase ''can be drawn'' in the Recovery Act in a way that is consistent with the current state of technology. They are also necessary to keep pace with technological change, which has enabled firms to offer consumers mobile electronic records of their health information that contain numerous integrations. To illustrate the intended meaning of the proposed revisions to the term ''personal health record,'' the Commission reiterates examples from the 2023 NPRM of two non-HIPAA covered diet and fitness apps available for consumer download in an app store. Under the amended Rule, each is a personal health record.

- *Example 1:* Diet and fitness app Y allows users to sync their app with third-party wearable fitness trackers. Diet and fitness app Y has the technical capacity to draw identifiable health information both from the user (*e.g.,* name, weight, height, age) and the fitness tracker (*e.g.,* user's name, miles run, heart rate), even if some users elect not to connect the fitness tracker.
- *Example 2:* Diet and fitness app Y has the ability to pull information from the user's phone calendar via the calendar API to suggest personalized healthy eating options. Diet and fitness app Y has the technical capacity to draw identifiable health information from the user (*e.g.,* name, weight, height, age) and non-health information (*e.g.,* calendar entry info, location, and time zone) from the user's calendar.

As these examples make clear, and in response to one commenter's concern that the changes would sweep in services that do not draw any health information,[128] the Commission notes the Rule still requires drawing PHR identifiable health information from at least one source to count as a personal health record.

The Commission declines to make other requested changes to the definition of personal health record. First, the Commission declines to include an express exemption for HIPAA-covered entities within the definition of personal health record because § 318.1 of the Rule already specifically exempts businesses or organizations covered by HIPAA.[129] Second, the Commission declines to exempt apps and services where there are available but unused or unpublicized APIs or integrations. Similarly, the Commission declines to exempt apps and services from the definition just because they are drawing information from multiple sources while undergoing product or beta testing and are not yet in their final form.[130] The Commission notes a product feature or integration that exists

[114] Consumer Reports at 5–6.

[115] AHIP at 2–3; CDT at 13 (arguing that changes remove ''incentives for companies to technically design products and services to not trigger the HBNR to avoid any need to provide consumer notice.'').

[116] AHIOS at 4; CARIN Alliance at 4.

[117] NAI at 6 (urging that the Commission make clear that a personal health record is one that ''not only has the technical capacity to draw PHR identifiable health information from multiple sources, but that it also has the functionality and actually does incorporate data from multiple sources.''); ANA at 7; ACLA at 1–2.

[118] NAI at 6.

[119] Chamber at 4–5; Priv. for Am. at 5–6; NAI at 6.

[120] CCIA at 6.

[121] CTA at 11; AdvaMed at 5; CHI at 5.

[122] CHI at 5 (asking the Commission to clarify that an ''app having the ability to draw from multiple sources with some changes to the app's coding/APIs is not within this definition's threshold.''); ACLA at 1 (arguing ''[i]f a feature is unused by individuals 'because it remains a Beta feature,' then in fact it does not have the 'technical capacity' to draw an individual's information from other sources, unless and until its functionality has been enabled by the vendor. The mere possibility that an application vendor *might* sometime in the future enable that functionality should not bring the electronic record within the scope of the definition of 'personal health record.' '') (emphasis in original); CTA at 11 (arguing Rule should instead have bright-line test that assesses whether the app actually draws health information from multiple sources); AdvaMed at 5 (arguing the Commission should decline to adopt multiple sources changes because it could cause confusion and potentially sweep in apps or services with features that have not been made available to consumers, such as APIs connected to the PHR that have not been publicized).

[123] WPF at 9.

[124] Omada at 5; Datavant at 3.

[125] HIMSS at 3 (urging the Commission to work with Congress to craft a definition more consonant with technological realities).

[126] AHIOS at 4; MRO at 4.

[127] NAI at 6.

[128] NAI at 6.

[129] *See, e.g.,* 16 CFR 318.1(a) (Rule ''does not apply to HIPAA-covered entities, or to any other entity to the extent that it engages in activities as a business associate of a HIPAA-covered entity.''); *see also* 16 CFR 318.2 (exempting business associates and HIPAA-covered entities from the Rule's definitions of ''PHR related entity'' and ''vendor of personal health records.'').

[130] ACLA at 1–2; CTA at 11; AdvaMed at 5.

and that is able to draw PHR identifiable health information counts as a source under the Rule. Exempting such instances would be contrary to the purpose of the Rule and would impermissibly limit notification of breaches just because a product feature is not widely disseminated, used, or in its final form. The Commission notes under the Rule, a covered entity that experienced a breach of security of unsecured PHR identifiable health information triggering the Rule would not be exempt because the breach occurred in the context of such scenarios.

Further, and importantly, the Rule is triggered only by breaches of unsecured PHR identifiable health information and does not apply to information that is protected or ''secured'' through the use of a technology or methodology specified by the Secretary of Health and Human Services in the guidance issued under section 13402(h)(2) of the American Reinvestment and Recovery Act of 2009, 42 U.S.C. 17932(h)(2).[131] The Rule, therefore, creates appropriate incentives for product testing with de-identified data or that secures information through certain specifications, such as through specified encryption methods.

Third, the Commission declines, as one commenter requested,[132] to expressly exempt scenarios where a change is required to an app's coding to draw information from another source. The Commission notes, however, it does not intend to cover instances where an app can draw from multiple sources only through changes to the design or underlying software code and where the app developer does not implement those changes.

[131] Per HHS guidance, electronic health information is ''secured'' if it has been encrypted according to certain specifications set forth by HHS, or if the media on which electronic health information has been stored or recorded is destroyed according to HHS specifications. *See* 74 FR 19006; *see also* U.S. Dep't of Health & Human Servs., *Guidance to Render Unsecured Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals* (July 26, 2013), *https://www.hhs.gov/hipaa/for-professionals/breach-notification/guidance/index.html*. PHR identifiable health information would be considered ''secured'' if such information is disclosed by, for example, a vendor of personal health records, to a PHR related entity or a third party service provider, in an encrypted format meeting HHS specifications, and the PHR related entity or third party service provider stores the data in an encrypted format that meets HHS specifications and also stores the encryption and/or decryption tools on a device or at a location separate from the data.

[132] CHI at 5 (asking the Commission to clarify that an ''app having the ability to draw from multiple sources with some changes to the app's coding/APIs is not within this definition's threshold.'').

In addition, the Commission declines to remove from the definition of personal health record the requirement that it be ''managed, shared, and controlled by or primarily for the individual.'' This language mirrors the Recovery Act's statutory definition of personal health record.[133] Further, this language provides a boundary to the definition. Even if a website or app has the technical capacity to draw information from multiple sources (for example, because it has integrations for advertising or analytics), it must still be ''managed, shared, and controlled by or primarily for the individual'' to be covered by the Rule.

Generally, a personal health record is an electronic record of an individual's health information by which the individual maintains access to the information and may have, for example, the ability to manage, track, control, or participate in his or her own health care. If these elements are not present, the website or app may not be ''managed, shared, and controlled by or primarily for the individual,'' and would not, therefore, constitute a personal health record.

C. Clarification Regarding Types of Breaches Subject to the Rule

1. The Commission's Proposals

a. The Commission's Proposal Regarding ''Breach of Security''

The Commission proposed a definitional change to clarify that a breach of security under the Rule encompasses unauthorized acquisitions that occur as a result of a data breach *or* an unauthorized disclosure. The Commission's proposal underscores that a breach of security is not limited to data exfiltration, and includes unauthorized disclosures (such as, but not limited to, a company's unauthorized sharing or selling of consumers' information to third parties that is inconsistent with the company's representations to consumers). The Rule previously defined ''breach of security'' as the acquisition of unsecured PHR identifiable health information of an individual in a personal health record without the authorization of the individual, which language mirrored the definition of ''breach of security'' in section 13407(f)(1) of the Recovery Act.

Accordingly, consistent with the Recovery Act definition, the Policy Statement, FTC enforcement actions under the Rule, and public comments received, the Commission proposed amending the definition of ''breach of security'' in § 318.2 by adding the following sentence to the end of the existing definition: ''[a] breach of security includes an unauthorized acquisition of unsecured PHR identifiable health information in a personal health record that occurs as a result of a data breach or an unauthorized disclosure.'' The change was intended to make clear to the marketplace that a breach includes an unauthorized acquisition of identifiable health information that occurs as a result of a data breach or an unauthorized disclosure, such as a voluntary disclosure made by the PHR vendor or PHR related entity where such disclosure was not authorized by the consumer.

The NPRM, like the 2009 Rule, continued to include a rebuttable presumption for unauthorized access to an individual's data; it stated when there is unauthorized access to data, unauthorized acquisition will be presumed unless the entity that experienced the breach ''has reliable evidence showing that there has not been, or could not reasonably have been, unauthorized acquisition of such information.''

b. The Commission's Related Proposal To Not Define the Term ''Authorization'' in the Rule

In the 2023 NPRM, the Commission stated it had considered defining the term ''authorization,'' which appears in § 318.2's definition of ''breach of security,'' but did not propose any such change in the NPRM.

The Commission considered defining ''authorization'' to mean the affirmative express consent of the individual and then defining ''affirmative express consent'' consistent with State laws that define consent, such as the California Consumer Privacy Rights Act, Cal. Civ. Code 1798.140(h).[134] Such changes would have ensured notification is required anytime there is acquisition of

[133] 42 U.S.C. 17921(11).

[134] As noted in the 2023 NPRM, the Commission considered defining ''affirmative express consent'' as any freely given, specific, informed, and unambiguous indication of an individual's wishes demonstrating agreement by the individual, such as by a clear affirmative action, following a clear and conspicuous disclosure to the individual, apart from any ''privacy policy,'' ''terms of service,'' ''terms of use,'' or other similar document, of all information material to the provision of consent. Acceptance of a general or broad terms of use or similar document that contains descriptions of agreement by the individual along with other, unrelated information, does not constitute affirmative express consent. Hovering over, muting, pausing, or closing a given piece of content does not constitute affirmative consent. Likewise, agreement obtained through use of user interface designed or manipulated with the substantial effect of subverting or impairing user autonomy, decision-making, or choice, does not constitute affirmative express consent. *See* 88 FR 37830 n.78.

unsecured PHR identifiable health information without the individual's affirmative express consent for that acquisition—such as when an app discloses unsecured PHR identifiable health information to another company, having obtained nominal ''consent'' from the individual by using a small, greyed-out, pre-selected checkbox following a page of dense legalese.

The Commission did not, however, propose to define ''authorization'' because (1) the 2009 Rule Commentary already provided guidance on the types of disclosures the Commission considers to be ''unauthorized''; [135] (2) recent Commission orders, such as the Commission's enforcement actions against GoodRx and Easy Healthcare,[136] also make clear that the use of ''dark patterns,'' which have the effect of manipulating or deceiving consumers, including through use of user interfaces designed with the substantial effect of subverting or impairing user autonomy and decision-making, do not satisfy the standard of ''meaningful choice''; and (3) Commission settlements establish important guidelines involving authorization (the Commission's recent settlement with GoodRx, alleging violations of the Rule, highlights that disclosures of PHR identifiable health information inconsistent with a company's privacy promises constitute an unauthorized disclosure).

The Commission sought public comment about:

- Whether the commentary above and FTC enforcement actions under the Rule provide sufficient guidance to put companies on notice about their obligations for obtaining consumer authorization for disclosures, or whether defining the term ''authorization'' would better inform companies of their compliance obligations.
- To the extent that including such definitions would be appropriate, the definitions of ''authorization'' and ''affirmative express consent,'' as described above, and the extent to which such definitions are consistent with the language and purpose of the Recovery Act.
- What constitutes an acceptable method of authorization, particularly when unauthorized sharing is occurring.[137]
- Whether there are certain types of sharing for which authorization by consumers is implied because such sharing is expected and/or necessary to provide a service to consumers.

2. Public Comments

a. Public Comments Regarding ''Breach of Security''

Many commenters supported the Commission's proposed amendment to the definition of ''breach of security.'' [138] One commenter noted the change is consistent with the broad definition of ''breach of security'' in the Recovery Act, which refers explicitly to the acquisition of PHR identifiable health information without the authorization of an individual (rather than the authorization of an entity holding the data, as is the case where a breach involves data theft or exfiltration).[139] Commenters also noted the amendment would ensure notice, accountability, and regulatory oversight, regardless of the underlying cause of the unauthorized acquisition.[140] Commenters noted that breaches encompass more than just cybersecurity intrusions.[141] Commenters also argued that a company's voluntary unauthorized disclosure can be just as damaging as data theft.[142] For instance, a commenter noted that unauthorized disclosures of health information may cause embarrassment, perpetuate stigma about patients' conditions, deter patients from seeking care, interfere in the patient-physician relationship, or impact patients' employment.[143] Moreover, voluntary, unauthorized disclosures increase the risk of additional unauthorized acquisition and sharing of this information among bad actors.[144]

Some commenters supported expanding or changing the definition further. Specifically, some commenters urged the Commission to amend the definition to encompass (1) exceeding authorized access or use of PHR identifiable health information, such as where a company collects data for one purpose, but later uses or discloses that data for a second, undisclosed purpose; [145] or (2) the collection or retention of PHR identifiable health information beyond what is necessary to provide the associated service to an individual consumer.[146] One commenter asked the Commission to clarify that the Rule would be triggered by unauthorized use of or access to information derived from PHR identifiable health information, and to define the phrase acquisition.[147]

Some commenters, however, urged the Commission to not amend the definition at all. These commenters expressed concern the amendment would cause the Rule to exceed what Congress intended in the Recovery Act and transform the Rule into an opt-in notice and consent privacy regime.[148] Commenters argued further the proposed changes would cause consumer notice fatigue,[149] consumer panic,[150] or over-reporting by companies.[151] One commenter urged the Commission to limit the definition of ''acquisition'' to actual acquisition, and exclude instances of access or disclosure where the information was not actually acquired by a third party.[152] Commenters argued the proposed definition would be burdensome and force companies to limit certain beneficial disclosures to certain third parties, such as disclosures to support internal operations, detect security vulnerabilities or fraud, for law enforcement, and other purposes.[153]

Some commenters also urged that the Commission adopt carve-outs so that certain conduct would not be deemed breaches of security under the Rule. Commenters requested exemptions consistent with or found in HIPAA or

[135] *See, e.g.,* 74 FR 42967.

[136] *United States* v. *GoodRx Holdings, Inc.,* No. 23–cv–460 (N.D. Cal. 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/2023090-goodrx-holdings-inc; United States* v. *Easy Healthcare Corp.,* No. 1:23–cv–3107 (N.D. Ill. 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/202-3186-easy-healthcare-corporation-us-v.*

[137] For example, the Commission sought comment about when a vendor of personal health records or a PHR-related entity is sharing information covered by the Rule, is it acceptable for that entity to obtain the individual's authorization to share that information when an individual clicks ''agree'' or ''accept'' in connection with a pre-checked box disclosing such sharing? Is it sufficient if an individual agrees to terms and conditions disclosing such sharing but that individual is not required to review the terms and conditions? Or is it sufficient if an individual uses a health app that discloses in its privacy policy that such sharing occurs, but the app knows via technical means that the individual never interacts with the privacy policy? *See* 88 FR 37832.

[138] *See, e.g.,* TMA at 3; U.S. PIRG at 2–3; AAFP at 3; AHIMA at 3; AMA at 3–4; AMIA at 3; AOA at 2–3; AHIOS at 3; CDT at 11–12; CHIME at 4; EPIC at 5–6.

[139] Consumer Rep.'s at 4.

[140] CDT at 11–12; U.S. PIRG at 2–3.

[141] AMA at 4; CDT at 11–12; EPIC at 5.

[142] AAFP at 3; CDT at 11–12.

[143] AOA at 2.

[144] AHIMA at 3.

[145] FPF at 12–15.

[146] EPIC at 5–7; U.S. PIRG at 2–3.

[147] Mozilla at 6–7.

[148] Chamber at 6; Priv. for Am. at 2–5; ANA at 6–7.

[149] SIIA at 3; CTA at 13–14.

[150] CCIA at 4–5, 7 (arguing that requiring notification for unauthorized disclosures could cause consumers to worry in the absence of harm, such as where it is ''typical'' to disclose such information.)

[151] CTA at 13–14.

[152] *Id.* at 14–16.

[153] TechNet at 3; Chamber at 7; CCIA at 5–6.

under State breach notification laws, such as exemptions for disclosures to certain types of entities or for certain purposes, or where there is inadvertent or unintentional access, use, or disclosure.[154] Commenters also proposed safe harbors for companies that implement recognized security or privacy safeguards; [155] and one commenter proposed safe harbors that would apply where data is shared with ''affiliated businesses,'' where there is inadvertent but ''good-faith'' access by a company employee, where a company makes good faith efforts to inform consumers of disclosures to third parties, and where companies take steps to contractually limit downstream uses of the data.[156] Other commenters expressed support for exempting disclosures of PHR identifiable health information to public health authorities for public health purposes, noting the amended definition could discourage such disclosures.[157]

b. Public Comments Regarding Defining ''Authorization''

Commenters were divided as to whether the Commission should define ''authorization.'' Some commenters supported defining ''authorization'' to provide greater guidance to companies, to promote transparency, and to discourage buried or inconspicuous disclosures relating to health information, or approaches to consent that are not meaningful because they are confusing or coercive.[158] To further regulatory consistency, some commenters supported adding a definition of ''authorization'' that is consistent with how that term is defined in other health-related laws, such as under HIPAA [159] or State health privacy laws that define consent or authorization (such as the California Consumer Privacy Rights Act [160] or the Washington My Health, My Data Act).[161]

By contrast, some commenters opposed defining the term—or opposed a requirement under the Rule that entities be required to get authorization before disclosing PHR identifiable health information.[162] Commenters argued that Congress had not granted the Commission the authority to define ''authorization'' in the Recovery Act,[163] or that doing so would import a substantive consent requirement that is outside the scope of the Rule, converting a breach notice Rule into an opt-in privacy regime.[164] Other commenters noted that requiring a specifically defined authorization would create an inflexible standard that would not evolve with changes in technology.[165] Other commenters opposed a requirement that consumers should be required to review terms before agreeing to use a service, contending that this would not increase consumer understanding of terms.[166]

Some commenters endorsed other approaches that would exempt from any requirement of affirmative express consent certain types of disclosures of PHR identifiable health information, such as to service providers, data processors, and entities that assist with combatting fraud and promoting safety.[167] Some commenters urged a disclosure be deemed authorized if the disclosure is consistent with a company's privacy notices or policies or where applicable State privacy laws require affirmative consent or provide for the right to opt-out, without the need to define affirmative express consent under the Rule.[168] One commenter argued that authorization should be met when a consumer agrees to opt-in to certain data sharing, such as by clicking a box proximate to a disclosure of material terms.[169]

3. The Commission Adopts the Proposed Changes to the Definition of ''Breach of Security''

After carefully considering the public comments, the Commission adopts the proposed amendment without change. The final rule definition is consistent with the statutory definition in the Recovery Act, the Policy Statement,[170] and recent Commission enforcement actions under the Rule. The Commission notes the statutory definition in the Recovery Act is sufficiently broad to cover both cybersecurity intrusions as well as a company's intentional but unauthorized disclosures of consumers' PHR identifiable health information to third party companies. In addition, the Commission finds persuasive the comment noting the Recovery Act's definition of ''breach of security'' refers to the acquisition PHR identifiable health information without the authorization of an individual, rather than the authorization of the entity holding the data.[171] The definition is

[154] CHI at 4 (stating the FTC ''should explicitly except the same situations from disclosure that are excepted from HIPAA disclosures, and/or try to align exceptions with those found in State privacy statutes.''); CTA at 16; HIA at 2; TechNet at 3 (arguing the Rule should adopt exemptions that encompass ''actions taken to prevent and detect security incidents, to comply with a civil, criminal, or regulatory inquiry or investigation, to cooperate with law enforcement agencies concerning conduct or activity that the data controller reasonably and in good faith believes may be illegal, to perform internal operations consistent with a consumer's expectations, and to provide a product or service that a consumer requested.''); CCIA at 5–6 (arguing the Rule should exempt disclosures relating to a host of purposes, including: preventing and detecting security incidents and fraud, complying with legal process, cooperating with law enforcement, performing internal operations consistent with consumer expectations, providing a service requested by the consumer, protecting ''the vital interests of the consumer,'' or processing data relating to public health); Chamber at 7 (arguing if the Commission does amend the definition of breach of security, it ''should provide exceptions for legitimate and societally beneficial uses of data that other privacy laws have for failure to honor opt-in including but not limited to network security, prevention and detection of fraud, protection of health, network maintenance, and service/product improvement.''); LAB at 2.

[155] DirectTrust at 1–2.

[156] ATA Action at 2.

[157] Network for Pub. Health L. and Texas A&M Univ. at 1–2.

[158] AHIP at 4; Light Collective at 4; MRO at 2–3; Mozilla at 4; CARIN Alliance at 10; Consumer Rep.'s at 9; *see also* PharmedOut at 3 (arguing that defining ''authorization'' is crucial but urging the Commission go further and place substantive restrictions on what companies can do with consumer health data.).

[159] AdvaMed at 7 (arguing that any definition of ''authorization'' or ''affirmative express consent'' should take into account the necessity for medical technologies and medical technology companies to be able to operate and communicate under standards consistent with those governing HIPAA covered entities and others in the health care ecosystem. These standards permit certain uses and disclosures of individually identifiable health information without express consent where necessary for the provision of timely and effective health care); MRO at 3; AHIMA at 7–8.

[160] AHIOS at 3.

[161] Consumer Rep.'s at 9.

[162] HIA at 2 (arguing that ''[r]outine disclosures of data should be allowed in certain contexts without additional need for authorizations''); CTA at 16–17; AdvaMed at 7–8; ACLA at 6; Confidentiality Coal. at 4–5.

[163] Confidentiality Coal. at 4–5.

[164] CTA at 16–17 (arguing that the Rule does not allow the Commission to impose ''substantive consent requirements'' that would be burdensome and ''likely not administrable for many companies.'').

[165] SIIA at 4.

[166] CHI at 7.

[167] FPF at 10 (arguing that ''an organization may share information with a service provider operating on their behalf to provide storage; may share information to protect the safety or vital interests of an individual or react to a public health emergency; or to protect themselves against security incidents and fraud. In each of these situations, data protection laws typically invoke a variety of non-consent measures, including data minimization, transparency, notice to the end-user or the regulator, and opportunities to object.''); Chamber at 7.

[168] Confidentiality Coal. at 4–5; SIIA at 4; CHI at 7.

[169] CTA at 17.

[170] The Commission's Policy Statement makes clear that ''[i]ncidents of unauthorized access, including sharing of covered information without an individual's authorization, triggers notification obligations under the Rule,'' and that a breach ''is not limited to cybersecurity intrusions or nefarious behavior.'' Policy Statement at 2.

[171] Consumer Rep.'s at 5 (noting ''the Recovery Act frames breaches of security in relation to individuals, rather than to vendors of personal health records or PHR related entities,'' and defines

also consistent with public comments received by the Commission in 2020 (when the Commission announced its regular, ten-year review of the Rule and requested public comments about potential Rule changes [172]), which urged the Commission to clarify what constitutes an unauthorized acquisition under the Rule.[173] Importantly, the amendment to the definition of ''breach of security'' in § 318.2 does not depart from the 2009 Rule Commentary or the Commission's enforcement policy under the Rule. Instead, it further underscores the 2009 Rule Commentary and subsequent Commission enforcement actions that unauthorized disclosures (*i.e.,* sharing inconsistent with consumer expectations) can be a ''breach of security'' that triggers the Rule.[174]

The Commission declines to adopt any specific exemptions or safe harbors to the definition of breach of security. Unlike the section of the Recovery Act that governs breach notifications under HIPAA,[175] Congress did not provide for any specific, enumerated exemptions for breaches under the Commission's Rule. Moreover, the Commission's Rule provides for a rebuttable presumption for certain types of access: when there is unauthorized access to data, unauthorized acquisition will be presumed unless the entity that experienced the breach ''has reliable evidence showing that there has not been, or could not reasonably have been, unauthorized acquisition of such information.'' That is, companies can rebut the presumption of acquisition in instances of unauthorized access by providing reliable evidence disproving acquisition. The Commission has previously offered guidance on what counts as unauthorized access and reiterates that guidance here.[176]

4. The Commission Affirms Its Proposal Not To Define ''Authorization''

After carefully considering the public comments, the Commission declines to define ''authorization,'' as that term appears in § 318.2's definition of ''breach of security.'' The Commission finds persuasive the public comments suggesting that imposing an affirmative express consent requirement would not be appropriate or warranted in all cases.

The Commission believes whether a disclosure is authorized under the Rule is a fact-specific inquiry that will depend on the context of the interactions between the consumer and the company; the nature, recipients, and purposes of those disclosures; the company's representations to consumers; and other applicable laws. The Commission reiterates the 2009 Rule Commentary, which states a use of data is ''authorized'' only where it is consistent with a company's disclosures and consumers' reasonable expectations and where there is meaningful choice in consenting to sharing—buried disclosures do not suffice.[177]

The Commission's recent enforcement actions alleging violations of the Rule against GoodRx and Easy Healthcare further highlight that disclosures of PHR identifiable health information inconsistent with a company's privacy promises constitute an unauthorized disclosure. These recent Commission orders also make clear that the use of ''dark patterns,'' which have the effect of manipulating or deceiving consumers, including through use of user interfaces designed with the substantial effect of subverting or impairing user autonomy and decision-making, undercut an entity's assertion that consumers exercised ''meaningful choice.''

In response to public comments seeking more guidance on what constitutes an unauthorized disclosure under the Rule,[178] the Commission

breach of security as ''acquisition of such information without the authorization of the individual.'')

[172] 85 FR 31085 (May 22, 2020).

[173] *See* Public Comments in response to May 2020 Request for Public Comments in connection with regular, ten-year review of Rule: AMA at 5–6 (''The FTC should define 'unauthorized access' as presumed when entities fail to disclose to individuals how they access, use, process, and disclose their data and for how long data are retained. Specifically, an entity should disclose to individuals exactly what data elements it is collecting and the purpose for their collection''; ''[T]he FTC should define 'unauthorized access' as presumed when an entity fails to disclose to an individual the specific secondary recipients of the individual's data.''); AMIA at 2 (recommending the FTC ''[e]xpand on the concept of 'unauthorized access' under the definition of 'Breach of security,' to be presumed when a PHR or PHR related entity fails to adequately disclose to individuals how user data is accessed, processed, used, reused, and disclosed.''); OAG–CA at 5–6 (urging the FTC to include ''impermissible acquisition, access, use, disclosure'' under the definition of breach.). These comments can be found at *https://www.regulations.gov/docket/FTC-2020-0045*.

[174] The 2009 Rule Commentary noted other examples illustrating that unauthorized sharing or transferring of information constitutes a breach of security, including that the unauthorized downloading or transfer of information by an employee can constitute a breach of security; that inadvertent access by an unauthorized employee reading or sharing information triggers the Rule's notification obligations; and notes that given the highly personal nature of health information, ''the Commission believes that consumers would want to know if such information was read or shared without authorization.'' *See* 74 FR 42966–67.

[175] 42 U.S.C. 17921; *see also* U.S. Dep't of Health & Human Servs., *Breach Notification* (July 26, 2013), *https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html.* Under the Recovery Act's definition of ''breach of security'' for the Rule governing HIPAA-covered entities and business associates, the statute explicitly provides for three exceptions: (1) unintentional acquisition, access, or use of protected health information by a workforce member or person acting under the authority of a covered entity or business associate, if such acquisition, access, or use was made in good faith and within the scope of authority; (2) the inadvertent disclosure of protected health information by a person authorized to access protected health information at a covered entity or business associate to another person authorized to access protected health information at the covered entity or business associate, or organized health care arrangement in which the covered entity participates; and (3) if the covered entity or business associate has a good faith belief that the unauthorized person to whom the impermissible disclosure was made, would not have been able to retain the information. *See* 45 CFR 164.400 through 164.414. In the first two cases, the information cannot be further used or disclosed in a manner not permitted by the Privacy Rule. These exceptions are not found in the provisions of the Recovery Act authorizing the FTC's Health Breach Notification Rule; this makes sense, given there is no analogous Privacy Rule, Security Rule, or required Business Associate agreements outside the HIPAA sphere governing entities covered by the FTC's Health Breach Notification Rule.

[176] The Rule continues to provide that, when there is unauthorized access to data, unauthorized acquisition will be presumed unless the entity that experienced the breach ''has reliable evidence showing that there has not been, or could not reasonably have been, unauthorized acquisition of such information.'' As noted in the 2009 Rule Commentary, the presumption was intended to address the difficulty of determining whether access to data (*i.e.,* the opportunity to view the data) did or did not lead to acquisition (*i.e.,* the actual viewing or reading of the data). In these situations, the Commission stated that the entity that experienced the breach is in the best position to determine whether unauthorized acquisition has taken place. In describing the rebuttable presumption, the Commission provided several examples. It noted that no breach of security has occurred if an unauthorized employee inadvertently accesses an individual's PHR and logs off without reading, using, or disclosing anything. If the unauthorized employee read the data and/or shared it, however, he or she ''acquired'' the information, thus triggering the notification obligation in the Rule. Similarly, the Commission provided an example of a lost laptop: If an entity's employee loses a laptop in a public place, the information would be accessible to unauthorized persons, giving rise to a presumption that unauthorized acquisition has occurred. The entity can rebut this presumption by showing, for example, that the laptop was recovered, and that forensic analysis revealed that files were never opened, altered, transferred, or otherwise compromised. *See* 74 FR 42966.

[177] The 2009 Rule Commentary states: ''[g]iven the highly personal nature of health information, the Commission believes that consumers would want to know if such information was read or shared without authorization.'' It further states that data sharing to enhance consumers' experience with a PHR is authorized only ''as long as such use is consistent with the entity's disclosures and individuals' reasonable expectations'' and that ''[b]eyond such uses, the Commission expects that vendors of personal health records and PHR related entities would limit the sharing of consumers' information, unless the consumers exercise meaningful choice in consenting to such sharing. Buried disclosures in lengthy privacy policies do not satisfy the standard of 'meaningful choice.' '' 74 FR 42967.

[178] TechNet at 4; Tranquil Data at 4.

offers the following, non-exhaustive examples relating to authorization:

• *Example 1—Unauthorized Disclosure (Affirmative Misrepresentation):* A medication app offers a personal health record (not covered by HIPAA) which allows users to track information about their prescription medication history, such as prescription names, dosages, pharmacy and refill information, and the user's health conditions. The app voluntarily discloses PHR identifiable health information to third party companies for advertising and advertising-related analytics, in violation of the app's privacy representations to its users. The third parties that receive the PHR identifiable health information are able to use the information for their own business purposes, such as to improve the third party's own products and services, to infer information about consumers, or to compile profiles about consumers to use for targeted advertising. These disclosures are not authorized under the Rule because they are inconsistent with consumer expectations—the disclosures violate the app's privacy representations, and consumers would also not expect their PHR identifiable health information (which they input into the app to track their medications and health conditions) would be disclosed to, and used by, third party companies that use the data for their own economic benefit.

• By contrast, disclosures of PHR identifiable health information by the app in Example 1 would be authorized if made to service providers in the following circumstances: (1) the service providers assist with functions that are necessary to the operation and functioning of the medication app, or with services the consumer requested; (2) the service providers are contractually prohibited from using, sharing, or disclosing the PHR identifiable health information for any purpose beyond providing services to the medication app; and (3) the medication app's privacy notice clearly and conspicuously discloses the specific purposes for which it shares users' PHR identifiable health information with these service providers. Such authorized disclosures could include those to cloud storage providers that host user data in the health record in a secure fashion; payment processors who process user payments to the app; vendors that facilitate refill reminders or other communications from the app developer that directly relate to the provision of the personal health record or services the consumer requested; analytics providers that assist with tracking analytics relating to the app's functionality; [179] or companies that help to detect, prevent, or mitigate fraud or security vulnerabilities. Such disclosures are authorized because they are consistent with consumer expectations. Importantly, this sharing is disclosed to consumers in a clear and conspicuous manner, and is essential, and limited to, sharing the PHR identifiable health information with service providers solely to provide users with a safe and reliable personal health record experience.

• *Example 2—Unauthorized Disclosure (Deceptive Omission).* The medication app from Example 1 shares PHR identifiable health information with a third party for purposes of targeting consumers with ads. The app does not disclose the sharing and also fails to obtain affirmative express consent from users whose information it shares. The third party company can use the PHR identifiable health information to market and advertise—on behalf of the medication app, on behalf of other companies, or on behalf of itself. It can also use the information to improve its own products and services. Such disclosures are not authorized because they are not consistent with consumer expectations (*i.e.,* without disclosure and without affirmative express consent, consumers would not expect that their PHR identifiable health information would be shared, sold, or otherwise exploited for a purpose other than providing the user with a personal health record, and are neither essential nor limited to sharing the PHR identifiable health information solely to provide users with a safe and reliable personal health record experience). This conclusion is also consistent with Commission enforcement actions relating to the sharing of health information (*e.g.,* GoodRx and Easy Healthcare), and those relating to the sharing of other types of sensitive information.[180]

• *Example 3—Authorized Disclosure (Public Health Reporting):* A COVID–19 contact tracing app not covered by HIPAA allows users to self-report their COVID–19 diagnosis, and to notify the user's contacts of their diagnosis, or others with whom the individual may have come into physical contact. PHR identifiable health information about the individual's COVID–19 diagnosis is transmitted to public health authorities for public health-related purposes, such as public health reporting and analysis or to track areas where the virus is spreading the most rapidly. The contact tracing app discloses to users clearly and conspicuously the specific purposes for which it shares their PHR identifiable health information with public health authorities. These disclosures are authorized, and consistent with consumer expectations, because they are consistent with the company's relationship with the consumer (a PHR that allows a user to report their COVID–19 diagnosis in order to notify others) and are also appropriately disclosed.

Examples 1 and 3 provide guidance about scenarios in which limited disclosures of PHR identifiable health information are permitted without opt-in consent because it is necessary to provide a personal health record to a consumer, is consistent with consumer expectations, the sharing is disclosed to consumers, and (in the case of Example 1) the sharing is subject to protections like service provider agreements that limit the use of the data only for the purpose of providing that service to the consumer. Examples 1 and 3 are also consistent with HIPAA and State health privacy laws.[181] For instance, HIPAA permits disclosures for treatment, payment, and operations without patient authorization.

The Commission notes ''breach of security'' could cover more than just an unauthorized disclosure to a third party. For example, depending on the facts and scope of the authorizations, such as in the company's promises and disclosures to consumers, a ''breach of security'' could include unauthorized *uses.* There may be a ''breach of security'' where an entity exceeds authorized access to use PHR identifiable health information, such as where it obtains the data for one legitimate purpose, but later uses that data for a secondary purpose that was not originally authorized by the individual.

Finally, the Commission notes unauthorized access or use of derived PHR identifiable health information may also constitute a breach of security. The Commission noted in its 2023 NPRM that PHR identifiable health information includes ''health

[179] This would include an analytics provider whose services are essential to the proper functioning of the app and not tied to marketing or advertising—this includes analytics tools to assist with crash reporting or to assess usage patterns (such as the frequency of use of certain features).

[180] *Fed. Trade Comm'n et al.* v. *Vizio, Inc. et al.,* No. 17–cv–00758 (D.N.J. 2017), *https://www.ftc.gov/legal-library/browse/cases-proceedings/162-3024-vizio-inc-vizio-inscape-services-llc.*

[181] For example, Washington State's My Health, My Data Act permits sharing consumer health data to the ''extent necessary to provide a product or service that the consumer to whom such consumer health data relates has requested from such regulated entity or small business.'' *See* Revised Code of Washington (RCW) 19.373.030 (1)(b)(ii).

information derived from consumers' interactions with apps and other online services (such as health information generated from tracking technologies employed on websites or mobile applications or from customized records of website or mobile application interactions), as well as emergent health data (such as health information inferred from non-health-related data points, such as location and recent purchases).'' [182]

D. Clarification of What Constitutes a ''PHR Related Entity''

1. The Commission's Proposal Regarding ''PHR Related Entity''

The NPRM proposed to revise the definition of ''PHR related entity'' in two ways. Consistent with its clarification that the Rule applies to health apps, the Commission proposed amending the definition of ''PHR related entity'' to make clear the Rule covers entities that offer products and services through the online services, including mobile applications, of vendors of personal health records. In addition, the Commission proposed revising the definition of ''PHR related entity'' to provide that entities that access or send unsecured PHR identifiable health information to a personal health record—rather than entities that access or send any information to a personal health record—are PHR related entities.

The Commission explained the first change (to cover online services) was necessary as websites are no longer the only means through which consumers access health information online. The Commission explained the second change—narrowing the scope of ''PHR related entities'' to entities that access or send unsecured PHR identifiable health information—was intended to eliminate potential confusion about the Rule's breadth and promote compliance by narrowing the scope of entities that qualify as PHR related entities.[183] The Commission identified remote blood pressure cuffs, connected blood glucose monitors, and fitness trackers as examples of internet-connected devices that could qualify as a PHR related entity when individuals sync them with a personal health record (*e.g.,* a health app).[184] The Commission explained, however, that a grocery delivery service that sends information about food purchases to a diet and fitness app would not be a PHR related entity if it does not access unsecured PHR identifiable health information in a personal health record or send unsecured PHR identifiable health information to a personal health record.

The proposed Rule also revised § 318.3(b) by adding language establishing that a third party service provider is not rendered a PHR related entity when it accesses unsecured PHR identifiable health information in the course of providing services. The Commission explained it did not intend for any entity (such as a firm performing attribution and analytics services for a health app) to be considered both a PHR related entity (to the extent it accesses unsecured PHR identifiable health information in a personal health record) and a third party service provider, which could create competing notice obligations and confuse consumers with notice from an unfamiliar company. The Commission explained it considers such firms to be third party service providers that must notify the health app developers for whom they provide services, who in turn would notify affected individuals.

The Commission explained that distinguishing between third party service providers and PHR related entities would create incentives for responsible data stewardship and for de-identification because a firm would only become an entity covered by the Rule in relation to unsecured PHR identifiable health information. To the extent that firms must deal with unsecured PHR identifiable health information, PHR vendors would have incentives to select and retain service providers capable of treating data responsibly (*e.g.,* by not engaging in any onward disclosures of data that could result in a reportable breach) and incentives to oversee their service providers to ensure ongoing responsible data stewardship (which would avoid a breach).

The Commission observed in most cases, third party service providers are likely to be non-consumer facing. The Commission noted examples of PHR related entities would include, as noted above, makers of fitness trackers and health monitors when consumers sync their devices with a mobile health app. The Commission noted further examples of third party service providers would include entities that provide support or administrative functions to vendors of personal health records and PHR related entities.

2. Public Comments Regarding ''PHR Related Entity''

The Commission received numerous public comments about the changes to the definition of PHR related entity. Most commenters supported the Commission's approach.[185] One commenter, an industry association for advertisers, noted that addition of the term ''unsecured'' in the definition of ''PHR related entity'' created a limitation on the definition's scope that counterbalances the breadth of including ''any online service'' in the definition.[186] Moreover, this commenter noted, the addition of ''unsecured'' creates appropriate incentives for firms to secure PHR identifiable health information and to choose partners who will be good data stewards.[187] This commenter noted that limiting the definition to ''unsecured'' PHR identifiable health information was consistent with the original intent of the Rule, to cover only the most sensitive types of data not covered by HIPAA.[188]

A few commenters proposed changes to the definition of ''third party service provider'' to further distinguish the term from ''PHR related entity.'' One commenter recommended defining ''third party service provider'' as an

[182] 88 FR 37823.

[183] The proposed definition stated that a PHR related entity is an entity, other than a HIPAA-covered entity or an entity to the extent that it engages in activities as a business associate of a HIPAA-covered entity, that (1) offers products or services through the website, including any online service, of a vendor of personal health records; (2) offers products or services through the websites, including any online services, of HIPAA-covered entities that offer individuals personal health records; or (3) accesses unsecured PHR identifiable health information in a personal health record or sends unsecured PHR identifiable health information to a personal health record. Although the Rule is only triggered when there is a breach of security involving unsecured PHR identifiable health information, the Commission explained it believed there is a benefit to revising the third prong of PHR related entity to make clear that only entities that access or send unsecured PHR identifiable health information to a personal health record—rather than entities that access or send any information to a personal health record—are PHR related entities. Otherwise, many entities could be a PHR related entity under the definition's third prong and such entities would then, in the event of a breach, need to analyze whether they experienced a reportable breach under the Rule. If an entity, per the proposed revision, does not qualify as a PHR related entity in the first place, there would be no need to consider whether it experienced a reportable breach. 88 FR 37825 n.54.

[184] The Commission explained, for example, the maker of a wearable fitness tracker may be both a vendor of personal health records (to the extent that its tracker interfaces with its own app, which also accepts consumer inputs) and a PHR related entity (to the extent that it sends information to another company's health app). The Commission noted that regardless of whether the maker of the fitness tracker is a vendor of personal health records or a PHR related entity, its notice obligations are the same: it must notify individuals, the FTC, and in some case, the media, of a breach. 16 CFR 318.3(a), 318.5(b). 88 FR 37825 n.55.

[185] ANI at 1; AAFP at 3; AHIMA at 3; AHIOS at 4; AOA at 3; CARIN Alliance at 3; CDT at 12; CHIME at 3; Confidentiality Coal. at 6; Consumer Rep.'s at 6; CHI at 5; DirectTrust at 4; EFF at 2; EPIC at 7.

[186] NAI at 4–5.

[187] *Id.* at 5.

[188] *Id.* at 4.

entity that only processes data.[189] This commenter argued the Commission could then impose liability on service providers for further use, sale, disclosure for incompatible purposes.[190] Another commenter recommended aligning the definition of ''third party service provider'' with the definition of ''business associate'' under HIPAA.[191]

Some commenters raised concerns that the Commission's approach did not provide sufficient clarity for companies trying to understand their obligations as either a third party service provider or PHR related entity.[192] Some commenters requested more examples of types of firms falling within each definition (*e.g.,* examples clearly establishing the status of health data brokers, health marketing firms, search engines, email providers, cloud storage providers) [193]—to facilitate compliance,[194] avoid overlapping notice requirements [195] and to prevent a loophole through which firms may attempt to avoid obtaining consumers' authorization for data disclosures and to avoid providing breach notifications.[196] One commenter urged the Commission to exempt from the definition of ''PHR related entity'' any firm that complies with the privacy and data security requirements of HIPAA.[197]

In response to the Commission's request for comment on whether an analytics firm would be a third party service provider, many commenters responded that an analytics firm should fall within that definition [198] for the reasons the Commission articulated: It would be confusing to consumers to receive a notice from a back-end service provider rather than the firm with whom the consumer has the relationship, and categorizing analytics firms (and firms that provide other services) as service providers will create incentives for PHR vendors and PHR related entities to choose their service providers with care. A few commenters, however, expressed concern about covering advertising, analytics, and cloud firms—and health information service providers (''HISPs'') more generally—as they are unable to determine whether the data they receive contains unsecured PHR identifiable health information; only the vendor of the PHR knows what their data transmissions contain.[199] One commenter urged the Commission to address the data recipient's unawareness of the content of the data by creating a safe harbor that exempts advertising, analytics and cloud providers that contractually limit their customers, vendors, or partners from sharing health information with them.[200]

3. The Commission Adopts the Proposed Changes to ''PHR Related Entity''

After considering the comments received, the Commission adopts the proposed changes regarding ''PHR related entity'' without further change. The Commission affirms that (1) PHR related entities include entities offering products and services not only through the websites of vendors of personal health records, but also through any online service, including mobile applications; (2) PHR related entities encompass only entities that access or send unsecured PHR identifiable health information to a personal health record; and (3) while some third party service providers may access unsecured PHR identifiable health information in the course of providing services, this does not render the third party service provider a PHR related entity.

In response to commenters who expressed concern that certain data recipients will not be able to understand their obligations under the Rule because they are unaware of the content of the data transmissions they receive, the Commission highlights § 318.3(b), which states: ''For purposes of ensuring implementation of this requirement, vendors of personal health records and PHR related entities shall notify third party service providers of their status as vendors of personal health records or PHR related entities subject to this Part.'' This requirement puts data recipients on notice about the potential content of the data transmissions they receive.

Firms may also facilitate compliance by stipulating by contract whether transmissions of data will contain unsecured PHR identifiable health information. Both the sender and recipient of the data can monitor for compliance with those contractual agreements through the use of automated tools, internal auditing, external auditing, or other mechanisms, as appropriate to the size and sophistication of the firms and the sensitivity of the data. For example, a large advertising platform that has routinely received unsecured PHR identifiable health information, notwithstanding partners' promises not to send this information, may have different obligations to monitor the data it receives than small firms that do not engage in high-risk activities where the contract precludes sending such data and there is no history of such transmissions.

The Commission believes this approach—notice to service providers pursuant to § 318.3(b) coupled with contracts and oversight—is more appropriate than creating a safe harbor in the Rule that exempts firms that enter into contracts, as there is evidence from FTC cases that firms do not always abide by contractual obligations to safeguard data.[201]

The Commission declines to change the definition of ''third party service provider'' to distinguish it further from a ''PHR related entity,'' for two reasons. First, the Commission notes the current definitions of ''third party service provider'' and ''PHR related entity'' align closely with the language prescribed by section 13407 and section 13424(b)(1)(A) of the Recovery Act. Jettisoning the current language entirely, as some commenters suggested, would not be consistent with the Recovery Act's requirements. Second, the Commission believes the current language, in conjunction with the examples provided below, will provide sufficient guidance to the market as to which types of firms fit within each definition.

In response to comments that requested examples of the types of firms that fall into the category of ''third party service provider'' or ''PHR related entity,'' the Commission provides the following examples. The Commission believes these examples, in conjunction with the language in § 318.3(b), will provide sufficient clarity about the obligations of third party service providers and PHR related entities to promote compliance, avoid overlapping notice, and prevent loopholes.

[189] FPF at 10.

[190] *Id.*

[191] AdvaMed at 8.

[192] SIIA at 3; CARIN Alliance at 4.

[193] AHIMA at 3–4; AMIA at 3–4; CHI at 5; Direct Trust at 1; Light Collective at 4–5.

[194] SCRS at 1.

[195] NAI at 5.

[196] MRO at 3.

[197] AdvaMed at 5.

[198] NAI at 5; TMA at 3; Consumer Rep.'s at 11.

[199] CCIA at 7–8; CTA at 9–10; SIIA at 3; Direct Trust at 5.

[200] CTA at 13.

[201] Compl. at ¶ 21, *In the Matter of Flo Health, Inc.,* FTC File No. 1923133 (Jan. 13, 2021), *https://www.ftc.gov/legal-library/browse/cases-proceedings/192-3133-flo-health-inc;* Compl. at ¶ 14(d), *In the Matter of UPromise, Inc.,* FTC File No. 1023116 (Mar. 27, 2012), *https://www.ftc.gov/legal-library/browse/cases-proceedings/102-3116-c-4351-upromise-inc; Cf.* Compl. at ¶ 40, *U.S.* v. *Easy Healthcare Corporation,* No. 1:23–cv–3107 (N.D. Ill. 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/202-3186-easy-healthcare-corporation-us-v* (alleging that the defendant's disclosures of consumers' health information violated the policies of platforms to which it had agreed).

• *Example 1:* Four separate firms provide data security, cloud computing, advertising and analytics services to a health app (a personal health record), as specified by their service provider contracts, for the health app vendor's benefit. To perform the services specified in their respective contracts, the firms access unsecured PHR identifiable health information. The firms are ''third party service providers'' of the vendor of the personal health record (the maker of the health app) because they provide services to a vendor of a personal health record (the maker of the health app) in connection with the offering or maintenance of the app, and they access unsecured PHR identifiable health information as a result of these services. In the event of a breach, they should abide by their obligations as third party service providers.

• *Example 2:* An analytics firm provides analytics services to a health app (a personal health record). The analytics firm and health app vendor do not have a customized service provider contract, although the health app vendor agrees to the analytics firm's standard terms of service. The analytics firm accesses unsecured PHR identifiable health information (device identifier and whether the consumer has paid for therapy). The analytics firm uses that data both to provide analytics services to the health app and for its own benefit, for research and development and product improvement. The analytics firm is a third party service provider to the extent that it provides analytics services to the health app for the health app's benefit because it is then providing services to a vendor of a PHR in connection with the offering of the PHR and accessing unsecured PHR identifiable health information as a result of such services. However, the analytics firm is a PHR related entity, rather than a third party service provider, to the extent that it offers its services through the health app for its own purposes (*i.e.,* for research and development and product improvement) rather than to provide the services. In the event of a breach, the analytics firm must fulfill its notification obligations under the Rule according to which function it was performing in connection with the breach. If the functions are indistinguishable, then, pursuant to § 318.3(b), the Commission will consider the firm a third party service provider for policy reasons: a firm that functions, at least in part, as a service provider may not be consumer-facing, such that the consumer may be surprised by a breach notification from that entity. As a policy matter, it is better for the consumer to receive notice from the health app with whom the consumer directly interacts.

• *Example 3:* A health tracking website (a personal health record) integrates a search bar branded with its maker's logo, which enables its maker (a search engine firm) to offer its services through the website. The search engine firm is a PHR related entity because it offers its services through the website, which is a personal health record. The search bar branded with its maker's logo is consumer-facing, so the consumer would not be surprised to receive a notice from that company if it experiences a reportable breach. By contrast, if the health tracking website had contracted with the search engine firm to provide back-end search services to the website (rather than offering its own branded product or service through the website), and the search engine firm had accessed unsecured PHR identifiable health information as a result of such services, it would be a third party service provider. In the event of a breach, it should abide by its obligations as a third party service provider.

• *Example 4:* Digital readings from a fitness tracker offered by Company A can be integrated into a sleep app offered by Company B (in which the consumer may input other health information). Company A is a PHR related entity to the extent that it offers its fitness tracker product through an online service (Company B's sleep app), and to the extent that it sends unsecured PHR identifiable health information (fitness tracker readings) to a personal health record (the sleep app).

E. Facilitating Greater Opportunity for Electronic Notice

1. The Commission's Proposal Regarding Electronic Notice

The Commission proposed to authorize expanded use of email and other electronic means of providing clear and effective notice of a breach to consumers. In furtherance of this objective, the Commission proposed to update § 318.5 to specify that vendors of personal health records or PHR related entities that discover a breach of security must provide written notice at the last known contact information of the individual. Such written notice may be sent by electronic mail, if an individual has specified electronic mail as the primary contact method, or by first-class mail. The Commission proposed defining ''electronic mail'' in § 318.2 to mean email in combination with one or more of the following: text message, within-application messaging, or electronic banner. The Commission further specified that any notification delivered via electronic mail should be clear and conspicuous, and the proposed Rule defined ''clear and conspicuous.'' To assist entities that are required to provide notice to individuals under the Rule, the Commission developed a model notice for entities to use to notify individuals.[202]

2. Public Comments Regarding Electronic Notice

Nearly every comment submitted on this proposed change supported the Commission's efforts to update the Rule to allow for greater electronic notice.[203] One commenter noted electronic notices increase the likelihood that individuals will receive the notice, may reduce the time it takes for individuals to receive notice, and reduce the burden on entities providing notice.[204] Many commenters also supported the Commission's efforts to provide notice via more than one channel through the new definition of ''electronic mail.'' [205]

However, not all commenters agreed with the Commission's proposal and some commenters offered other suggestions. Some objected to defining ''electronic mail'' to mean anything more than ''email,'' stating that electronic mail is commonly understood to mean email and nothing else.[206] A few commenters noted that defining multiple forms of electronic notice could result in entities collecting more information than necessary (and consumers having to provide more information than needed) in order to comply with the Rule.[207] Others preferred a single notice, arguing that multiple forms of notice is burdensome

[202] This model notice was attached as appendix A to the NPRM. 88 FR 37837.

[203] AHIP at 5; AAFP at 3; AHIMA at 5; AHIOS at 3; Anonymous 3 at 1; Anonymous 10 at 1; Beth Barnett; CARIN Alliance at 7; CHI at 5–6; CHIME at 4; Consumer Reports at 8–9; CTA at 21; EPIC at 10; HIMSS at 4; George Mathew at 1; MRO at 3; NAI at 7; Dharini Padmanabhan at 1; Nancy Piwowar at 1. One commenter also stated while there are clear advantages to allowing increased use of electronic notification of data breaches, this notification method could also increase the likelihood that breaches escape public scrutiny. Identity Theft Res. Ctr. (''ITRC'') at 2.

[204] AdvaMed at 5.

[205] AAFP at 3; AHIMA at 5; Anonymous 3 at 1; CARIN Alliance at 7; CHIME at 4; CCIA at 7; EPIC at 10; NAI at 7.

[206] ACLA at 5; Mass. Health Data Forum (''MHDF'') at 9.

[207] Consumer Rep.'s at 7–8; CTA at 22. Consumer Reports further suggested the Commission clarify that substitute notice may be effectuated under the Rule via text message, in-app messaging, or electronic banners for consumers that do not wish to share a mailing or email address. Consumer Rep.'s at 8.

and could result in over-notification, confusion, and notice fatigue among consumers.[208] One commenter stated the Commission should revise the definition of ''electronic mail'' to mean ''one or more of the following that is reasonable and appropriate based on the relationship between the individual and the relevant vendor of personal health records or PHR related entity: email, text message, within-application messaging, or electronic banner.'' [209] Another commenter encouraged the FTC to clarify the in-app messaging method must include push notifications in the event of a breach so consumers are made aware of a breach as soon as possible.[210] One commenter urged the Commission to specify in § 318.5(i) that a banner notice in the affected app or a website home page notice must be posted for a period of 90 days.[211] Another commenter noted that the different mechanisms listed in the proposed rule are not equivalent—this commenter noted that some are push notifications that a consumer is likely to see without directly interacting with the application, website, or device and some require consumer interaction with the application, website, or device in order to see the notification.[212] This commenter recommended that the requirement be selection of one push notification but that additional options like in-app notifications and website banners be supported as additional, secondary notice options.[213] One commenter stated the FTC may want to consider adding a provision allowing an individual to request a copy of the notice in other accessible formats, such as for hearing- or vision-impaired people, or in a non-English language.[214] Another commenter argued the Commission should take into consideration TCPA and CAN–SPAM compliance regarding the delivery of electronic notification. Another commenter stated the Commission's proposal to require two contact methods imposes a higher requirement than HIPAA and State breach notification laws.[215]

Many commenters endorsed the Commission's proposal that any notification delivered via electronic mail should be ''clear and conspicuous,'' a newly defined term in the Rule.[216] One commenter stated that consistent with FTC's desire for entities to provide a clear and conspicuous notice, the Commission should consider requiring an email subject line that starts with ''Breach of Your Health Information'' so that attention is appropriately drawn to the importance of the message content.[217] One commenter disagreed with the new definition, arguing that the definition is unnecessary and confusing, and urged the Commission to insert the ''clear and conspicuous'' definition directly into § 318.5 of the Rule.[218]

Regarding the model notice, nearly all who commented on this topic urged the Commission to make the model notice voluntary.[219] One commenter suggested that using the model should be a safe harbor that shields entities from enforcement.[220]

3. The Commission Adopts the Proposed Changes Regarding Electronic Notice

The Commission adopts without change the modifications regarding § 318.5 involving electronic notice and adopts without change the definition of ''electronic mail'' in § 318.2. The Commission declines to make the other changes commenters requested. First, the Commission believes it is critical, especially given how consumers are accessing information today, to modernize the methods of notice to facilitate greater opportunities for electronic notice. The Commission believes the changes to § 318.5 and the new definition of ''electronic mail'' [221] in § 318.2 accomplish this objective.

In response to concerns raised about the two-part electronic notice, the Commission agrees with commenters who stated it increases the likelihood that individuals will encounter such notices.[222] The Commission does not agree that it is burdensome for entities to comply with this requirement. For example, an entity who complies with the notice requirement by notifying consumers via email plus posting a website notice likely would not need to expend significant additional time and resources by issuing the second part of the notice (*i.e.,* the website notice), and any ''cost'' of posting such a notice is outweighed by the benefit to consumers of learning of a breach involving their health information. The Commission also is not persuaded that consumers who, for example, receive an email about a breach coupled with an in-app notice about the same breach will be confused. The Commission believes consumers will understand that such notices relate to the same incident, especially given the Rule's requirement that the notices be ''clear and conspicuous.'' The Commission also does not find it problematic that the Rule requires notice effectuated via ''electronic mail'' to occur via two methods while other breach notice laws require one method. The Commission also notes while these amendments are intended to facilitate greater electronic notice, the Rule still permits notice via first-class mail. Accordingly, the contention that this Rule requires two methods of electronic notice is incorrect.

The Commission also declines, in response to public comments,[223] to mandate how notifications are effectuated when sent via ''electronic mail,'' as the Commission believes it is important to not be overly prescriptive given rapidly changing technologies.

[208] AdvaMed at 6; ACLA at 5; AHIP at 5; CTA at 21–22;

[209] AdvaMed at 6.

[210] AHIMA at 5.

[211] TechNet at 5.

[212] MHDF at 10.

[213] *Id.*

[214] AHIP at 5.

[215] CHI at 6.

[216] AMA at 5; CHIME at 5; EPIC at 9.

[217] TMA at 4.

[218] NAI at 7.

[219] AdvaMed at 6; AHIP at 6; AMA at 6; CCIA at 7; CHI at 6; Consumer Rep.'s at 8–9; NAI at 7–8. One commenter stated that making the model notice mandatory can lead to industry consistency and it may be easier for consumers to understand the message and the contents if they are familiar with a uniform, standardized notice. AHIMA at 5. While the Commission generally agrees that uniform, consistent notices assist with consumer comprehension, the Commission declines to make the model notice compulsory because the facts and circumstances of each breach will vary. Plus, § 318.6 sets forth certain required elements of the content of the notice, so the presence of these elements in all breach notices achieves some degree of consistency across notices.

[220] AHIP at 6.

[221] The Commission disagrees with the commenters who urged the Commission to avoid defining ''electronic mail'' to mean anything more than ''email.'' ACLA at 5; MHDF at 9. The definition in § 318.2 is clear and unambiguous. Plus, section 13402(e)(1) of the Recovery Act requires that notification be provided via ''written notification by first-class mail'' or ''electronic mail.'' Accordingly, the Commission must use ''electronic mail.''

[222] AAFP at 3–4 (noting AAFP appreciates ''the proposed structure of providing notice in two different electronic formats to increase the likelihood individuals will see them''); CHIME at 5 (''CHIME is supportive of the FTC's approach to revise the ''method of notice section'' and to structure the breach notification in two parts in order to increase the likelihood that consumers encounter the notice.''); EPIC at 10 (''By requiring email *and* an in-app or website notice option, the expanded definition enables entities to have the best chance at notifying consumers regardless of whether they reliably check their email or continue to use the entity's app or website.''). The Commission also disagrees with the commenter who recommended that the Commission abandon the two-part notice and create a new definition of ''electronic mail'' where, for example, only a website notice alone would satisfy the notice requirement if such a notice was ''reasonable and appropriate.'' AdvaMed at 6. The Commission disagrees with this approach and declines to adopt it.

[223] *See supra* notes 210–213.

The Commission emphasizes though, as described below, that the notice must satisfy the Rule's definition of ''clear and conspicuous.''

Nor does the Commission believe, as some commenters argued, the two-part electronic notification will result in additional collections of information by notifying entities. The Commission agrees with commenters who stated entities are generally already collecting the information needed for notice via ''electronic mail'' and a data minimization issue does not exist.[224]

In response to the commenter who suggested the FTC consider adding a provision allowing an individual to request a copy of the notice in other accessible formats, such as for hearing- or vision-impaired people, or in non-English languages,[225] the Commission previously addressed a similar comment in the 2009 Rule Commentary. There, the Commission noted that section 13402(e)(l) of the Recovery Act requires that notification be provided via ''written notification by first-class mail'' or ''electronic mail.'' The Commission emphasized then, as we do today, that the Rule does not preclude notifications in accessible formats. The Commission supports their use in appropriate circumstances, in addition to the forms of notice prescribed by the Rule.[226]

The Commission also adopts without modification the definition of ''clear and conspicuous.'' The Commission agrees with the commenter who indicated it is imperative that a breach notice be reasonably understandable and call attention to the significance of the information that is included in the notice.[227] The Commission believes its definition of ''clear and conspicuous'' will assist in achieving this objective. The Commission declines, however, to mandate specific language for the email subject line to satisfy the Rule's ''clear and conspicuous'' requirement, as one commenter had suggested.[228] The Commission emphasizes, however, that the clear and conspicuous requirement would require a notifying entity to use an email subject line that draws the reader's attention to the email notice. The Commission also declines to adopt the suggestion that the definition of ''clear and conspicuous'' be incorporated directly into § 318.5. The Commission believes the entities seeking information on what ''clear and conspicuous'' means will find it clearer to consult the definition in § 318.2.

Turning to the model notice,[229] as the Commission noted in the NPRM, the model was intended for entities to use, in their discretion, to notify individuals, and the Commission adopts the same position here.[230] The model is voluntary and while the Commission believes it represents a best practice, using the model is not required to achieve compliance with the Rule.

The Commission declines to adopt the position that use of the model notice provides a safe harbor, although the Commission would take into consideration in an enforcement action an entity who follows the model notice. Further, the Commission notes an entity who follows the model notice can nevertheless violate the Rule in other ways. For example, an entity could follow the model notice but fail to provide timely notice. In such instances, providing a safe harbor because the entity utilized the model notice would be inappropriate.

F. Revisions to the Required Content of Notice

1. The Commission's Proposal Regarding Content of Notice

The Commission proposed five changes to the content of the notice. First, in § 318.6(a), as part of relaying what happened regarding the breach, the Commission proposed the notice to individuals also include a brief description of the potential harm that may result from the breach, such as medical or other identity theft. Second, the Commission proposed to amend the requirements for the notice under § 318.6(a) to include the full name, website, and contact information (such as a public email address or phone number) of any third parties that acquired unsecured PHR identifiable health information as a result of a breach of security, if this information is known to the vendor of personal health records or PHR related entity (such as where the breach resulted from disclosures of users' sensitive health information without authorization). Third, the Commission proposed modifications to § 318.6(b), which requires that the notice include a description of the types of unsecured PHR identifiable health information that were involved in the breach. The Commission proposed this exemplar list be expanded to include additional types of PHR identifiable health information, such as health diagnosis or condition, lab results, medications, other treatment information, the individual's use of a health-related mobile application, and device identifier. Fourth, the Commission proposed revising § 318.6(d) of the Rule to require the notice to individuals include additional information providing a brief description of what the entity that experienced the breach is doing to protect affected individuals, such as offering credit monitoring or other services. Fifth, the Commission proposed modifying § 318.6(e) so the contact procedures specified by the notifying entity must include two or more of the following: toll-free telephone number; email address; website; within-application; or postal address.

2. Public Comments Regarding Content of Notice

a. Proposal That Notice Include Description of Potential Harm That May Result From a Breach

The Commission's proposal to modify § 318.6(a) to include in the notice to individuals a brief description of the potential harm that may result from a breach drew a wide range of comments. On the one hand, many commenters supported the Commission's proposal.[231] For example, one commenter noted this proposal would help individuals better understand the connection between the information breached and the potential harm that could result from the breach of such information.[232] Other commenters stated that providing the potential harms from a breach better equips consumers to address injuries and mitigate harms from it.[233] One commenter stated including some potential harms would be helpful, but notifying entities should also include language in the notice stating that other harms may occur.[234] This same commenter suggested the Commission consider selecting the most common types of breaches and listing some but not all of the potential consequences from each.[235]

On the other hand, many commenters criticized this proposal.[236] Some

[224] CARIN Alliance at 6; EPIC at 10.

[225] *See supra* note 214.

[226] 74 FR 42972.

[227] AMA at 5.

[228] *See supra* note 217.

[229] The model notice is found in appendix A.

[230] 88 FR 37827.

[231] AAFP at 4; AMA at 6; AOA at 5; Anonymous 3; AHIOS at 3; CARIN Alliance at 7–8; CHIME at 3, 6; Consumer Reports at 9–10; EFF at 2; EPIC at 10–11; HIMSS at 3–4; ITRC at 2; Members of the House of Representatives at 1–2; Dharini Padmanabhan at 1.

[232] AMA at 6.

[233] Consumer Rep.'s at 9–10; EPIC at 10–11.

[234] MHDF at 10–11.

[235] *Id.*

[236] AdvaMed at 6–7; AHIP at 6; ACLA at 4–5; Confidentiality Coal. at 7; CTA at 23–24; MHDF at 10; NAI at 9.

commenters argued this proposal will result in notifying entities having to speculate about potential harms that may never occur or providing a list of harms that may be incomplete.[237] Others pointed out that notifying individuals about potential harms could cause consumer anxiety, consumer confusion, and detract from actions the individuals should take.[238] One commenter noted the Commission's proposal might lead consumers to believe the harms listed in the notice are the only possible harms from a breach, when in fact consumers may suffer other harms not disclosed in the notice.[239] This same commenter also noted it is opposed to entities stating there are no known harms that may result from a breach solely because a notifying entity is unaware of any specific bad outcomes.[240]

b. Proposal That Notice Include Full Name, Website and Contact Information of Third Parties That Acquired Unsecured PHR Identifiable Health Information

Next, the Commission proposed to amend the requirements for the notice under § 318.6(a) to include the full name, website, and contact information (such as a public email address or phone number) of any third parties that acquired unsecured PHR identifiable health information as a result of a breach of security. Although several commenters supported this proposal,[241] many others pointed out it is problematic in certain circumstances.[242] A few commenters noted the proposal is ill-suited for security breaches, such as a hacking, where providing consumers with the name and contact information of an actor who committed a security breach (*e.g.,* a hacker) could result in further malicious action against the target entity.[243] One commenter noted for security breaches, the malicious actor or hacker would not be responsive to consumers.[244] Further, one commenter noted this requirement could hamper law enforcement efforts.[245] One commenter also indicated this requirement could frustrate investigative efforts or have a chilling effect on an inadvertent recipient from reporting a wrongful disclosure.[246]

c. Proposal That Notice Include Description of Types of Unsecured PHR Identifiable Health Information Involved in a Breach

Third, the Commission proposed modifications to § 318.6(b), which requires the notice to individuals include a description of the types of unsecured PHR identifiable health information that were involved in the breach. The Commission proposed this exemplar list be expanded to include additional types of PHR identifiable health information, such as health diagnosis or condition, lab results, medications, other treatment information, the individual's use of a health-related mobile application, and device identifier. Several commenters supported this proposal.[247] One commenter noted it is important for consumers to receive notice of the specific types of PHR identifiable health information involved in a breach, given that the exposure of health information can lead to a wide spectrum of harms.[248] Another commenter stated providing individuals with a more expansive list of exposed data points will also give them a more complete picture of the risks they face.[249]

d. Proposal That Notice Include Description of What Entity Is Doing To Protect Affected Individuals

Fourth, the Commission proposed revising § 318.6(d) of the Rule to require that the notice to individuals include additional information providing a brief description of what the entity that experienced the breach is doing to protect affected individuals, such as offering credit monitoring or other services. This proposal attracted support from multiple commenters.[250] One commenter stated that informing individuals about these steps is important so that they know what additional actions they should take to protect themselves from potential harm.[251] Another similarly stated that knowing what the notifying entity is doing to protect affected individuals can help consumers who are considering making purchase decisions for fraud detection or credit monitoring.[252] One commenter stated that requiring notifying entities to share this information will incentivize them to take proactive measures to mitigate harms to consumers.[253]

Some commenters, however, raised concerns about this proposal. For instance, one commenter believed the Rule already encompasses this requirement and therefore the Commission's proposal could result in duplicative information being provided in the notice.[254] Another commenter stated the FTC needs to go further in ensuring that notification requirements help consumers understand what remedies are available when their health information is breached.[255]

e. Proposal That Notice Include Two or More Contact Procedures

Fifth, the Commission proposed amendments to § 318.6(e) so the contact procedures specified by the notifying entity in its breach notification must include two or more of the following: toll-free telephone number; email address; website; within-application; or postal address. Many commenters expressed support for this proposal.[256] One commenter noted multiple contact options ensures that victims of all backgrounds and technical capabilities are able to contact the notifying entity to learn more about how to protect themselves after a breach.[257] Another commenter noted that providing multiple contact options encourages and facilitates communication between the individual and the notifying entity.[258] One commenter, however, expressed concern the proposal is burdensome, the HIPAA breach notice rule requires only one method of contact, and HHS has not identified any concerns with individuals having difficulty obtaining information from covered entities using one contact method under HIPAA's breach notice rule.[259]

[237] AdvaMed at 6–7; AHIP at 6; MHDF at 10; NAI at 9.

[238] ACLA at 4–5; AMIA at 5; NAI at 9.

[239] MHDF at 10.

[240] *Id.* at 10–11.

[241] AAFP at 4; AHIMA at 5–6; AMA at 6; AMIA at 5; AOA at 5; CARIN Alliance at 7; Consumer Rep.'s at 9–10; EFF at 2; EPIC at 10–11; HIMSS at 3–4; ITRC at 2; Members of the House of Representatives at 1–2.

[242] ACLA at 4–5; AHIP at 6; CHI at 6; Confidentiality Coalition at 7; CTA at 24.

[243] ACLA at 4–5; Confidentiality Coal. at 7.

[244] Confidentiality Coal. at 7.

[245] CTA at 24.

[246] AHIP at 6.

[247] AAFP at 4; AHIMA at 6; AMA at 6; AOA at 5; CARIN Alliance at 7; Consumer Rep.'s at 9–10; Ella Balasa at 2; HIMSS at 3–4; ITRC at 2; NAI at 9.

[248] Light Collective at 2.

[249] ITRC at 2.

[250] AAFP at 4; AMA at 6; AOA at 4; CARIN Alliance at 7–8; HIMSS at 3–4; ITRC at 2.

[251] AMA at 6.

[252] AHIMA at 5–6.

[253] Consumer Rep.'s at 9–10.

[254] Confidentiality Coal. at 7.

[255] Light Collective at 6–7.

[256] AAFP at 4; AHIMA at 6; AHIP at 5; Anonymous 3 at 1; AOA at 5; CARIN Alliance at 8; Consumer Rep.'s at 9–10; EPIC at 9–10; HIMSS at 3–4; ITRC at 2; Dharini Padmanabhan at 1.

[257] AHIMA at 6.

[258] AMA at 6.

[259] AdvaMed at 6–7.

3. The Commission Changes Regarding Content of Notice

a. The Commission Declines To Adopt Proposal That Notice Include Description of Potential Harm That May Result From a Breach

The Commission believes, in light of the public comments, that the downsides of requiring in the notice a description of the potential harms that may result from a breach outweigh the upsides. The Commission is concerned about requiring a consumer notice to include possible harms that may never materialize. In such cases, consumers may experience needless anxiety and take actions that are not necessary, leading to consumer frustration. The Commission also is concerned this proposal may result in entities describing potential harms so generically that the description provides minimal value to consumers, or, alternatively, that entities will provide a laundry list of potential harms, making such a list meaningless to consumers. The Commission also agrees with one commenter who noted this proposal might lead consumers to believe the harms listed in the notice are the only possible harms from a breach, when in fact consumers may suffer other harms not disclosed in the notice.[260]

Accordingly, the Commission declines to adopt this proposal.[261] The Commission believes the remaining elements of the content of the notice will supply individuals with sufficient information about a breach, especially given the other modifications to § 318.6. The Commission also emphasizes in certain cases where harms are concrete and known, notifying entities should as a best practice inform individuals about those harms in the notice.

b. The Commission Modifies Proposal That Notice Include Full Name, Website, and Contact Information of Third Parties That Acquired Unsecured PHR Identifiable Health Information

In light of the public comments, the Commission is modifying § 318.6(a) to require notifying entities to provide the full name or identity (or where providing name or identity would pose a risk to individuals or the entity providing notice, a description) of the third parties that acquired the PHR identifiable health information as a result of a breach of security.[262] The Commission believes it is important for consumers to know who acquired their PHR identifiable health information as a result of a breach. At the same time, the Commission acknowledges in some scenarios it could be problematic to require notifying entities to provide the contact information of those who acquired PHR identifiable health information.

Accordingly, this revised provision is intended to still provide individuals with information about who acquired their health information. Under § 318.6(a), notifying entities are required to provide the full name or identity of the third parties that acquired the PHR identifiable health information as a result of a breach of security, except where providing the full name or identity of the third parties would pose a risk to affected individuals or the entity providing notice. In cases where providing the name or identity of the third parties that acquired the PHR identifiable health information as a result of a breach of security would pose a risk to affected individuals or the entity providing notice (*e.g.,* providing the name of hacker could subject affected individuals or the entity providing notice to further harm), § 318.6(a) permits notifying entities to describe the type of third party (*e.g.,* hacker) who acquired individuals' PHR identifiable health information.

c. The Commission Adopts Proposal That Notice Include Description of Types of Unsecured PHR Identifiable Health Information Involved in a Breach

The Commission agrees with the many public comments supporting this proposal.[263] The Commission concurs with the commenter who noted it is important for consumers to receive notice of the specific types of PHR identifiable health information involved in a breach,[264] and the commenter who stated that providing affected individuals with a more expansive list of health data points implicated in a breach will help them better understand the risks they face.[265] The Commission adopts this proposal without modification.

d. The Commission Adopts Proposal That Notice Include Description of What Entity Is Doing To Protect Affected Individuals

Several commenters supported the Commission proposal that the notice to individuals include a description of what the notifying entity is doing to protect affected individuals.[266] The Commission concurs with the commenter who stated that informing affected individuals about the steps notifying entities are taking to protect them is important so that affected individuals know what additional actions they should take to protect themselves from potential harm.[267] The Commission similarly agrees with the commenter who stated that knowing what the notifying entity is doing to protect affected individuals can help consumers who are considering making purchase decisions like fraud detection or credit monitoring.[268] The Commission also agrees with the commenter who stated that requiring notifying entities to share information about what they are doing to protect affected individuals will incentivize notifying entities to take proactive measures to mitigate harms to consumers.[269]

In response to the one commenter who noted the 2009 Rule already includes this proposed requirement,[270] the Commission notes § 318.6(d) from the 2009 Rule requires notifying entities to include in the notice to individuals what the entity is doing to investigate the breach, to mitigate any losses, and to protect against any further breaches. Accordingly, under the 2009 Rule, there is no explicit requirement for the notifying entity to state in the individual notice what the entity is doing to protect affected individuals. Given this, the Commission does not believe individuals will receive duplicative information.

In response to the commenter who argued the Commission needs to help consumers understand post-breach remedies,[271] the Commission believes this concern is addressed by the combination of § 318.6(c), which requires notifying entities to include in the notice steps individuals should take to protect themselves from potential harm resulting from the breach, and § 318.6(d), which requires notifying entities to include in the notice the steps the notifying entity is taking to protect affected individuals following the breach.

The Commission adopts proposed § 318.6(d) without modification.

e. The Commission Adopts Proposal That Notice Include Two or More Contact Procedures

In response to the comment that providing two or more contact

[260] MHDF at 10.

[261] The Commission has updated the model notice in appendix A to reflect this change.

[262] The Commission has updated the model notice in appendix A to reflect this change.

[263] *See supra* note 247.

[264] *See supra* note 248.

[265] *See supra* note 249.

[266] *See supra* note 250.

[267] *See supra* note 251.

[268] *See supra* note 252.

[269] *See supra* note 253.

[270] *See supra* note 254.

[271] *See supra* note 255.

procedures in the notice is burdensome,[272] the Commission believes if this proposal results in any burden to notifying entities, such burden will be minimal given the ease with which compliance with this provision can be achieved, and outweighed by the benefits to consumers who will have increased options to communicate with notifying entities. Second, in response to the comment that the HIPAA Breach Notification Rule requires only one contact method,[273] the Commission notes while there are many similarities between the FTC's and HHS's respective breach notification rules and the agencies have consulted to harmonize the two rules, there are differences between them, and the Commission believes it is important to update this provision to reflect new modes of communication and facilitate greater opportunities for communication between affected individuals and notifying entities.

The Commission notes multiple commenters supported this proposal.[274] Specifically, the Commission agrees with the commenter who stated multiple contact procedures enables greater opportunities for affected individuals to communicate with notifying entities.[275] The Commission also agrees with the commenter who noted multiple contact options ensures that affected individuals from all backgrounds and technical capabilities are able to contact the notifying entity following a breach.[276] The Commission therefore adopts proposed § 318.6(e) without modification.

G. Timing of Notice to the FTC

1. The Commission's Proposal Regarding Timing of Notice

Although the Commission did not propose any timing changes in the NPRM, the Commission requested comments on several issues related to timing, including the timing of the notification to the FTC. Regarding the notification timeline to the FTC, the Commission sought comment on whether it should extend the timeline to give entities more time to investigate breaches and better ascertain the number of affected individuals or whether an extension would simply facilitate dilatory action and minimize the opportunity for an important dialogue with Commission staff during the fact-gathering stage immediately following a breach.

2. Public Comments Regarding Timing of Notice

Several commenters expressed support for extending the notification timeline to the FTC.[277] Commenters provided several reasons why the existing requirement of notice to the FTC ''as soon as possible and in no case later than ten business days following the date of discovery of the breach'' for breaches involving 500 or more individuals should be amended. For example, commenters noted that ten days does not provide entities with sufficient time to adequately investigate incidents and fully understand the facts, possibly leading to notices that may be incomplete and require amendment or correction.[278] Others commented that the existing requirement diverts key resources from investigating potential breaches, indicating when a breach is suspected or has been discovered, the target entity's focus should be responding to the incident, conducting a thorough investigation of what may have occurred, and addressing and mitigating vulnerabilities to ensure additional information is not compromised.[279]

Several commenters urged the FTC to align the timeframe to notify the FTC with the timing requirement under HIPAA's Health Breach Notification Rule,[280] which requires notification to the Secretary of HHS without unreasonable delay and in no case later than 60 calendar days following a breach.[281] One commenter, irrespective of HIPAA, suggested the Commission give entities up to 60 days to investigate a breach and provide notification to the Commission.[282] One commenter recommended the FTC adopt a ''risk-based'' notification approach whereby the agency could create a shorter notification timeline for high-risk incidents and a longer notification timeline or even no notification for low-risk incidents.[283]

3. The Commission Adopts Changes to the Timing of Notice

Having considered the public comments, the Commission agrees with commenters who recommended that the notification timeline to the FTC for breaches of security involving 500 or more individuals should be adjusted. The Commission agrees that in certain incidents, especially large, complex breaches, it can be challenging for entities to fully understand the scope of a breach in ten business days, leading to the possibility of incomplete breach notices.

Accordingly, the Commission is revising § 318.4(b) to read: ''All notifications required under § 318.5(c) involving the unsecured PHR identifiable health information of 500 or more individuals shall be provided contemporaneously with the notice required by paragraph (a) of this section.'' This change requires entities, for breaches involving 500 or more individuals, to notify the FTC consistent with the notice required by § 318.4(a)—*i.e.,* without unreasonable delay and in no case later than 60 calendar days after the discovery of a breach of security. This change also requires the notice to the FTC be sent at the same time as the notice to the individuals. This requirement thus ensures the notice to the FTC includes all of the information provided in the notice to the individual. It also avoids a scenario where individuals receive notice before the FTC receives notice and affected individuals contact the FTC about a breach for which the Commission has not been notified.

As a result of this change, the Commission anticipates entities will have sufficient time to provide complete and fulsome notifications to the Commission. The Commission emphasizes, however, that notice to the FTC should occur ''without unreasonable delay,'' with 60 days serving as the outer limit.[284] The Commission believes, consistent with public comments, this change effectively harmonizes the notification timeline to the FTC with the notification timeline to the Secretary of HHS under the HIPAA Breach Notification Rule.

[272] *See supra* note 259.

[273] *Id.*

[274] *See supra* note 256.

[275] *See supra* note 258.

[276] *See supra* note 257.

[277] AdvaMed at 9; AHIP at 7; ACLA at 3–4; ATA Action at 2; CCIA at 8; CHI at 6; CTA at 20–21; TechNet at 5.

[278] AdvaMed at 9; ACLA at 3–4; AHIP at 7; TechNet at 5–6.

[279] ACLA at 3–4; CTA at 19–21.

[280] 45 CFR 164.400 through 414.

[281] AdvaMed at 9; AHIP at 7; ACLA at 3; ATA Action at 2; TechNet at 5–6.

[282] ACLA at 3–4.

[283] CTA at 19–21.

[284] As the Commission stated in the 2009 Rule Commentary, in some cases, it may be an ''unreasonable delay'' to wait until the 60th day to provide notification. For example, if a vendor of personal health records or PHR related entity learns of a breach, gathers all necessary information, and has systems in place to provide notification within 30 days, it would be unreasonable to wait until the 60th day to send the notice. Similarly, the Commission noted there may be circumstances where a vendor of personal health records discovers that its third party service provider has suffered a breach before the service provider notifies the vendor that the breach has occurred. In such circumstances, the vendor should begin taking steps to address the breach immediately, and should not wait until receiving notice from the service provider. 74 FR 42971 n.94 (2009).

The Commission also believes this notification timeline satisfies the Recovery Act requirement that notice be provided ''immediately.'' [285] The Commission also notes this change does not affect in any way the timing of the notice to the FTC for breaches involving less than 500 individuals.

Finally, a small number of commenters addressed other issues related to timing, such as the timeline for providing notice to consumers or the media. The Commission believes, for the reasons stated in the commentary accompanying the 2009 NPRM and the 2009 Rule Commentary, the current timelines are appropriate to give consumers and the media timely notice without overburdening notifying firms.[286]

H. Proposed Changes To Improve Rule's Readability

1. The Commission Proposed Changes To Promote Readability

The Commission proposed several changes to improve the Rule's readability. Specifically, the Commission proposed to include explanatory parentheticals for internal cross-references, add statutory citations in relevant places, consolidate notice and timing requirements in single sections, and revise the Enforcement section to state more plainly the penalties for non-compliance.

2. Public Comments Regarding Readability

Commenters supported the Commission's proposed changes to improve the Rule's readability and promote comprehension by including explanatory parentheticals and statutory citations.[287] Commenters also expressed support for the proposed changes to improve the Rule's readability and promote compliance by consolidating into single sections, respectively, the Rule's breach notification and timing requirements.[288] Commenters also favored the proposal to modify § 318.7 to make plain that a violation of the Rule constitutes a violation of a rule promulgated under section 18 of the FTC Act and is subject to civil penalties, stating this clarification will decrease the burden on the FTC in enforcement actions and prevent unintended barriers to enforcement.[289]

3. The Commission Adopts Changes Regarding Readability

In light of support from commenters and the Commission's belief that these proposed changes improve readability, the Commission adopts these changes without modification.[290]

[285] 42 U.S.C. 17932(e)(3). Like the Department of Health and Human Services previously concluded with respect to notification to the Secretary under the HIPAA Breach Notification Rule (74 FR 42753 (2009)), the Commission concludes this interpretation satisfies the statutory requirement that notifications of larger breaches be provided to the FTC immediately as compared to the notifications of smaller breaches (*i.e.,* those involving less than 500 individuals), which the statute allows to be reported annually to the FTC.

[286] 74 FR 17918 (2009); 74 FR 42971 (2009).

[287] AMA at 6; CARIN Alliance at 9.

[288] AHIMA at 7; AMA at 6–7.

[289] AHIMA at 7; AMA at 6–7; AHIOS at 5; MRO at 4. As part of its comment, AMA recommended the FTC, as Rule violations are filed, use actual examples as case study models for future educational resources. The Commission notes that its existing enforcement actions under the Rule already provide guidance for the marketplace and the FTC also has issued business guidance regarding the Rule. *E.g.,* Fed. Trade Comm'n, *Collecting, Using, or Sharing Consumer Health Information? Look to HIPAA, the FTC Act, and the Health Breach Notification Rule* (Sept. 2023), *https://www.ftc.gov/business-guidance/resources/collecting-using-or-sharing-consumer-health-information-look-hipaa-ftc-act-health-breach* (last visited Jan. 11, 2023); Fed. Trade Comm'n, *Health Breach Notification Rule: The Basics for Business* (Jan. 2022), *https://www.ftc.gov/business-guidance/resources/health-breach-notification-rule-basics-business* (last visited Jan. 11, 2024); Fed. Trade Comm'n, *Complying with FTC's Health Breach Notification Rule* (Jan. 2022), *https://www.ftc.gov/business-guidance/resources/complying-ftcs-health-breach-notification-rule-0* (last visited Jan. 11, 2024) One commenter also asserted the Commission was seeking to apply the NPRM's proposed changes retrospectively to breaches of security that were discovered on or after September 24, 2009. This commenter urged the Commission to modify § 318.8 so that the Rule would only apply to breaches of security discovered at least 30 days after the effective date of this final rule. TechNet at 5–6. The 2023 NPRM set out the entire part for the convenience of commenters but did not propose any changes to § 318.8. The Commission notes this effective date section was codified in 2009 when part 318 was added to the CFR and has been in effect since September 24, 2009. As explained in the 2009 Rule Commentary, ''the Commission does not have discretion to change the effective date of the rule because the Recovery Act establishes the effective date.'' See 74 FR 42976; see also 42 U.S.C. 17937(g)(1) (''The provisions of this section shall apply to breaches of security that are discovered on or after the date that is 30 days after the date of publication of such interim final regulations.''). The Commission emphasizes that this final rule does not apply retroactively.

[290] Relatedly, the Commission also is making a non-substantive grammatical change to § 318.5(a)(2)(ii), which involves substitute notice. This provision currently states: ''Such a notice in media or web posting shall include a toll-free phone number, which shall remain active for at least 90 days, where an individual can learn whether or not the individual's unsecured PHR identifiable health information may be included in the breach.'' The Commission is revising § 318.5(a)(2)(ii) so it reads: ''Such a notice in media or web posting shall include a toll-free phone number, which shall remain active for at least 90 days, where an individual can learn if the individual's unsecured PHR identifiable health information may have been included in the breach.'' The Commission made this grammatical change to improve the rule's readability; the change does not alter the provision's substantive meaning.

III. Paperwork Reduction Act

The Paperwork Reduction Act (''PRA''), 44 U.S.C. chapter 35, requires Federal agencies to seek and obtain Office of Management and Budget (''OMB'') approval before undertaking a collection of information directed to ten or more persons.[291] This final rule is modifying an existing collection of information,[292] which OMB has approved through July 31, 2025 (OMB Control No. 3084–0150). As required by the PRA, the Commission sought OMB review of the modified information collection requirement at the time of the publication of the NPRM. OMB directed the Commission to resubmit its request at the time the final rule is published. Accordingly, simultaneously with the publication of this final rule, the Commission is resubmitting its clearance request to OMB. FTC staff has estimated the burdens associated with the amendments as set forth below.

FTC staff estimates the amendments to 16 CFR part 318 will likely result in more reportable breaches by covered entities to the FTC. In the event of a breach of security, the covered firms will be required to investigate and, if certain conditions are met, notify consumers, the Commission, and, in some cases, the media.[293]

Based on industry reports, FTC staff estimates the amendments will cover approximately 193,000 entities, which, in the event they experience a breach, may be required to notify consumers, the Commission, and, in some cases, the media. While there are approximately 1.8 million apps in the Apple App Store [294] and 2.4 million apps in the Google Play Store,[295] as of March 2024, it appears that roughly 193,000 of the apps offered in either store are categorized as ''Health and Fitness.'' [296]

[291] 44 U.S.C. 3502(3)(A)(i).

[292] *See* 44 U.S.C. 3502(3)(A)(i).

[293] Third party service providers who experience a breach are required to notify the vendor of personal health records or PHR related entity, which in turn is then required to notify consumers. The Commission expects the cost of notification to third party service providers would be small, relative to the entities that have to notify consumers. As part of the NPRM, the Commission solicited public comment on this issue and data that may be used to quantify the costs to third party service providers. The Commission did not receive any responsive submissions pertaining to this issue.

[294] *See* App Store—Apple, *https://www.apple.com/app-store/.*

[295] *See* AppBrain: Number of Android Apps on Google Play (Mar 2024), *https://www.appbrain.com/stats/number-of-android-apps.*

[296] *See* Business of Apps, ''App Data Report: App Store Stats, Downloads, Revenues and App Rankings,'' *https://www.businessofapps.com/data/report-app-data/* (reporting 90,913 apps in the Apple iOS App Store and 102,402 apps in the Google Play Store were categorized as ''Health and

Continued

The Commission received three comments in response to the NPRM arguing the Rule's scope is broader than apps categorized as ''Health and Fitness'' and the NPRM's PRA analysis therefore underestimated the number of covered entities and the resulting number of reportable breaches.[297] As discussed above,[298] the Commission is adopting these amendments to clarify that the Rule applies to mobile health applications and similar technologies. The Commission also highlighted several key limitations to the Rule's scope.[299] Thus, the 193,000 covered entities is a rough proxy for all covered PHRs, because it encompasses mobile health applications categorized as ''Health and Fitness.'' Similar health technologies are included in the roughly 193,000 covered entities because most websites and connected health devices that will be covered by the amendments act in conjunction with an app.[300]

FTC staff estimates these entities will, cumulatively, experience 82 breaches per year for which notification may be required. With the proviso that there is insufficient data at this time about the number and incidence rate of breaches at entities covered by the amendments (due to underreporting prior to issuance of the Policy Statement), FTC staff determined the number of estimated breaches by calculating the breach incidence rate for HIPAA-covered entities, and then applied this rate to the estimated total number of entities that will be subject to the amendments.[301] Additionally, as the number of breaches per year has grown significantly in the recent years,[302] and FTC staff expects this trend to continue, FTC staff relied on the average number of breaches from 2021 through 2023 to estimate the annual breach incidence rate for HIPAA-covered entities.

Specifically, HHS's OCR reported 715 breaches in 2021, 719 breaches in 2022, and 733 breaches in 2023,[303] which results in an average of 722 breaches between 2021 and 2023. Based on the 1.7 million entities that are covered by the HIPAA Breach Notification Rule[304] and the average number of breaches for 2021–2023, FTC staff determined an annual breach incidence rate of 0.000425 (722/1.7 million). Accordingly, multiplying the breach incidence rate (0.000425) by the estimated number of entities covered by the amendments (193,000) results in an estimated 82 breaches per year.[305]

Costs

To determine the costs for purposes of this analysis, FTC staff has developed estimates for two categories of potential costs: (1) the estimated annual burden hours and labor cost of determining what information has been breached, identifying the affected customers, preparing the breach notice, and making the required report to the Commission; and (2) the estimated capital and other non-labor costs associated with notifying consumers.

Estimated Annual Burden Hours: 12,300.

Estimated Annual Labor Cost: $883,140.

First, to determine what information has been breached, identify the affected customers, prepare the breach notice, and make the required report to the Commission, FTC staff estimates covered firms will require per breach, on average, 150 hours of employee labor at a cost of $10,770.[306] This estimate does not include the cost of equipment or other tangible assets of the breached firms because they likely will use the equipment and other assets they have for ordinary business purposes. Based on the estimate that there will be 82 breaches per year the annual hours of burden for affected entities will be 12,300 hours (150 hours × 82 breaches) with an associated labor cost of $883,140 (82 breaches × $10,770).

Estimated Capital and Other Non-Labor Costs: $91,984,370.

The capital and non-labor costs associated with breach notifications depend upon the number of consumers contacted and whether covered firms are likely to retain the services of a forensic expert. For breaches affecting large numbers of consumers, covered firms are likely to retain the services of a forensic expert. FTC staff estimates, for each breach requiring the services of forensic experts, forensic experts will spend approximately 40 hours to assist in the response to the cybersecurity intrusion, at an estimated cost of $20,000.[307] FTC staff estimates the

Fitness''). Together, this suggests there are approximately 193,000 Health and Fitness apps. This figure is likely both under- and over-inclusive as a proxy for covered entities. For example, this figure does not include apps categorized elsewhere (*i.e.,* outside ''Health and Fitness'') that may be PHRs. However, at the same time, this figure also overestimates the number of covered entities, since many developers make more than one app and may specialize in the Health and Fitness category.

[297] *See* Chamber at 2; CHI at 6–7; CCIA at 8–9.

[298] *See* section II.1.c.

[299] *Id.*

[300] Indeed, one of the commenters who argued the Rule's coverage is broader than projected in the NPRM's PRA analysis acknowledged that there has been growth in the number of websites and apps since the 2009 PRA analysis estimated 700 covered entities to be covered by the Rule. Chamber at 2. Further, the approximately 193,000 covered entities may overestimate the number of covered entities, as some apps or websites may not qualify as a covered entity given the Rule's boundaries. For example, a website or app must have the technical capacity to draw information from multiple sources and that same website or app must still be ''managed, shared, and controlled by or primarily for the individual'' to be covered by the Rule.

[301] FTC staff used information publicly available from HHS on HIPAA related breaches because the HIPAA Breach Notification Rule is similarly constructed. However, while there are similarities between HIPAA-covered entities and HBNR-covered entities, it is not necessarily the case that rates of breaches would follow the same pattern. For instance, HIPAA-covered entities are generally subject to stronger data security requirements under HIPAA, but also may be more likely targets for security incidents (*e.g.,* ransomware attacks on hospitals and other medical treatment centers covered by HIPAA have increased dramatically in recent years); thus, this number could be an under- or overestimate of the number of potential breaches per year.

[302] According to HHS's Office for Civil Rights (''OCR''), the number of breaches per year grew from 276 in 2013 to 739 breaches in 2023. *See Breach Portal,* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf* (last visited March 1, 2024). The data was downloaded on March 1, 2024, resulting in limited data for 2024. Thus, breaches from 2024 were excluded from the calculations. However, breach investigations that remain open (under investigation) from years prior to 2024 are included in the count of yearly breaches.

[303] *See Breach Portal,* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf* (last visited March 1, 2024).

[304] In a **Federal Register** publication titled ''Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement'', OCR proposes increasing the number of covered entities from 700,000 to 774,331. 86 FR 6446, 6497 (Jan. 21, 2021). For purposes of calculating the annual breach incidence rate, FTC staff utilized 700,000 covered entities because the proposed estimate of 774,331 covered entities represents a projected increase that has not been finalized by OCR. The OCR publication also lists the number of covered Business Associates as 1,000,000. 86 FR 6528. FTC staff arrived at 1.7 million entities subject to the HIPAA Breach Notification Rule by adding 700,000 covered entities and 1,000,000 Business Associates.

[305] One commenter argued that basing the NPRM's projection of the annual number of breaches on the breach incidence rate for HIPAA-covered entities is problematic because the NPRM's proposed definition of a breach of security ''goes far and beyond'' the HIPAA definition of a breach. CCIA at 8–9. To the extent the commenter is referring to the fact that the Rule's definition of breach of security covers unauthorized disclosures, the Commission notes the HIPAA Breach Notification Rule similarly covers unauthorized disclosures. *See Breach Notification Rule,* U.S. Dep't of Health & Human Servs., Office for Civil Rights, *https://www.hhs.gov/hipaa/for-professionals/breach-notification/index.html* (''A breach is, generally, an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the protected health information.'').

[306] This estimate is the sum of 40 hours of marketing managerial time (at an average wage of $76.10), 40 hours of computer programmer time ($49.42), 20 hours of legal staff ($78.74), and 50 hours of computer and information systems managerial time ($83.49). *See* Occupational Employment and Wage Statistics, U.S. Bureau of Labor Statistics (May 2022), *https://www.bls.gov/oes/current/oes_nat.htm#00-0000.*

[307] This estimate is the sum of 40 hours of forensic expert time at a cost of $500 per hour,

services of forensic experts will be required in 60% of the 82 breaches. Based on the estimate that there will be 49 breaches per year requiring forensic experts (60% × 82 breaches), the annual hours burden for affected entities will be 1,960 hours (49 breaches requiring forensic experts × 40 hours) with an associated cost of $980,000 (49 breaches requiring forensic experts × $20,000).

Using the data on HIPAA-covered breach notices available from HHS for the years 2018–2023, FTC staff estimates the average number of individuals affected per breach is 93,497.[308] Given an estimated 82 breaches per year, FTC staff estimates an average of 7,666,754 consumers per year will receive a breach notification (82 breaches × 93,497 individuals per breach).

Based on a recent study of data breach costs, FTC staff estimates the cost of providing notice to consumers to be $11.87 per breached record.[309] This estimate includes the costs of electronic notice, letters, outbound calls or general notice to data subjects; and engagement of outside experts.[310] Applied to the above-stated estimate of 7,666,754 consumers per year receiving breach notification yields an estimated total annual cost for all forms of notice to consumers of $91,004,370 (7,666,754 consumers × $11.87 per record). Accordingly, the estimated capital and non-labor costs total $91,984,370 ($980,000 + $91,004,370).

FTC staff notes these estimates likely overstate the costs imposed by the amendments because FTC staff made conservative assumptions in developing many of the underlying estimates. Moreover, many entities covered by the amendments already have similar notification obligations under State data breach laws.[311] In addition, the Commission has taken several steps designed to limit the potential burden on covered entities that are required to provide notice, including by providing exemplar notices that entities may choose to use if they are required to provide notifications and expanding the use of electronic notifications.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[312] requires that the Commission provide an Initial Regulatory Flexibility Analysis (''IRFA'') with a proposed rule and a Final Regulatory Flexibility Analysis (''FRFA'') with a final rule, unless the Commission certifies that the rule will not have a significant economic impact on a substantial number of small entities. As discussed in the IRFA, the Commission believes the final rule will not have a significant economic impact upon small entities.

In this document, the Commission largely adopts the amendments proposed in its NPRM. The Commission believes the amendments will not have a significant economic impact upon small entities, although they may affect a substantial number of small businesses. Among other things, the amendments clarify certain definitions, revise the disclosures that must accompany notice of a breach under the Rule, and modernize the methods of notice to allow additional use of electronic notice such as email by entities affected by a breach. In addition, the amendments improve the Rule's readability by clarifying cross-references and adding statutory citations. The Commission does not anticipate that these changes will add significant additional costs for entities covered by the Rule, and by authorizing electronic notice in additional circumstances, the amendments may reduce costs for many entities covered by the Rule. Therefore, the Commission certifies that the amendments will not have a significant economic impact on a substantial number of small entities. Although the Commission certifies under the RFA that the Rule will not have a significant impact on a substantial number of small entities, and hereby provides notice of that certification to the Small Business Administration (''SBA''), the Commission has determined, nonetheless, that it is appropriate to publish an FRFA to inquire into the impact of the proposed amendments on small entities.

A. Need for and Objectives of the Amendments

The objective of the amendments is to clarify existing notice obligations for entities covered by the Rule. The legal basis for the amendments is section 13407 of the Recovery Act.

B. Significant Issues Raised in Public Comments

Although the Commission received several comments that argued that the amendments would be burdensome for businesses, none argued specifically that smaller businesses in particular would be subject to special burdens. The Commission did not receive any comments filed by the Chief Counsel for Advocacy of the SBA.

C. Small Entities to Which the Amendments Will Apply

The amendments, like the current Rule, will apply to vendors of personal health records, PHR related entities, and third party service providers, including developers and purveyors of health apps, connected health devices, and similar technologies. As discussed in the Commission's PRA estimates above, FTC staff estimates the amendments will apply to approximately 193,000 covered entities. The Commission estimates that a substantial number of these entities likely qualify as small businesses. According to the Statistics on Small Businesses Census data, approximately 94% of ''Software Publishers'' (the category to which health and fitness apps belong) are small businesses.[313]

which yields a total cost of $20,000 (40 hours × $500/hour).

[308] HHS Breach Data, *supra* note 303. This analysis uses the last six years of HHS breach data to generate the average, in order to account for the variation in number of individuals affected by breaches observed in the HHS data over time.

[309] *See* IBM Security, Costs of a Data Breach Report 2023 (2023), *https://www.ibm.com/reports/data-breach* (''2023 IBM Security Report''). The research for the 2023 IBM Security Report is conducted independently by the Ponemon Institute, and the results are reported and published by IBM Security. Figure 2 of the 2023 IBM Security Report shows that cost per record of a breach was $165 per record in 2023, $164 in 2022, and $161 in 2021, resulting in an average cost of $163.33. Figure 5 of the 2023 IBM Security Report shows that 8.3% ($0.37m/$4.45m) of the average cost of a data breach are due to ''Notification'' costs. The fraction of average breach costs due to ''Notification'' were 7.1% in 2022 and 6.4% in 2021 (IBM Security, Costs of a Data Breach Reports 2022 and 2021). Using the average of these numbers (7.27%), FTC staff estimates that notification costs per record across the three years are 7.27% × $163.33 = $11.87 per record.

[310] *See* 2023 IBM Security Report at 72.

[311] Many State data breach notification statutes require notification when a breach occurs involving certain health or medical information of individuals in that State. *See, e.g.,* Ala. Code 8–38–1 *et seq.;* Alaska Stat. 45.48.010 *et seq.;* Ariz. Rev. Stat. 18–551 *et seq.;* Ark. Code 4–110–101 *et seq.;* Cal. Civ. Code 1798.80 *et seq.;* Cal. Health & Safety Code 1280.15; Colo. Rev. Stat. 6–1–716; Del. Code Ann. tit. 6 12B–101 *et seq.;* D.C. Code 28–3851 *et seq.;* Fla. Stat. 501.171; 815 Ill. Comp. Stat. 530/5 *et seq.;* Md. Code Com. Law 14–3501 et seq; Mo. Rev. Stat. 407.1500; Nev. Rev. Stat. 603A.010 *et seq.;* N.H. Rev. Stat. 359–C:19–C:21; N.H. Rev. Stat. 332–I:5; N.D. Cent. Code 51–30–01–07; Or. Rev. Stat. 646A.600–646A.628; R.I. Gen. Laws 11–49.3–1—11–49.3–6; SDCL 22–40–19—22–40–26; Tex. Bus. & Com. Code 521.002, 521.053, 521.151–152; 9 V.S.A. 2430, 2435; Va. Code 18.2–186.6; Va. Code 32.1–127.1:05; Va. Code 58.1–341.2; Wash. Rev. Code 19.255.010 *et seq.*

[312] 5 U.S.C. 601–612.

[313] *2017 SUSB Annual Data Tables by Establishment Industry,* U.S. Census Bureau (May 2021), *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html,* using ''Data by Enterprise Receipts Size.'' The U.S. Small Business Administration (''SBA'') categorizes Software Publishers as a small business if the annual receipts are less than $41.5 million; the 2017 data is the most recent data available reporting receipts size.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements, Including Classes of Covered Small Entities and Professional Skills Needed To Comply

The Recovery Act and the amendments contain certain reporting requirements. The amendments will clarify which entities are subject to those reporting requirements. Specifically, the Act and amendments require vendors of personal health records and PHR related entities to provide notice to consumers, the Commission, and in some cases the media in the event of a breach of unsecured PHR identifiable health information. The Act and amendments also require third party service providers to provide notice to vendors of personal health records and PHR related entities in the event of such a breach. If a breach occurs, each entity covered by the Act and amendments will expend costs to determine the extent of the breach and the individuals affected. If the entity is a vendor of personal health records or a PHR related entity, additional costs will include the costs of preparing a breach notice, notifying the Commission, compiling a list of consumers to whom a breach notice must be sent, and sending a breach notice. Such entities may incur additional costs in locating consumers who cannot be reached, and in certain cases, posting a breach notice on a website, notifying consumers through media advertisements, or sending breach notices through press releases to media outlets.

In-house costs may include technical costs to determine the extent of breaches; investigative costs of conducting interviews and gathering information; administrative costs of compiling address lists; professional/legal costs of drafting the notice; and potentially, costs for postage, web posting, and/or advertising. Costs may also include the purchase of services of a forensic expert. As discussed in the context of the PRA, FTC staff estimates that compliance with these requirements will likely result in $883,148 in labor costs and $91,984,370 in capital and other non-labor costs. The estimated cost per covered entity is $481 (the total labor, capital, and non-labor costs of $92,867,518 divided by 193,000 covered entities). The SBA categorizes Software Publishers with annual receipts under $41.5 million as a small business; the per entity cost of $481 represents 0.0001% of this annual receipts threshold.

E. Significant Alternatives to the Amendments

In drafting the Rule, the Commission has made every effort to avoid unduly burdensome requirements for entities. In particular, the Commission believes that the changes to facilitate electronic notice will assist small entities by significantly reducing the costs of sending breach notices. In addition, the Commission is making available exemplar notices that entities covered by the Rule may use, in their discretion, to notify individuals. The Commission anticipates these exemplar notices will further reduce the burden on entities that are required to provide notice under the Rule. The Commission is not aware of alternative methods of compliance that will reduce the impact of the amendments on small entities, while also comporting with the Recovery Act. The statutory requirements are specific as to the timing, method, and content of notice.

V. Other Matters

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

List of Subjects in 16 CFR Part 318

Breach, Consumer protection, Health, Privacy, Reporting and recordkeeping requirements, Trade practices.

■ Accordingly, the Federal Trade Commission revises and republishes 16 CFR part 318 to read as follows:

PART 318—HEALTH BREACH NOTIFICATION RULE

Sec.

Authority: 42 U.S.C. 17937 and 17953.

§ 318.1 Purpose and scope.

(a) This part, which shall be called the ''Health Breach Notification Rule,'' implements section 13407 of the American Recovery and Reinvestment Act of 2009, 42 U.S.C. 17937. This part applies to foreign and domestic vendors of personal health records, PHR related entities, and third party service providers, irrespective of any jurisdictional tests in the Federal Trade Commission (FTC) Act, that maintain information of U.S. citizens or residents. This part does not apply to HIPAA-covered entities, or to any other entity to the extent that it engages in activities as a business associate of a HIPAA-covered entity.

(b) This part preempts State law as set forth in section 13421 of the American Recovery and Reinvestment Act of 2009, 42 U.S.C 17951.

§ 318.2 Definitions.

Breach of security means, with respect to unsecured PHR identifiable health information of an individual in a personal health record, acquisition of such information without the authorization of the individual. Unauthorized acquisition will be presumed to include unauthorized access to unsecured PHR identifiable health information unless the vendor of personal health records, PHR related entity, or third party service provider that experienced the breach has reliable evidence showing that there has not been, or could not reasonably have been, unauthorized acquisition of such information. A breach of security includes an unauthorized acquisition of unsecured PHR identifiable health information in a personal health record that occurs as a result of a data breach or an unauthorized disclosure.

Business associate means a business associate under the Health Insurance Portability and Accountability Act, Public Law 104–191, 110 Stat. 1936, as defined in 45 CFR 160.103.

Clear and conspicuous means that a notice is reasonably understandable and designed to call attention to the nature and significance of the information in the notice.

(1) *Reasonably understandable.* You make your notice reasonably understandable if you:

(i) Present the information in the notice in clear, concise sentences, paragraphs, and sections;

(ii) Use short explanatory sentences or bullet lists whenever possible;

(iii) Use definite, concrete, everyday words and active voice whenever possible;

(iv) Avoid multiple negatives;

(v) Avoid legal and highly technical business terminology whenever possible; and

(vi) Avoid explanations that are imprecise and readily subject to different interpretations.

(2) *Designed to call attention.* You design your notice to call attention to the nature and significance of the information in it if you:

(i) Use a plain-language heading to call attention to the notice;

(ii) Use a typeface and type size that are easy to read;

(iii) Provide wide margins and ample line spacing;

(iv) Use boldface or italics for key words; and

(v) In a form that combines your notice with other information, use distinctive type size, style, and graphic devices, such as shading or sidebars, when you combine your notice with other information. The notice should stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

(3) *Notices on websites or within-application messaging.* If you provide a notice on a web page or using within-application messaging, you design your notice to call attention to the nature and significance of the information in it if you use text or visual cues to encourage scrolling down the page if necessary to view the entire notice and ensure that other elements on the website or software application (such as text, graphics, hyperlinks, or sound) do not distract attention from the notice, and you either:

(i) Place the notice on a screen that consumers frequently access, such as a page on which transactions are conducted; or

(ii) Place a link on a screen that consumers frequently access, such as a page on which transactions are conducted, that connects directly to the notice and is labeled appropriately to convey the importance, nature and relevance of the notice.

Covered health care provider means a provider of services (as defined in 42 U.S.C. 1395x(u)), a provider of medical or other health services (as defined in 42 U.S.C. 1395x(s)), or any other entity furnishing health care services or supplies.

Electronic mail means email in combination with one or more of the following: text message, within-application messaging, or electronic banner.

Health care services or supplies means any online service such as a website, mobile application, or internet-connected device that provides mechanisms to track diseases, health conditions, diagnoses or diagnostic testing, treatment, medications, vital signs, symptoms, bodily functions, fitness, fertility, sexual health, sleep, mental health, genetic information, diet, or that provides other health-related services or tools.

HIPAA-covered entity means a covered entity under the Health Insurance Portability and Accountability Act (HIPAA), Public Law 104–191, 110 Stat. 1936, as defined in 45 CFR 160.103.

Personal health record (PHR) means an electronic record of PHR identifiable health information on an individual that has the technical capacity to draw information from multiple sources and that is managed, shared, and controlled by or primarily for the individual.

PHR identifiable health information means information that:

(1) Relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and

(i) Identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe that the information can be used to identify the individual; and

(2) Is created or received by a:

(i) Covered health care provider;

(ii) Health plan (as defined in 42 U.S.C. 1320d(5));

(iii) Employer; or

(iv) Health care clearinghouse (as defined in 42 U.S.C. 1320d(2)); and

(3) With respect to an individual, includes information that is provided by or on behalf of the individual.

PHR related entity means an entity, other than a HIPAA-covered entity or an entity to the extent that it engages in activities as a business associate of a HIPAA-covered entity, that:

(1) Offers products or services through the website, including any online service, of a vendor of personal health records;

(2) Offers products or services through the websites, including any online service, of HIPAA-covered entities that offer individuals personal health records; or

(3) Accesses unsecured PHR identifiable health information in a personal health record or sends unsecured PHR identifiable health information to a personal health record.

State means any of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Third party service provider means an entity that:

(1) Provides services to a vendor of personal health records in connection with the offering or maintenance of a personal health record or to a PHR related entity in connection with a product or service offered by that entity; and

(2) Accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured PHR identifiable health information as a result of such services.

Unsecured means PHR identifiable information that is not protected through the use of a technology or methodology specified by the Secretary of Health and Human Services in the guidance issued under section 13402(h)(2) of the American Reinvestment and Recovery Act of 2009, 42 U.S.C. 17932(h)(2).

Vendor of personal health records means an entity, other than a HIPAA-covered entity or an entity to the extent that it engages in activities as a business associate of a HIPAA-covered entity, that offers or maintains a personal health record.

§ 318.3 Breach notification requirement.

(a) *In general.* In accordance with §§ 318.4 (regarding timeliness of notification), 318.5 (regarding methods of notice), and 318.6 (regarding content of notice), each vendor of personal health records, following the discovery of a breach of security of unsecured PHR identifiable health information that is in a personal health record maintained or offered by such vendor, and each PHR related entity, following the discovery of a breach of security of such information that is obtained through a product or service provided by such entity, shall:

(1) Notify each individual who is a citizen or resident of the United States whose unsecured PHR identifiable health information was acquired by an unauthorized person as a result of such breach of security;

(2) Notify the Federal Trade Commission; and

(3) Notify prominent media outlets serving a State or jurisdiction, following the discovery of a breach of security, if the unsecured PHR identifiable health information of 500 or more residents of such State or jurisdiction is, or is reasonably believed to have been, acquired during such breach.

(b) *Third party service providers.* A third party service provider shall, following the discovery of a breach of security, provide notice of the breach to an official designated in a written contract by the vendor of personal health records or the PHR related entity to receive such notices or, if such a designation is not made, to a senior official at the vendor of personal health records or PHR related entity to which it provides services, and obtain acknowledgment from such official that such notice was received. Such notification shall include the identification of each customer of the vendor of personal health records or PHR related entity whose unsecured PHR identifiable health information has been, or is reasonably believed to have been, acquired during such breach. For

purposes of ensuring implementation of this paragraph (b), vendors of personal health records and PHR related entities shall notify third party service providers of their status as vendors of personal health records or PHR related entities subject to this part. While some third party service providers may access unsecured PHR identifiable health information in the course of providing services, this does not render the third party service provider a PHR related entity.

(c) *Breaches treated as discovered.* A breach of security shall be treated as discovered as of the first day on which such breach is known or reasonably should have been known to the vendor of personal health records, PHR related entity, or third party service provider, respectively. Such vendor, entity, or third party service provider shall be deemed to have knowledge of a breach if such breach is known, or reasonably should have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of such vendor of personal health records, PHR related entity, or third party service provider.

§ 318.4 Timeliness of notification.

(a) *In general.* Except as provided in paragraph (d) of this section (exception for law enforcement), all notifications required under § 318.3(a)(1) (required notice to individuals), (a)(3) (required notice to media), and (b) (required notice by third party service providers), shall be sent without unreasonable delay and in no case later than 60 calendar days after the discovery of a breach of security.

(b) *Timing of notice to FTC.* All notifications required under § 318.5(c) (regarding notice to FTC) involving the unsecured PHR identifiable health information of 500 or more individuals shall be provided contemporaneously with the notice required by paragraph (a) of this section. All logged notifications required under § 318.5(c) (regarding notice to FTC) involving the unsecured PHR identifiable health information of fewer than 500 individuals may be sent annually to the Federal Trade Commission no later than 60 calendar days following the end of the calendar year.

(c) *Burden of proof.* The vendor of personal health records, PHR related entity, and third party service provider involved shall have the burden of demonstrating that all notifications were made as required under this part, including evidence demonstrating the necessity of any delay.

(d) *Law enforcement exception.* If a law enforcement official determines that a notification, notice, or posting required under this part would impede a criminal investigation or cause damage to national security, such notification, notice, or posting shall be delayed. This paragraph (d) shall be implemented in the same manner as provided under 45 CFR 164.528(a)(2), in the case of a disclosure covered under § 164.528(a)(2).

§ 318.5 Methods of notice.

(a) *Individual notice.* A vendor of personal health records or PHR related entity that discovers a breach of security shall provide notice of such breach to an individual promptly, as described in § 318.4 (regarding timeliness of notification), and in the following form:

(1) Written notice at the last known address of the individual. Written notice may be sent by electronic mail if the individual has specified electronic mail as the primary method of communication. Any written notice sent by electronic mail must be Clear and Conspicuous. Where notice via electronic mail is not available or the individual has not specified electronic mail as the primary method of communication, a vendor of personal health records or PHR related entity may provide notice by first-class mail at the last known address of the individual. If the individual is deceased, the vendor of personal health records or PHR related entity that discovered the breach must provide such notice to the next of kin of the individual if the individual had provided contact information for his or her next of kin, along with authorization to contact them. The notice may be provided in one or more mailings as information is available.

(2) If, after making reasonable efforts to contact all individuals to whom notice is required under § 318.3(a), through the means provided in paragraph (a)(1) of this section, the vendor of personal health records or PHR related entity finds that contact information for ten or more individuals is insufficient or out-of-date, the vendor of personal health records or PHR related entity shall provide substitute notice, which shall be reasonably calculated to reach the individuals affected by the breach, in the following form:

(i) Through a conspicuous posting for a period of 90 days on the home page of its website; or

(ii) In major print or broadcast media, including major media in geographic areas where the individuals affected by the breach likely reside. Such a notice in media or web posting shall include a toll-free phone number, which shall remain active for at least 90 days, where an individual can learn if the individual's unsecured PHR identifiable health information may have been included in the breach.

(3) In any case deemed by the vendor of personal health records or PHR related entity to require urgency because of possible imminent misuse of unsecured PHR identifiable health information, that entity may provide information to individuals by telephone or other means, as appropriate, in addition to notice provided under paragraph (a)(1) of this section.

(b) *Notice to media.* As described in § 318.3(a)(3), a vendor of personal health records or PHR related entity shall provide notice to prominent media outlets serving a State or jurisdiction, following the discovery of a breach of security, if the unsecured PHR identifiable health information of 500 or more residents of such State or jurisdiction is, or is reasonably believed to have been, acquired during such breach.

(c) *Notice to FTC.* Vendors of personal health records and PHR related entities shall provide notice to the Federal Trade Commission following the discovery of a breach of security, as described in § 318.4(b) (regarding timing of notice to FTC). If the breach involves the unsecured PHR identifiable health information of fewer than 500 individuals, the vendor of personal health records or PHR related entity may maintain a log of any such breach and submit such a log annually to the Federal Trade Commission as described in § 318.4(b) (regarding timing of notice to FTC), documenting breaches from the preceding calendar year. All notices pursuant to this paragraph (c) shall be provided according to instructions at the Federal Trade Commission's website.

§ 318.6 Content of notice.

Regardless of the method by which notice is provided to individuals under § 318.5 (regarding methods of notice), notice of a breach of security shall be in plain language and include, to the extent possible, the following:

(a) A brief description of what happened, including: the date of the breach and the date of the discovery of the breach, if known; and the full name or identity (or, where providing the full name or identity would pose a risk to individuals or the entity providing notice, a description) of any third parties that acquired unsecured PHR identifiable health information as a result of a breach of security, if this information is known to the vendor of

personal health records or PHR related entity;

(b) A description of the types of unsecured PHR identifiable health information that were involved in the breach (such as but not limited to full name, Social Security number, date of birth, home address, account number, health diagnosis or condition, lab results, medications, other treatment information, the individual's use of a health-related mobile application, or device identifier (in combination with another data element));

(c) Steps individuals should take to protect themselves from potential harm resulting from the breach;

(d) A brief description of what the entity that experienced the breach is doing to investigate the breach, to mitigate harm, to protect against any further breaches, and to protect affected individuals, such as offering credit monitoring or other services; and

(e) Contact procedures for individuals to ask questions or learn additional information, which must include two or more of the following: toll-free telephone number; email address; website; within-application; or postal address.

§ 318.7 Enforcement.

Any violation of this part shall be treated as a violation of a rule promulgated under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices, and thus subject to civil penalties (as adjusted for inflation pursuant to § 1.98 of this chapter), and the Commission will enforce this part in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*

§ 318.8 Applicability date.

This part shall apply to breaches of security that are discovered on or after September 24, 2009.

§ 318.9 Sunset.

If new legislation is enacted establishing requirements for notification in the case of a breach of security that apply to entities covered by this part, the provisions of this part shall not apply to breaches of security discovered on or after the effective date of regulations implementing such legislation.

By direction of the Commission, Commissioners Holyoak and Ferguson dissenting.

April J. Tabor,

Secretary.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A—Health Breach Notification Rule Exemplar Notices

The notices below are intended to be examples of notifications that entities may use, in their discretion, to notify individuals of a breach of security pursuant to the Health Breach Notification Rule. The examples below are for illustrative purposes only. You should tailor any notices to the particular facts and circumstances of your breach. While your notice must comply with the Health Breach Notification Rule, you are not required to use the notices below.

Mobile Text Message and In-App Message Exemplars

Text Message Notification Exemplar 1

Due to a security breach on our system, *the health information you shared with us through [name of product] is now in the hands of unknown attackers.* Visit [add non-clickable URL] to learn what happened, how it affects you, and what you can do to protect your information. We also sent you an email with additional information.

Text Message Notification Exemplar 2

You shared health information with us when you used [product name]. *We discovered that we shared your health information with third parties for [describe why the company shared the info] without your permission.* Visit [add non-clickable URL] to learn what happened, how it affects you, and what you can do to protect your information. We also sent you an email with more information.

In-App Message Notification Exemplar 1

Due to a security breach on our system, *the health information you shared with us through [name of product] is now in the hands of unknown attackers.* This could include your [Add specifics—*for example, your name, email, address, blood pressure data*]. Visit [URL] to learn what happened, how it affects you, and what you can do to protect your information. We also sent you an email with additional information.

In-App Message Notification Exemplar 2

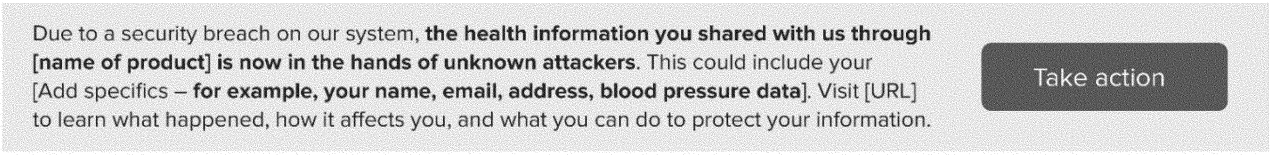
You shared health information with us when you used [product name]. *We discovered that we shared your health information with third parties for [if known, describe why the company shared the info] without your permission.* This could include your [Add specifics—*for example, your name, email, address, blood pressure data*]. Visit [URL] to learn what happened, how it affects you, and what you can do to protect your information. We also sent you an email with additional information.

Web Banner Exemplars

Web Banner Notification Exemplar 1

Due to a security breach on our system, *the health information you shared with us through [name of product] is now in the hands of unknown attackers.* This could include your [Add specifics—*for example, your name, email, address, blood pressure data*]. Visit [URL] to learn what happened, how it affects you, and what you can do to protect your information.

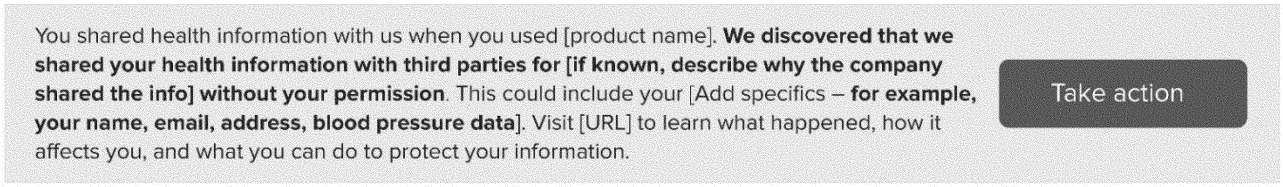
- *Recommend:* Include clear ''Take action'' call to action button, such as the example below:



Web Banner Notification Exemplar 2

You shared health information with us when you used [product name]. *We discovered that we shared your health information with third parties for [if known, describe why the company shared the info] without your permission.* This could include your [Add specifics—*for example, your name, email, address, blood pressure data*]. Visit [URL] to learn what happened, how it affects you, and what you can do to protect your information.

- *Recommend:* Include clear ''Take action'' call to action button, such as the example below:



Email Exemplars

Exemplar Email Notice 1

Email Sender: [Company] <company email>
Email Subject Line: [Company] Breach of Your Health Information

Dear [Name],

We are contacting you because an attacker recently gained unauthorized access to our system and stole health information about our customers, including you.

What happened and what it means for you

On [March 1, 2024], we learned that an attacker had accessed a file containing our customers' health information on [February 28, 2024]. The file included your name, the name of your health insurance company, your date of birth, and your group or policy number.

What you can do to protect yourself

You can take steps now to reduce the risk of identity theft.

1. *Review your medical records, statements, and bills for signs that someone is using your information.* Under the health privacy law known as HIPAA, you have the right to access your medical records. Get your records and review them for any treatments or doctor visits you don't recognize. If you find any, report them to your healthcare provider in writing. Then go to *www.IdentityTheft.gov/steps* to see what other steps you can take to limit the damage.

Also review the Explanation of Benefits statement your insurer sends you when it pays for medical care.

Some criminals wait before using stolen information so keep monitoring your benefits and bills.

2. *Review your credit reports for errors.* You can get your free credit reports from the three credit bureaus at *www.annualcreditreport.com* or call 1–877–322–8228. Look for medical billing errors, like medical debt collection notices that you don't recognize. Report any medical billing errors to all three credit bureaus by following the ''What To Do Next'' steps on *www.IdentityTheft.gov.*

3. *Sign up for free credit monitoring to detect suspicious activity.* Credit monitoring detects and alerts you about activity on your credit reports. Activity you don't recognize could be a sign that someone stole your identity. We're offering free credit monitoring for two years through [name of service]. Learn more and sign up at [URL].

4. *Consider freezing your credit report or placing a fraud alert on your credit report.* A credit report freeze means potential creditors can't get your credit report without your permission. That makes it less likely that an identity thief can open new accounts in your name. A freeze remains in place until you ask the credit bureau to temporarily lift it or remove it.

A fraud alert will make it harder for someone to open a new credit account in your name. It tells creditors to contact you before they open any new accounts in your name or change your accounts. A fraud alert lasts for one year. After a year, you can renew it.

To freeze your credit report, contact *each of the three credit bureaus,* Equifax, Experian, and TransUnion.

To place a fraud alert, contact *any one of the three credit bureaus,* Equifax, Experian, and TransUnion. As soon as one credit bureau confirms your fraud alert, the others are notified to place fraud alerts on your credit report.

Credit bureau contact information

Equifax, *www.equifax.com/personal/credit-report-services,* 1–800–685–1111
Experian, *www.experian.com/help,* 1–888–397–3742
TransUnion, *www.transunion.com/credit-help,* 1–888–909–8872

Learn more about how credit report freezes and fraud alerts can protect you from identity theft or prevent further misuse of your personal information at *www.consumer.ftc.gov/articles/what-know-about-credit-freezes-and-fraud-alerts.*

What we are doing in response

We hired security experts to secure our system. We are working with law enforcement to find the attacker. And we are investigating whether we made mistakes that made it possible for the attackers to get in.

Learn more about the breach.

Go to [URL] to learn more about what happened and what you can do to protect yourself. If we have any updates, we will post them there.

If you have questions or concerns, call us at [telephone number], email us at [address], or go to [URL].

Sincerely,
First name Last Name
[Role], [Company]

Exemplar Email Notice 2

Email Sender: [Company] <company email>
Email Subject Line: Unauthorized disclosure of your health informationby [Company]

Dear [Name],

We are contacting you because you use our company's app [name of app]. When you downloaded our app, we promised to keep your personal health information private. Instead, we disclosed health information about you without your approval.

What happened?

We told [insert Company name, identity, or, where providing full name or identity would pose a risk to individuals or the entity providing notice, a description of type of company] that you use our app, and between [January 10, 2024] and [March 1, 2024], we gave them your name and your email address.

We gave [insert Company name, identity, or where providing full name or identity would pose a risk to individuals or the entity providing notice, a description of type of company] this information so they could use it for advertising and marketing purposes. For example, to target you for ads for cancer drugs.

What we are doing in response

We will stop selling or sharing your health information with other companies. We will stop using your health information for advertising or marketing purposes. We have asked Company XYZ to delete your health information, but it's possible they could continue to use it for advertising and marketing.

What you can do

We made important changes to our app to fix this problem. Download the latest updates to our app then review your privacy settings. You can also contact Company XYZ to request that it delete your data.

Learn more

Learn more about our privacy and security practices at [URL]. If we have any updates, we will post them there.

If you have any questions or concerns, call us at [telephone number] or email us at [address].

Sincerely,

First name Last Name
[Role], [Company]

Exemplar Email Notice 3

Email Sender: [Company] <company email>
Email Subject Line: [Company] Breach of Your Health Information

Dear [Name],

We are contacting you about a breach of your health information collected through the [product], a device sold by our company, [Company].

What happened?

On [March 1, 2024], we discovered that our employee had accidentally posted a database online on [February 28, 2024]. That database included your name, your credit or debit card information, and your blood pressure readings. We don't know if anyone else found the database and saw your information. If someone found the database, they could use personal information to steal your identity or make unauthorized charges in your name.

What you can do to protect yourself

You can take steps now to reduce the risk of identity theft.

1. *Get your free credit report and review it for signs of identity theft.* Order your free credit report at *www.annualcreditreport.com.* Review it for accounts and activity you don't recognize. Recheck your credit reports periodically.

2. *Consider freezing your credit report or placing a fraud alert on your credit report.* A credit report freeze means potential creditors can't get your credit report without your permission. That makes it less likely that an identity thief can open new accounts in your name. A freeze remains in place until you ask the credit bureau to temporarily lift it or remove it.

A fraud alert will make it harder for someone to open a new credit account in your name. It tells creditors to contact you before they open any new accounts in your name or change your accounts. A fraud alert lasts for one year. After a year, you can renew it.

To freeze your credit report, contact *each of the three credit bureaus,* Equifax, Experian, and TransUnion.

To place a fraud alert, contact *any one of the three credit bureaus,* Equifax, Experian, and TransUnion. As soon as one credit bureau confirms your fraud alert, the others are notified to place fraud alerts on your credit report.

Credit bureau contact information

Equifax, www.equifax.com/personal/credit-report-services, 1–800–685–1111

Experian, www.experian.com/help, 1–888–397–3742

TransUnion, www.transunion.com/credit-help, 1–888–909–8872

Learn more about how credit report freezes and fraud alerts can protect you from identity theft or prevent further misuse of your personal information at *www.consumer.ftc.gov/articles/what-know-about-credit-freezes-and-fraud-alerts.*

3. *Sign up for free credit monitoring to detect suspicious activity.* Credit monitoring detects and alerts you about activity on your credit reports. Activity you don't recognize could be a sign that someone stole your identity. We're offering free credit monitoring for two years through [name of service]. Learn more and sign up at [URL].

What we are doing in response

We are investigating our mistakes. We know the database shouldn't have been online and it should have been encrypted. We are making changes to prevent this from happening again.

We are working with experts to secure our system. We are reviewing our databases to make sure we store health information securely.

Learn more about the breach.

Go to [URL] to learn more about what happened and what you can do to protect yourself. If we have any updates, we will post them there.

If you have questions or concerns, call us at [telephone number], email us at [address], or go to [URL].

Sincerely,

First name Last Name
[Role], [Company]

Appendix B—Joint Statement by FTC Chair and Commissioners

Joint Statement of Chair Lina M. Khan, Commissioner Rebecca Kelly Slaughter, and Commissioner Alvaro M. Bedoya

Today, the FTC finalizes an update to the Health Breach Notification Rule (''the Final Rule'') that ensures its protections keep pace with the rapid proliferation of digital health records. We do so to fulfill a clear statutory directive given to us by Congress.

In 2009, as part of the American Recovery and Reinvestment Act (''ARRA''), Congress passed the Health Information Technology for Economic and Clinical Health Act (''HITECH Act'').[314] Among other things, the HITECH Act sought to fill the gaps left by the privacy and security protections created under the Health Insurance Portability and Accountability Act (''HIPAA''), which was passed more than a decade earlier.[315] Specifically, it expanded the kinds of entities subject to the privacy and security provisions of HIPAA,[316] gave state attorneys general enforcement powers,[317] and—most relevant here—directed the Commission to issue a rule requiring entities not covered by HIPAA to provide notification of any breach of unsecured health records.[318] The Commission issued the original rule in 2009.[319] In 2020, the Commission initiated its regular decennial rule review and, in 2021, the Commission issued a policy statement clarifying how the rule applies to health apps and other connected devices.[320] In the years since, the Commission has brought enforcement actions against health apps alleging violations of the Health Breach Notification Rule.[321] Today's issuance of the Final Rule codifies this approach, honoring the statutory directive that people must be notified when their health records are breached.

The dissent argues that the Commission's action ''exceeds the Commission's statutory authority.'' [322] But its analysis contravenes a plain reading of the statute.

In the HITECH Act, Congress directed the FTC to issue rules requiring vendors of personal health records (''PHR'') to notify consumers and the FTC following ''a breach of security of unsecured PHR identifiable health information.'' [323] The statute defines the term ''PHR identifiable health information'' as ''individually identifiable health information, as defined in section 1320d(6) of this title.'' [324] Section 1320d(6), a portion of the Social Security Act created by HIPAA, defines ''individually identifiable health information'' as ''any information . . . that is created or received by a health care provider, health plan, employer, or health care clearinghouse.'' [325] Section 1320d(3), another section of the Social Security Act created by HIPAA, defines ''health care provider'' as, first, ''a provider of services'' as defined in section 1395x(u); [326] second, ''a provider of medical or other health services'' as defined in section 1395x(s); [327] and, third, ''any other person furnishing health care services or supplies.'' [328]

The term ''health care services or supplies,'' undefined in the statute, is defined in the Final Rule as follows:

Health care services or supplies means any online service such as a website, mobile application, or internet-connected device that provides mechanisms to track diseases, health conditions, diagnoses or diagnostic testing, treatment, medications, vital signs, symptoms, bodily functions, fitness, fertility, sexual health, sleep, mental health, genetic information, diet, or that provides other health-related services or tools.[329]

The dissent argues that this definition violates certain canons of statutory construction.[330] But its effort to cabin the third category of HIPAA's ''health care provider'' reads it out of existence, violating the canon that holds interpretations giving effect to every clause of a statute are superior to those that render distinct clauses superfluous.[331] Specifically, the second

[314] Am. Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115 (2009) at Sec. 13400 *et seq.*

[315] Health Insurance Portability and Accountability Act, Public Law 104–191, 110 Stat. 1936, 2022 (1996) at Sec. 1171, codified at 42 U.S.C. 1320d.

[316] Health Information Technology for Economic and Clinical Health Act, Public Law 111–5, Div. A, Title XIII, Subtitle D, sections 13401 and 13404 (codified at 42 U.S.C. 17937(a))

[317] *Id.* 13410(e).

[318] *Id.* 13407(g)(1).

[319] 74 FR 42962 (Aug. 25, 2009).

[320] Statement of the Commission on Breaches by Health Apps and Other Connected Devices (Sept. 15, 2021), *https://www.ftc.gov/system/files/documents/public_statements/1596364/statement_of_the_commission_on_breaches_by_health_apps_and_other_connected_devices.pdf.*

[321] *See, e.g.,* Fed. Trade Comm'n, FTC Enforcement Action to Bar GoodRx from Sharing Consumers' Sensitive Health Info for Advertising (Feb. 1, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-enforcement-action-bar-goodrx-sharing-consumers-sensitive-health-info-advertising;* Fed. Trade Comm'n, Ovulation Tracking App Premom Will be Barred from Sharing Health Data for Advertising Under Proposed FTC Order (May 17, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/05/ovulation-tracking-app-premom-will-be-barred-sharing-health-data-advertising-under-proposed-ftc.*

[322] Dissenting Statement of Comm'rs Melissa Holyoak and Andrew Ferguson at 1 (Apr. 25, 2024) (hereinafter ''Dissent'').

[323] Health Information Technology for Economic and Clinical Health Act, Public Law 111–5, Div. A, Title XIII, Subtitle D, section 13407 (codified at 42 U.S.C. 17937(a)).

[324] 42 U.S.C. 17937(f)(2).

[325] 42 U.S.C. 1320d(6).

[326] *See* 42 U.S.C. 1395x(u) (''The term ''provider of services'' means a hospital, critical access hospital, rural emergency hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1395f(g) and section 1395n(e) of this title, a fund.'').

[327] 42 U.S.C. 1395x(s) (listing a vast array of services, tests, supplies, and measurements, comprising over 2000 words and 15 categories, one of which has over 30 subcategories).

[328] 42 U.S.C. 1320d(3) (emphasis added).

[329] HBNR Final Rule § 318.2(e).

[330] Dissent at 2 (''When a statute contains a list, ''each word in that list presumptively has a 'similar' meaning'' under the canon of *noscitur a sociis.* And when a general term follows a list of specific terms, the *ejusdem generis* canon teaches that the general term ''should usually be read in light of those specific words to mean something 'similar.' '' Together, these canons instruct that the final category of health care provider that includes the general term ''other person'' must be similar to the more specific terms that precede it.'' (citations omitted)).

[331] *Marx* v. *Gen. Revenue Corp.,* 568 U.S. 371, 386 (2013) (Thomas, J.) (''Finally, the canon against

Continued

category of ''health care provider'' already comprises a vast array of ''provider[s] of medical and other services.'' [332] If the Commission were to interpret the third category as comprising, as the dissent recommends, only ''traditional forms of health care providers,'' this distinct provision would be entirely redundant.

The dissent's approach also fails to give meaning to other textual differences between the second and third category. The second category in the definition of ''health care provider'' discusses a ''provider'' and ''medical'' services.[333] The third category, by contrast, drops the terms ''provider'' in favor of ''person furnishing'' and drops ''medical'' in favor of ''health care.'' [334] Honoring the materially different words of the statute requires us to read these two categories as covering distinct, not entirely overlapping, entities.[335] The Final Rule faithfully follows these textual markers and identifies specific services and tools that comprise ''health care services or supplies.'' [336] Contrary to this plain reading of the text, the dissent claims that Congress must have meant for this provision to apply only to ''traditional forms of health care providers.'' [337] But we cannot subordinate the text of the statute to speculative accounts of what Congress intended.

The dissent also notes that the Department of Health and Human Services (''HHS'') ''has never interpreted the term 'health care provider' to reach the expansive, creative conclusion that the Commission does today.'' [338] HHS has, however, interpreted ''health care provider,'' and its interpretation of this term is consistent with the Commission's definition.[339] In the HIPAA Privacy Rule, HHS defines first two categories of ''health care provider'' using the same language as the statute, but the third category is changed from ''any other person furnishing health care services or supplies'' to ''any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.'' [340] HHS also defines ''health care'' broadly, as any ''care, services, or supplies related to the health of an individual.'' [341]

Notably, in its 1999 Notice of Proposed Rulemaking for the HIPAA Privacy Rule, HHS originally had proposed to define the term ''health care'' as constituting ''the provision of care, services, or supplies. . . .'' [342] But, in its final rule, HHS eliminated the concept of ''provision'' in order to distinguish the broader term of ''health care'' from the narrower term ''treatment.'' [343] HHS explained: ''We delete the term 'providing' from the definition [of health care] to delineate more clearly the relationship between 'treatment,' as the term is defined in § 164.501, and 'health care.' '' [344] HHS defined ''treatment,'' in contrast to ''health care,'' as ''the provision, coordination, or management of health care and related services.'' [345] In short, HHS defines ''health care'' broadly, covering all aspects related to the health of an individual, and defines ''treatment'' more narrowly, referring to the provision of medical care to an individual. The dissent's proposal to narrow the third category of ''health care provider'' to ''traditional forms of health care providers'' closely mirrors the approach that HHS rejected when it defined this term.[346]

The dissent also claims that changing the phrase ''can be drawn'' to ''has the technical capacity to draw'' violates the surplusage canon because it renders the limitation meaningless as to health apps, because ''virtually every app has the technical capacity to draw some information from more than one source.'' [347] This argument fails for two reasons. First, as the Statement of Basis and Purpose (''SBP'') explains, there are products and services that do not satisfy this requirement.[348] Second, even if the definition did reach every health app, that would not itself suggest that the Final Rule's definition was wrongly crafted. Rather, it would reflect the rapid growth in digital applications and services related to consumers' health.[349]

The practical ramifications of the dissent's legal shortcomings are significant.

Just last year, the Commission brought an action against Easy Healthcare Corporation, alleging privacy violations by its fertility tracking application Premom.[350] As laid out in the complaint, Premom—which encourages users to provide information about their menstrual cycles, fertility, and pregnancy, as well as to import their data from other services, such as Apple Health—shared information with advertisers and China-based companies through software development kits (''SDKs'') embedded in the application. The Commission's eight-count complaint against Easy Healthcare reflected the seriousness of this misconduct, charging the business with deceptive and unfair practices, as well as a violation of the Health Breach Notification Rule, which triggered civil penalties.

Under the dissent's analysis of health care services or supplies, the developer of the Premom application—Easy Healthcare—would not be covered by the Health Breach Notification Rule. This reading would mean that when companies like Easy Healthcare suffer a breach that may divulge health information to companies located in China, the Health Breach Notification Rule would not require them to disclose the breach to its users. It would also mean that when Easy Healthcare broadcasts women's sensitive health data across the vast commercial surveillance network propped up by SDKs and ad networks, the Health Breach Notification Rule would not require Easy Healthcare to alert women. Today's Final Rule rejects this atextual and cramped reading of the law, ensuring that businesses that hold themselves out as health care services companies—like Easy Healthcare—

surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme.'').

[332] 42 U.S.C. 1320(d)(3) (citing 42 U.S.C. 1395x(u)).

[333] 42 U.S.C. 1320(d)(3).

[334] *Id.*

[335] *See Southwest Airlines Co.* v. *Saxon,* 596 U.S. 450, 458 (2022) (Thomas, J.) (''Where a document has used one term in one place, and a materially different term in another, the presumption is that the different term denotes a different idea'' (cleaned up)).

[336] In addition to defining this term by identifying specific services, the Final Rule actually also narrowed the definition originally proposed in the NPRM, by eliminating ''includes'' from the definition. SBP at 27 (''[T]he Commission has substituted the word 'means' for 'includes' to avoid implying greater breadth than the Commission intends.'').

[337] Dissent at 3. This rejection of the text of the statute, in favor of vague speculation about what Congress intended, mirrors the argument advanced by the Chamber of Commerce (''the Chamber''). The Chamber purports to rely on a ''plain text reading'' of the statute but immediately switches—in the very same sentence—to vague notions of Congressional intent: ''It is clear from a plain text reading of both the HITECH Act and HIPPA [*sic*] that Congress intended for the HBNR to cover health records more aligned with the provision of health services provided by traditional health providers at a time when it was attempting to digitize traditional health records.'' Comment submitted by U.S. Chamber of Com., Health Breach Notification Rule, *Regulations.gov* (Aug. 8, 2023) at 3, *https://www.regulations.gov/comment/FTC-2023-0037-010.*

[338] Dissent at 3.

[339] That the HIPAA Privacy rule has a narrower overall scope does not change this fact.

[340] 45 CFR 160.103.

[341] *Id.* (emphasis added). The dissent asserts that we ''mischaracterize[] the HIPAA Privacy Rule, which only applies to HIPAA 'covered entities' and their 'business associates,'—*i.e.,* to traditional health care providers, that do not include the broad swath of app developers the Final Rule will encompass.'' Dissent at 4 n.24 (internal citations omitted). It is not clear how this qualifies as a mischaracterization. Indeed, this is precisely the stated purpose of the Health Breach Notification Rule: To cover entities that HIPAA does not. The dissent also notes that we fail to recognize that HHS provides two examples of ''health care.'' But, HHS expressly states that the definition ''includes, but is not limited to'' these categories. 45 CFR 160.103. In any case, the breadth of these categories further underscores the expansive scope of HHS's definition of health care. *Id.*

[342] Proposed Rule, Standards for Privacy of Individually Identifiable Health Information, 64 FR 59918, 60049 (Nov. 3, 1999) (emphasis added).

[343] 65 FR 82462, 82477.

[344] *Id.*

[345] 45 CFR 164.501.

[346] Dissent at 2.

[347] Dissent at 4.

[348] SBP at 29–30.

[349] The dissent's argument anachronistically assumes that Congress intended for the Rule to cover some health apps, but not other health apps. But, in fact, the Apple and Google app stores were in their infancy when Congress drafted this legislation in 2009, and so there is no indication that Congress was thinking about specific health apps at all. To the extent the dissent's argument is that Congress simply did not anticipate the vast number of products that would end up covered by the broad category of ''supplies and services,'' it is not within the Commission's authority to re-write the statute based on the Commission's belief of what Congress would have wanted. *MCI Telecomms. Corp.* v. *Am. Telephone & Telegraph Co.,* 512 U.S. 218, 229 (1994) (holding that FCC's authority to ''modify'' does not extend to eliminating altogether a statutory requirement).

[350] Press Release, Fed. Trade Comm'n, Ovulation Tracking App Premom Will be Barred from Sharing Health Data for Advertising Under Proposed FTC Order (May 17, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/05/ovulation-tracking-app-premom-will-be-barred-sharing-health-data-advertising-under-proposed-ftc.*

are considered ''health care services'' companies under the law.

Lastly, the dissent claims that the Final Rule introduces ambiguity where previous there was none. But *GoodRx* suggests otherwise. In a unanimous action, the Commission charged GoodRx with making unauthorized disclosures of people's health data to Facebook and Google, among others.[351] GoodRx, meanwhile, disputed the applicability of the HBNR to its practices, calling it a ''novel'' application.[352] By codifying how HBNR applies to online platforms and applications, today's Final Rule provides market participants with more clarity about what entities are covered—thereby providing greater certainty and notice.[353]

GoodRx marked the first time the Commission had ever enforced the Health Breach Notification Rule. A top priority for us at the Commission is ensuring we are faithfully discharging our statutory duties, rather than letting the authorities that Congress has granted us sit dormant, and we are proud of the work the Commission and the staff are doing to take care that the full set of laws assigned to the FTC are being faithfully executed.[354] We agree with the dissent that we must look out for the institutional integrity of the Commission. Failing to use the full scope of our statutory tools to protect Americans—and failing to update our application of these tools even as technologies change—would undermine the agency's integrity and credibility alike.

We are deeply grateful to the Division of Privacy and Identity Protection for leading the Commission's work to activate the Health Breach Notification Rule and for finalizing this Rule update. In an environment rife with new and evolving threats to Americans' health data, ensuring we are faithfully harnessing all of our statutory tools to protect people from data breaches is paramount.

Dissenting Statement of Commissioner Melissa Holyoak, Joined by Commissioner Andrew Ferguson

The Health Breach Notification Rule (''Final Rule'') that the Commission adopts today exceeds the Commission's statutory authority, puts companies at risk of perpetual non-compliance, and opens the Commission to legal challenge that could undermine its institutional integrity. I share the majority's goal of protecting the privacy and security of consumers' identifiable health information,[1] and I support vigorous enforcement of laws protecting sensitive personal information with which Congress has entrusted the FTC.[2] I would support finalizing a rule that extends and clarifies the scope of the Commission's enforcement in this important area of consumer protection if that rule were consistent with our grant of authority from Congress. But, no matter how the majority attempts to shoehorn its desired policy goal into a ''plain reading'' of the statute,[3] I cannot support a rule that exceeds the bounds Congress clearly established. Indeed, a core principle guiding my tenure at the Commission will be that our rules must effectuate the law as it is—not as the Commission may wish it to be. For these reasons, I respectfully dissent.

The American Recovery and Reinvestment Act of 2009 (''Recovery Act'')[4] authorized the Commission to issue a rule requiring vendors of ''personal health records'' (''PHRs'') and related entities that are not covered by HIPAA to notify individuals and the FTC of a ''breach of security'' of ''unsecured PHR identifiable health information.''[5] The Commission issued the Health Breach Notification Rule in 2009,[6] initiated a routine review of the Rule in 2020,[7] issued a policy statement re-interpreting the then-current Rule in 2021 (''2021 Policy Statement''),[8] issued a Notice of Proposed Rulemaking on June 9, 2023 (''NPRM''),[9] and today issues the Final Rule.[10]

I am encouraged that today the Commission is acting by rulemaking, as authorized by statute and following a period of notice and comment that elicited a range of views, rather than acting by fiat in a policy statement, as the Commission did in 2021.[11] I cannot endorse any policy statement that either displaces Congress's authority to make law or subverts the rulemaking process. The 2021 Policy Statement did both. The majority clearly recognizes this overreach. After all, if the 2021 Policy Statement had any force, today's rulemaking would be unnecessary.

Setting aside this troubling history, I turn to the Final Rule itself, which, unfortunately, I find equally troubling in its extension beyond the parameters established by Congress.

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[351] Press Release, Fed. Trade Comm'n, FTC Enforcement Action to Bar GoodRx from Sharing Consumers' Sensitive Health Info for Advertising (Feb. 1, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-enforcement-action-bar-goodrx-sharing-consumers-sensitive-health-info-advertising; See also,* Concurring Statement of Comm'r Christine S. Wilson, GoodRx Holdings, Inc. (Feb. 1, 2023), *https://www.ftc.gov/system/files/ftc_gov/pdf/2023090_goodrx_final_concurring_statement_wilson.pdf* (''Today's settlement marks the first enforcement matter in which the FTC has invoked the HBNR. I congratulate staff on this important step—the agency rightly is focused on protecting the privacy of sensitive health data and empowering consumers to make informed choices about the goods and services they use.''); *see also id.* at 5 (describing the GoodRx case as ''an important milestone in the Commission's privacy work.''). The dissent suggests that Commissioners Holyoak and Ferguson would have supported the application of HBNR to GoodRx.

[352] *See* GoodRx, GoodRx Response to FTC Settlement (Feb. 1, 2023) (''We believe this is a novel application of the Health Breach Notification Rule by the FTC. . . . We do not agree with the assertion that this was a violation of the HBNR.'').

[353] The dissent concedes that it does support an update to the rule that provides more clarity—and specifically an update that provides clarity to show that the rule covers GoodRx. Dissent at 7 (''I would support changes to the Rule that clarify the Rule's application to companies like GoodRx.''). That is precisely what today's Final Rule does. Previously, the rule did not define ''health care services or supplies,'' and today's Final Rule does. Previously, health apps like GoodRx stated that it was unclear whether the rule applies to them, and today's Final Rule makes clear that it does. This concession from the dissent suggests a more modest disagreement with the contours of how the Rule defines ''health care services or supplies,'' though—notably—the dissent does not provide an alternative definition.

[354] *See, e.g.,* Press Release, Fed. Trade Comm'n, FTC Hits R360 and its Owner With $3.8 Million Civil Penalty Judgment for Preying on People Seeking Treatment for Addiction (May 17, 2022), *https://www.ftc.gov/news-events/news/press-releases/2022/05/ftc-hits-r360-its-owner-38-million-civil-penalty-judgment-preying-people-seeking-treatment-addiction* (the Commission's first action brought under the Opioid Addiction Recovery Fraud Prevention Act); Harris Jewelry, Press Release, Fed. Trade Comm'n, FTC and 18 States Sue to Stop Harris Jewelry from Cheating Military Families with Illegal Financing and Sales Tactics (Jul. 20, 2022), *https://www.ftc.gov/news-events/news/press-releases/2022/07/ftc-18-states-sue-stop-harris-jewelry-cheating-military-families-illegal-financing-sales-tactics* (the Commission's first action brought under the Military Lending Act); Press Release, Fed. Trade Comm'n, Smart Home Monitoring Company Vivint Will Pay $20 Million to Settle FTC Charges That It Misused Consumer Credit Reports (Apr. 29, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/04/smart-home-monitoring-company-vivint-will-pay-20-million-settle-ftc-charges-it-misused-consumer* (the Commission's first action brought under the Red Flags Rule, brought under Acting Chair Slaughter); Press Release, Fed. Trade Comm'n, FTC Sues Burger Franchise Company That Targets Veterans and Others With False Promises and Misleading Documents (Feb. 8, 2022), *https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-sues-burger-franchise-company-targets-veterans-others-false-promises-misleading-documents* (the Commission's first action under the Franchise Rule since 2007); Press Release, Fed. Trade Comm'n, FTC Issues Rule to Deter Rampant Made in USA Fraud (Jul. 1, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/07/ftc-issues-rule-deter-rampant-made-usa-fraud* (issuance of the Made in the USA Rule, more than 25 years after Congress authorized the Commission to promulgate a rule).

[1] Like the majority, and other Commissioners before me, I support federal privacy legislation, particularly where such legislation could address gaps in sector-specific laws and level the playing field for companies navigating a patchwork of laws. And like the majority, and other Commissioners before me, I care deeply about protecting the privacy and security of consumers' health information, particularly where it falls outside the bounds of the Health Insurance Portability and Accountability Act (''HIPAA''). For more than two decades, the FTC has been in a leader in protecting consumers' health information. *See, e.g., Eli Lilly,* FTC File No. 0123214 (May 10, 2002), *https://www.ftc.gov/legal-library/browse/cases-proceedings/012-3214-eli-lilly-company-matter.* I look forward to continuing the Commission's important work in this area.

[2] *See, e.g.,* Children's Online Privacy Protection Rule, 16 CFR part 312, as authorized by the Children's Online Privacy Protection Act of 1998, 15 U.S.C. 6501 *et seq.*

[3] Joint Statement of Chair Lina M. Khan, Comm'r Rebecca Kelly Slaughter, and Comm'r Alvaro M. Bedoya at 2 (Apr. 24, 2024) (''Majority Statement'').

[4] Am. Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115 (2009).

[5] 42 U.S.C. 17937(a), (g).

[6] 74 FR 42962 (Aug. 25, 2009).

[7] 85 FR 31085 (May 22, 2020).

[8] *See* Statement of the Comm'n on Breaches by Health Apps and Other Connected Devices (Sept. 15, 2021), *https://www.ftc.gov/system/files/documents/public_statements/1596364/statement_of_the_commission_on_breaches_by_health_apps_and_other_connected_devices.pdf (''2021 Policy Statement'').*

[9] 88 FR 37819 (June 9, 2023).

[10] *See* Statement of Basis and Purpose (''SBP'') accompanying the Final Rule, Section I (summarizing procedural history).

[11] *See* 2021 Policy Statement, *supra* note 8.

Some background first. Under the Recovery Act, PHR identifiable health information means ''individually identifiable health information,'' as defined by the Social Security Act, 42 U.S.C. 1320d(6).[12] The Social Security Act defines ''individually identifiable health information'' as information that is ''created or received by a health care provider, health plan, employer, or health care clearinghouse.'' [13] The Social Security Act then defines ''health care provider'' to include three categories: ''[1] a provider of services (as defined in section 1395x(u) of this title), [2] a provider of medical or other health services (as defined in section 1395x(s) of this title), and [3] any other person furnishing health care services or supplies.'' [14]

The Commission takes liberties with the final category in that definition (''any other person furnishing health care services or supplies'') to adopt a new, capacious definition of ''covered health care provider'' and a new, similarly capacious definition of ''health care services and supplies,'' whose joint effect is to sweep a large swath of apps and app developers under the purview of the Final Rule. These expansive definitions are not consistent with the statute. Under longstanding principles of statutory interpretation, the final category of provider (''any other person . . .'') must be understood in relation to the first two categories (''provider of services'' and ''provider of medical or other health services'').[15] When a statute contains a list, ''each word in that list presumptively has a 'similar' meaning'' under the canon of *noscitur a sociis*.[16] And when a general term follows a list of specific terms, the *ejusdem generis* canon teaches that the general term ''should usually be read in light of those specific words to mean something 'similar.' '' [17] Together, these canons instruct that the final category of health care provider that includes the general term ''other person'' must be similar to the more specific terms that precede it.

The first two categories of health care provider incorporate the definitions of sections 1395x(u) and 1395x(s) of the Social Security Act, respectively.[18] The first category of provider includes ''a hospital, critical access hospital, rural emergency hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or . . . a fund.'' [19] The second category of provider includes an extensive list (section 1395x(s) includes 17 paragraphs and over 35 subparagraphs) of medical professionals including physicians, physician assistants, nurse practitioners, clinical psychologists, clinical social workers, and others, and the specific services administered by medical professionals.[20] These two categories comprise traditional forms of health care providers.

The final category, addressing ''any other person furnishing health care services or supplies,'' must therefore only include persons that are ''similar in nature'' to these first two categories.[21] The majority argues that my ''effort to cabin the third category . . . reads it out of existence, violating the canon that holds interpretations giving effect to every clause of a statute are superior to those that render distinct clauses superfluous.'' [22] This application of the canon is incorrect. Requiring similarity among categories does not result in superfluity; it merely prevents interpretations that extend beyond what the text permits. A catch-all's limited application due to its context is not a reason to expand that phrase to encompass dissimilar applications.

The Final Rule's definition of ''covered health care provider'' is not remotely similar, because it incorporates a new, astonishingly broad definition of ''health care services or supplies,'' which means ''any online service such as a website, mobile application, or internet-connected device that provides mechanisms to track diseases, health conditions, diagnoses or diagnostic testing, treatment, medications, vital signs, symptoms, bodily functions, fitness, fertility, sexual health, sleep, mental health, genetic information, diet, or that provides other health-related services or tools.'' [23] Thus, the Commission transforms ''health care provider,'' which both under common usage and in context of the statutory provision means entities such as physicians and hospitals, to now include any company ''furnishing'' a health-related app.[24] As a result, the Final Rule creates a tautology: Health app developers may be ''vendors of personal health records'' by offering an app containing health information that has been created or received by a health care provider, where the health app developer is itself the health care provider that creates or receives that health information by virtue of offering the app.

Notably, even though the Department of Health and Human Services (''HHS'') interprets this same provision of the Social Security Act, HHS has—notwithstanding the majority's assertion to the contrary [25]—never interpreted the term ''health care provider'' to reach the expansive, creative conclusion that the Commission does today.[26] The majority's argument misstates the scope and language of the HIPAA Privacy Rule, which only applies to HIPAA ''covered entities'' and their ''business associates,'' [27]—*i.e.,* to traditional health care providers that do not include the broad swath of app developers the Final Rule will encompass. Significantly, the majority omits from its characterization of the term ''health care'' HHS's own illustrations of that term, which highlight the proximity to traditional forms of health care by different kinds of medical professionals:

(1) Preventive, 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) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.[28]

The Majority Statement repeatedly says that HHS defines ''health care'' broadly,[29] but the language it cites provides no such support.

Aware of this incongruency, the Commission seeks to differentiate its use of ''health care provider'' from that of ''other government agencies.'' [30] Yet the Commission provides no explanation *why* its definition should differ, particularly where it is unclear whether the Commission has interpretative authority over the Social Security Act's definition of health care provider and where other agencies *are* delegated such interpretative authority.[31]

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[12] 42 U.S.C. 17937(f)(2).

[13] 42 U.S.C. 1320d(6).

[14] *Id.* 1320d(3).

[15] *See Yates* v. *United States,* 574 U.S. 528, 549–51 (2015) (Alito, J., concurring); Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 195–196,199–200 (2012).

[16] *Yates,* 574 U.S. at 549.

[17] *Id.* at 550.

[18] 42 U.S.C. 1320d(3).

[19] 42 U.S.C. 1395x(u).

[20] *Id.* 1395x(s).

[21] *Yates,* 574 U.S. at 545 (internal quotation marks omitted).

[22] Majority Statement at 2.

[23] Final Rule at 98.

[24] The SBP explains that an app developer (or any company ''furnishing'' a health app) would be covered as a health care provider because its health app is a health care service or supply. SBP at 7, 22–28.

[25] Majority Statement at 3.

[26] *See* NPRM at 37823.

[27] 45 CFR 160.102 through 103.

[28] *Id.* § 160.103.

[29] Majority Statement at 3–4.

[30] SBP at 26.

[31] *Id.* at 13 (noting that HHS interprets these provisions of the Social Security Act). *Cf. City of Arlington, Tex.* v. *F.C.C.,* 569 U.S. 290, 323 (2013) (Roberts, C.J., dissenting) (''When presented with an agency's interpretation of such a statute, a court cannot simply ask whether the statute is one that the agency administers; the question is whether authority over the particular ambiguity at issue has been delegated to the particular agency.'').

The Commission also takes troubling liberties with the statute's definition of ''personal health record,'' which are evident from a side-by-side comparison of the statute and the Final Rule:

Recovery act	Final rule
''an electronic record of PHR identifiable health information . . . on an individual that can be drawn from multiple sources and is managed, shared, and controlled by or primarily for the individual.'' [32].	''an electronic record of PHR identifiable health information on an individual that has the technical capacity to draw information from multiple sources and that is managed, shared, and controlled by or primarily for the individual.'' [33]

Under the Final Rule, a PHR need not actually draw health information from multiple sources, as the statute contemplates (because the statutory phrase ''that can be drawn'' modifies its immediate antecedent, ''health information''). Rather, under the Final Rule, a single source of health information will render an app a PHR as long as the ''PHR'' has the ''technical capacity'' to draw some other information elsewhere.[34] The implications of this change, in conjunction with the expansion of ''health care provider,'' are significant. Any retailer that offers an app that tracks health-related purchases (*e.g.,* bandages, vitamins, dandruff shampoo) may be a vendor of a PHR covered by the Rule if the app draws health information (*e.g.,* purchasing information) from the consumer and the app has the ''technical capacity'' to draw any information from any other source. As the Statement of Basis and Purpose notes, commenters warned that virtually every app has the technical capacity to draw some information from more than one source.[35] That expansive scope could be appropriate if Congress's language permitted it. But the Commission's interpretation, which effectively renders the Recovery Act's ''multiple sources'' requirement meaningless, ignores longstanding principles of statutory interpretation that require each provision of a statute to be given effect.[36]

The Commission's expansive definitions of ''covered health care provider,'' ''health care services and supplies,'' and ''personal health record'' have a profound effect on the scope of the Rule: Most companies that offer or disseminate health-related apps or similar products would be treated as ''covered health care providers'' that therefore hold ''PHR identifiable health information'' in their apps (*i.e.,* PHRs), such that they are vendors of PHRs—even if their app is merely health-adjacent.

Remarkably, the Commission imposes no limit on this extraordinary breadth in the Rule itself. Rather, in a post-NPRM attempt to check the scope, the Commission fashions a limiting principle: Apps are covered only if they are ''more than tangentially relating to health.'' [37] This extra-statutory, extra-regulatory limit has several significant problems.

First, if the majority were correct, from where would it draw the authority to impose this ''more than tangentially relating to health'' limitation? If Congress in fact commanded us to cover all the apps the majority claims, this extra-textual limitation would be beyond our power to impose.[38] Why, then, does the majority blink in the face of what it understands Congress to have required? There may be good policy reasons not to follow Congress's language—as the majority understands it—wherever it leads, but we do not have power to shortchange Congress's commands. That even the majority feels compelled to adopt this extra-textual limitation—again, as the majority understands the text—on the statute's reach suggests that the language probably does not mean what the majority says.

The second problem is substantive: What does this language mean? When does an app cross the line between tangentially related to health and more than tangentially related? If a gas station with a loyalty app sells Advil, is the app only tangentially related to health and outside the Final Rule's purview? If the gas station adds Robitussin and pregnancy tests to its inventory, does it cross the line to more than tangentially related to health? If a clothing store with an e-commerce app sells a handful of maternity shirts, is the app only tangentially related to health? If the store adds more maternity clothes, nursing bras, and some anti-nausea ginger tea to its in-app offerings, is the app more than tangentially related to health? If vitamins, over-the-counter medicines, acne creams, bandages, and similar items comprise 0.1% or 1% or 10% of a superstore's inventory, when is the retailer's e-commerce app more than tangentially related to health? I see no clear answers to any of these hypotheticals in today's Final Rule, which suggests that the marketplace will see no clear answers either.[39]

The third problem is procedural. The Commission did not propose this ambiguous but impactful limitation in a Notice of Proposed Rulemaking—likely because there is no statutory basis for this newly-created language. Rather, it introduces this crucial concept for the first time in a Statement of Basis and Purpose (a purely interpretive document) as a *post hoc* fix to the problem the Commission itself created with its expansive definitions. As a result, the Commission did not provide notice or receive public comment on the efficacy or propriety of this limitation, depriving the public of its opportunity to meaningfully participate in the rulemaking process and depriving itself of potentially valuable input from commenters.

The final problem is that this *post hoc,* extra-regulatory limitation renders the Commission's burden analysis inadequate. The Paperwork Reduction Act (''PRA'') requires the Commission to estimate the reportable breaches by entities covered by the Rule and compliance costs.[40] The Regulatory Flexibility Act (''RFA'') requires the Commission to assess the economic impact on small businesses.[41] Apparently relying on the SBP's ''more than tangentially related to health'' limitation, the PRA and RFA analyses only address breaches by apps categorized as ''Health and Fitness.'' [42] Because the Rule itself contains no such limitation, general retailers with e-commerce apps, gas stations with loyalty apps, and other similar generalists that sell any health-related items do not factor into these analyses. As a result, they likely dramatically underestimate the numbers of regulated entities, number of breaches, and costs to businesses.

Perhaps the breath of the Final Rule would be more of a theoretical than practical concern to businesses, if they could adopt practices sufficient to avoid any breach that would trigger notice obligations under the Final Rule, or, in the event of a breach, err on the side of notification. But § 318.3(b) of the Final Rule imposes affirmative obligations on companies to notify their service providers if they are covered by the Final Rule, regardless of whether they experience a breach.[43] To comply with this requirement, companies must know whether they are covered by the Rule—that is, which side of ''more than tangentially relating to health'' they fall on. Without clarity on that line, companies run the risk of being in

[32] 42 U.S.C. 17921(11).

[33] Final Rule at 99.

[34] *See* SBP at 32 (''Next, adding the phrase 'technical capacity to draw information' clarifies that a product is a personal health record if it can draw *any* information from multiple sources, even if it only draws *health* information from one source.'').

[35] *See id.* at 34.

[36] Scalia & Garner, *supra* note 15 at 174 (discussing surplusage canon).

[37] SBP at 28.

[38] *See Nat'l Fed'n of Indep. Business* v. *Dep't of Labor,* 595 U.S. 109, 117 (2022) (per curiam) (''Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.'').

[39] The expansive coverage increases the likelihood of creating unintended consequences. Will the gas station decline to add over-the-counter medicines to its inventory to avoid crossing the line of ''more than tangentially related to health''? Will the clothing retailer shy away from maternity apparel? Will the e-commerce giant avoid selling bandages and dandruff shampoo? These potentially detrimental outcomes undermine a Rule intended to benefit consumers.

[40] *See generally* 44 U.S.C. 3501 *et seq.;* SBP at 86.

[41] 5 U.S.C. 601 through 612.

[42] SBP at 86, 93.

[43] This may have been a sensible requirement in 2009, when the scope of the Rule was much narrower, but it has dramatic consequences in this much-expanded Rule.

perpetual violation of the Final Rule and, therefore, perpetually at the mercy of the Commission's enforcement discretion. The Commission, at this moment, may not intend to pursue such technical violations. But any expression of intended restraint will be cold comfort to companies that have seen the Commission's self-imposed restraint wax and wane in other areas.[44]

I find the majority's liberties with the statute particularly troubling because they are unnecessary to reach health apps. Indeed, the Commission's own recent enforcement action against digital healthcare platform GoodRx makes that clear. Only last year, a bipartisan Commission applied the 2009 Rule to GoodRx's online platform and app because the company received identifiable health information on prescription medications (among other things) from pharmacy benefit managers and pharmacies, among other sources, so that consumers could manage their information.[45] The majority argues that today's changes are necessary to provide clarity to the market about the Rule's scope,[46] but *GoodRx* has already done that—and I would support changes to the Rule that are consistent with the statute. In short, I agree with the majority's goals—safeguarding consumers' sensitive health information and implementing a Congressional mandate to put consumers on notice of the breach of that data—but I believe that we must effectuate those goals within the scope of the law as it is, rather than legislating in the guise of applying the law.

The FTC is a venerable institution that does vital work to protect consumers and promote competition, thanks to its hardworking and devoted career staff. I commend the staff attorneys, economists, and technologists who worked on the rule for their careful and thoughtful consideration of difficult issues. Ultimately, while I am sympathetic to the majority's goal, I fear that adopting a Final Rule that is irreconcilable with the statute and that puts companies in an untenable position puts the Commission at risk. Legal challenges may undermine the Commission's institutional integrity, and Congress may be reluctant to trust the Commission with other authority—even the much-needed authority to protect the privacy of consumers' sensitive personal information. I therefore respectfully dissent.

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[44] Significantly, the Majority Statement is silent as to the propriety and consequences of its ''tangentially related'' limiting principle, likely because this approach is indefensible.

[45] *See Concurring Statement of Commissioner Christine S. Wilson, GoodRx,* Matter No. 2023090 1 n.2 (Feb. 1, 2023) (''GoodRx has violated the HBNR based on a plain reading of the text, setting aside any gloss the Commission sought to add in its September 2021 Statement on Breaches by Health Apps and Other Connected Devices.''), *https://www.ftc.gov/system/files/ftc_gov/pdf/2023090_goodrx_final_concurring_statement_wilson.pdf.*

[46] Majority Statement at 5.

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